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FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 360

RIN 3064–AE32

Treatment of Financial Assets Transferred in Connection With a Securitization or Participation

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Final rule.

SUMMARY: The Federal Deposit Insurance Corporation (the ''FDIC'') is issuing a final rule (the ''Final Rule'') that revises certain provisions of its securitization safe harbor rule, which relates to the treatment of financial assets transferred in connection with a securitization or participation, in order to clarify the requirements of the securitization safe harbor as to the retention of an economic interest in the credit risk of securitized financial assets in connection with the effectiveness of the credit risk retention regulations adopted under Section 15G of the Securities Exchange Act.

DATES: Effective January 25, 2016.

FOR FURTHER INFORMATION CONTACT: Phillip E. Sloan, Counsel, Legal Division (703) 562–6137; or George H. Williamson, Manager, Division of Resolutions and Receiverships (571) 858–8199.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Deposit Insurance Corporation (FDIC), in regulations codified at 12 CFR 360.6 (the Securitization Safe Harbor Rule), set forth criteria under which in its capacity as receiver or conservator of an insured depository institution the FDIC will not, in the exercise of its authority to repudiate contracts, recover or reclaim financial assets transferred in connection with securitization transactions. Asset transfers that, under the Securitization Safe Harbor Rule, are not subject to recovery or reclamation through the exercise of the FDIC's repudiation authority include those that pertain to certain grandfathered transactions, such as, for example, asset transfers made prior to December 31, 2010 that satisfied the conditions (except for the legal isolation condition addressed by the Securitization Safe Harbor Rule) for sale accounting treatment under generally accepted accounting principles (GAAP) in effect for reporting periods prior to November 15, 2009 and that pertain to a securitization transaction that satisfied certain other requirements. In addition, the Securitization Safe Harbor Rule provides that asset transfers that are not grandfathered, but that satisfy the conditions (except for the legal isolation condition addressed by the Securitization Safe Harbor Rule) for sale accounting treatment under GAAP in effect for reporting periods after November 15, 2009 and that pertain to a securitization transaction that satisfies all other conditions of the Securitization Safe Harbor Rule (such asset transfers, together with grandfathered asset transfers, are referred to collectively as Safe Harbor Transfers) will not be subject to FDIC recovery or reclamation actions through the exercise of the FDIC's repudiation authority. For any securitization transaction in respect of which transfers of financial assets do not qualify as Safe Harbor Transfers but which transaction satisfies all of its other requirements, the Securitization Safe Harbor Rule provides that, in the event the FDIC as receiver or conservator remains in monetary default for a specified period under a securitization due to its failure to pay or apply collections or repudiates the securitization asset transfer agreement and does not pay damages within a specified period, certain remedies can be exercised on an expedited basis.

Paragraph (b)(5)(i) of the Securitization Safe Harbor Rule sets forth the conditions relating to credit risk retention that apply to transfers of financial assets in connection with securitizations that are not grandfathered by the Securitization Safe Harbor Rule. Under paragraph (b)(5)(i)(A) of the Securitization Safe Harbor Rule as currently in effect, prior to the effective date of regulations required under Section 15G of the Securities Exchange Act, 15 U.S.C. 78a *et seq.* (''Section 15G''), the documents governing such securitization must require that the sponsor retain an economic interest in not less than five (5) percent of the credit risk of the financial assets relating to the securitization. The requirement in paragraph (b)(5)(i)(A) of the Securitization Safe Harbor Rule, that *the documents* require retention of an economic interest, is consistent with many other provisions of the Securitization Safe Harbor Rule, which are similarly expressed as requirements for the securitization documentation, rather than as conditions requiring actual compliance with the provision that is required to be included in the documentation. As currently in effect, paragraph (b)(5)(i)(B) of the Securitization Safe Harbor Rule does not explicitly refer to the securitization documentation, but provides that, upon the effective date of the regulations required under Section 15G (the Section 15G Regulations), such regulations shall exclusively govern the requirement to retain an economic interest in the credit risk of the financial assets.

Section 15G provides that regulations issued thereunder become effective with respect to residential mortgage securitizations one year after the date on which the regulations are published in the **Federal Register** and, with respect to all other securitizations, two years after such publication date. The Section 15G Regulations were published in the **Federal Register** at 79 FR 77602 on December 24, 2014. The **Federal Register** publication of the Section 15G Regulations specifies ''compliance dates'' that correspond to these effective dates. However, the **Federal Register** publication also specifies February 23, 2015 as the ''effective date'' of the Section 15G Regulations in accordance with **Federal Register** editorial conventions, which require that a **Federal Register** publication specify as the effective date the date on which a rule affects the current Code of Federal Regulations.[1]

In connection with the notice of proposed rulemaking relating to the Section 15G Regulations, FDIC staff received a comment that suggested that

[1] See 79 FR 77602 (December 24, 2014).

certain other points relating to paragraph (b)(5)(i)(B) of the Securitization Safe Harbor Rule should be clarified.

On January 30, 2015, the FDIC published a notice of proposed rulemaking relating to the Securitization Safe Harbor Rule (the ''NPR''). The NPR was designed, in part, to eliminate any confusion that might be created by the use of ''effective date'' in the Section 15G Regulations **Federal Register** publication and to clarify when compliance with paragraph (b)(5)(i)(B) of the Securitization Safe Harbor Rule is required. In addition, the NPR included a proposed rule (the Proposed Rule) that addressed two of the points raised by the commenter.[2] The first is a clarification that paragraph (b)(5)(i)(B) was intended to require that, upon and following the applicable effective date under the Section 15G Regulations (such applicable effective dates (December 24, 2015 for residential mortgage securitizations and December 24, 2016 for all other securitizations) are referred to as the applicable compliance dates), the Securitization Safe Harbor Rule requirements as to risk retention are satisfied if the governing documents of a securitization transaction require retention of an economic interest in the financial assets in accordance with the Section 15G Regulations, and that if the documentation satisfies this condition (and assuming all other conditions of the Securitization Safe Harbor Rule are satisfied), the transaction will not lose the benefits of the safe harbor solely on the basis of any non-compliance with the Section 15G Regulations risk retention requirements.

The second is a clarification that paragraph (b)(5)(i)(B) of the Securitization Safe Harbor Rule does not require that any action be taken with respect to issuances of asset-backed securities that close prior to the applicable compliance date of the Section 15G Regulations.

These two clarifications, which were included in the Proposed Rule, together with an additional change suggested by a comment letter relating to the Proposed Rule, are included in the Final Rule.

II. Comment Received on the Proposed Rule

The FDIC received one comment letter, from an industry trade association, in response to the Proposed Rule. This letter supported the changes included in the Proposed Rule and requested that the Final Rule include one additional change relating to the credit risk retention condition of the Securitization Safe Harbor Rule. The commenter referred to the applicable compliance dates for the Section 15G Regulations and proposed that the Final Rule provide securitization sponsors the option, with respect to a securitization transaction, to comply with the credit risk retention condition of the Securitization Safe Harbor Rule by adopting the Section 15G risk retention requirements during the period preceding the applicable compliance date for such transaction, even though the Section 15G Regulations do not require such compliance before such applicable compliance date. The commenter stated that providing such optionality ''would effectuate the principle underlying the credit risk retention condition of the Securitization Safe Harbor Rule.'' [3]

III. Policy Objective

The policy objective underlying the Final Rule is to create certainty and eliminate unnecessary burdens in connection with the transition to the Section 15G Regulations requirements as to credit risk retention.

IV. The Final Rule

Overview

The Final Rule clarifies that the Securitization Safe Harbor Rule condition relating to credit risk retention requires that the documents governing a securitization transaction that closes on or after the applicable compliance date under the Section 15G Regulations must require that an economic interest in the credit risk of the financial assets is retained in accordance with the Section 15G Regulations. The Final Rule provision effecting this clarification also makes clear that the migration of the Securitization Safe Harbor Rule to the Section 15G Regulations governing credit risk retention will not require changes to documents governing securitizations that closed prior to the applicable compliance date. The provision also makes clear that the transition to the Section 15G standard is a documentation requirement and, thus, does not put investors at risk if a securitization sponsor, in violation of transaction documents, does not retain credit risk in accordance with the Section 15G Regulations.

Because securitization investors have relied on the Securitization Safe Harbor Rule to obtain an understanding of how the FDIC might exercise its powers if it is appointed receiver or conservator for an insured depository institution which transferred assets in connection with a securitization transaction, the FDIC believes that it is important to make clear to securitization market participants the date upon and after which the Securitization Safe Harbor will require reference to the Section 15G Regulations. In addition, the FDIC wants to eliminate possible confusion among market participants as to whether an asset-backed security issuance that complies with all requirements of the Securitization Safe Harbor Rule could forfeit the benefits afforded by the Securitization Safe Harbor Rule based on the action or inaction of a securitization sponsor or other party with respect to retention of credit risk following the date of such issuance. This is different from the Section 15G Regulations, under which non-compliance with the credit risk retention requirements will constitute a violation of the Regulations.

Consistent with the clarifications to the process for migration to the Section 15G Regulations included in the Proposed Rule, the Final Rule follows the commenter's suggestion and permits securitization sponsors to comply with the credit risk retention requirements of the Securitization Safe Harbor Rule by opting in the securitization's governing documents to require compliance with the Section 15G Regulations earlier than required by the Section 15G Regulations. It is the FDIC's view that since the Securitization Safe Harbor Rule has always required the transition to the Section 15G risk retention requirements, there is no compelling reason to require that securitization sponsors await the applicable compliance date in order to use one of the risk retention methods available under the Section 15G Regulations. In following the commenter's proposal, the FDIC wished to avoid imposing unnecessary burdens on sponsors that otherwise might need to establish a securitization structure for the issuance of multiple series before the applicable compliance date and then need to amend the structure after the applicable compliance date. The FDIC sees no reason to require such extra expense. The FDIC recognizes that permitting securitization sponsors to cause a securitization transaction to comply with the Securitization Safe Harbor Rule by exercising an option to require compliance with the Section 15G Regulations before the applicable compliance date also has the effect of allowing greater flexibility with respect to risk retention for purposes of complying with the Securitization Safe

[2] 80 FR 5076 (January 30, 2015).

[3] Letter dated March 30, 2015, p. 3.

Harbor Rule, and in some cases may permit sponsors to benefit from exemptions available under the Section 15G Regulations earlier than otherwise would be the case for purposes of the Securitization Safe Harbor Rule. In promulgating the Section 15G Regulations, the FDIC determined that the approach to risk retention adopted by those rules is effective and appropriate and, thus, the option of early adoption also is appropriate.

Section-by-Section Analysis

Definitions

The Final Rule adds a new definition, ''applicable compliance date'' to paragraph (a) of the Securitization Safe Harbor Rule. This definition reflects that the Section 15G Regulations impose two dates for compliance: December 24, 2015 for securitization of residential mortgages, and December 24, 2016 for all other securitizations.

Paragraph (b)(5)(i)

The Final Rule revises paragraph (b)(5)(i) of the Securitization Safe Harbor Rule to make the following three points clear:

(i) In order to qualify for the benefits of the Securitization Safe Harbor Rule, the documents governing the issuance of asset-backed securities in a securitization transaction must require retention of an economic interest in the credit risk of the financial assets relating to the securitization transaction in compliance with the Section 15G Regulations if such issuance occurs upon or following the date on which compliance with Section 15G is required for such type of securitization transaction;

(ii) The Securitization Safe Harbor Rule does not require inquiry as to whether the sponsor or other applicable party in fact complies with the risk retention requirements of the documentation; and

(iii) The Securitization Safe Harbor Rule requirements as to the Section 15G Regulations do not require changes to securitization documents governing asset-backed security issuances that are closed prior to the applicable compliance date under the Section 15G Regulations.

In addition, the Final Rule revises paragraph (b)(5)(i) of the Securitization Safe Harbor Rule to permit a securitization transaction, that closes between the date of the publication of the Final Rule in the **Federal Register** and the applicable compliance date related to such securitization transaction, to comply with the paragraph if the documents creating the securitization require retention of an economic interest in the credit risk of the financial assets in accordance with the requirements of the Section 15G Regulations as though such Regulations were then in effect. In the case of a securitization transaction of an entity established to issue obligations in more than one securitization transaction, the election to require in the documents creating the securitization transaction that risk be retained in accordance with the Section 15G Regulations can be set forth either in the specific securitization transaction documents or, provided that it governs the securitization transaction, in one of the documents establishing or otherwise governing the issuing entity.

V. Regulatory Analysis and Procedure

A. Paperwork Reduction Act

This rule would entail an information collection for sponsors that exercise the option to become subject to the Section 15G Regulations earlier than otherwise required. Because the information to be collected is the same, however, as that encompassed by the collection of information that was approved under OMB No. 3064–0183, no new submission is being made to OMB with respect to the Paperwork Reduction Act (44 U.S.C. 3501, *et seq.*).[4]

B. Regulatory Flexibility Act

The Regulatory Flexibility Act 5 U.S.C. 601, *et seq.* (RFA) requires each federal agency to prepare a final regulatory flexibility analysis in connection with the promulgation of a final rule, or certify that the final rule will not have a significant economic impact on a substantial number of small entities.[5] Pursuant to section 605(b) of the Regulatory Flexibility Act, the FDIC certifies that the Final Rule will not have a significant economic impact on a substantial number of small entities.

C. Small Business Regulatory Enforcement Act

The Office of Management and Budget has determined that the Final Rule is Not a ''major rule'' within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), (5 U.S.C. 801 *et seq.*). As required by the SBREFA, the FDIC will file the appropriate reports with Congress and the Government Accountability Office so that the Final Rule may be reviewed.

D. Plain Language

Section 722 of the Gramm-Leach-Bliley Act (Pub. L. 106–102, 113 Stat.1338, 1471), requires the Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The FDIC has sought to present the Final Rule in a simple and straightforward manner.

List of Subjects in 12 CFR Part 360

Banks, Banking, Bank deposit insurance, Holding companies, National banks, Participations, Reporting and recordkeeping requirements, Savings associations, Securitizations.

For the reasons stated above, the Board of Directors of the Federal Deposit Insurance Corporation amends 12 CFR part 360 as follows:

PART 360—RESOLUTION AND RECEIVERSHIP RULES

■ 1. The authority citation for part 360 continues to read as follows:

Authority: 12 U.S.C. 1817(b), 1818(a)(2), 1818(t), 1819(a) Seventh, Ninth and Tenth, 1820(b)(3), (4), 1821(d)(1), 1821(d)(10)(c), 1821(d)(11), 1821(d)(15)(D), 1821(e)(1), 1821(e)(8)(D)(i), 1823(c)(4), 1823(e)(2); Sec. 401(h), Pub. L. 101–73, 103 Stat. 357.

■ 2. Amend § 360.6 as follows:

■ a. Redesignate paragraphs (a)(1) through (11) as (a)(2) through (12) and add a new paragraph (a)(1).

■ b. Revise paragraph (b)(5)(i).

The addition and revision read as follows:

§ 360.6 Treatment of financial assets transferred in connection with a securitization or participation.

(a) * * *

(1) *Applicable compliance date* means, with respect to a securitization, the date on which compliance with Section 15G of the Securities Exchange Act, 15 U.S.C. 78a *et seq.,* added by Section 941(b) of the Dodd-Frank Wall Street Reform and Consumer Protection Act is required with respect to that securitization.

* * * * *

(b) * * *

(5) * * *

(i) *Requirements applicable to all securitizations.* (A) Prior to the

[4] The specific method of defining the respondent population differed in some respects for purposes of the FDIC's Section 15G PRA submission, OMB No. 3064–0183. The respondent population for that submission was based on an allocation to the bank regulatory agencies based on the number of sponsors regulated by them, with the remainder of sponsors allocated to the Securities and Exchange Commission. The allocation to the bank regulatory agencies was then divided among the FDIC and the other bank regulatory agencies. The respondents for purposes of this Rule are IDIs that are projected to sponsor securitizations and elect to comply early with the Section 15G Regulations, and the number of responses is based on the projected number of securitizations for which those sponsors would be expected to elect the early compliance option.

[5] *See* 5 U.S.C. 603, 604 and 605.

applicable compliance date for regulations required under Section 15G of the Securities Exchange Act, 15 U.S.C. 78a *et seq.,* added by Section 941(b) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, the documents creating the securitization shall require that the sponsor retain an economic interest in a material portion, defined as not less than five (5) percent, of the credit risk of the financial assets. This retained interest may be either in the form of an interest of not less than five (5) percent in each of the credit tranches sold or transferred to the investors or in a representative sample of the securitized financial assets equal to not less than five (5) percent of the principal amount of the financial assets at transfer. This retained interest may not be sold, pledged or hedged, except for the hedging of interest rate or currency risk, during the term of the securitization.

(B) For any securitization that closes upon or following the applicable compliance date for regulations required under Section 15G of the Securities Exchange Act, 15 U.S.C. 78a *et seq.,* added by Section 941(b) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, the documents creating the securitization shall instead require retention of an economic interest in the credit risk of the financial assets in accordance with such regulations, including the restrictions on sale, pledging and hedging set forth therein.

(C) Notwithstanding paragraph (b)(5)(i)(A) of this section, for any securitization that closes following ____ _____ November 24, 2015 and prior to the applicable compliance date for regulations required under Section 15G of the Securities Exchange Act, 15 U.S.C. 78a *et seq.,* added by Section 941(b) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, at the option of the sponsor, the requirements of paragraph (b)(5)(i)(B) of this section may be satisfied if (in lieu of the requirement set forth in paragraph (b)(5)(i)(A) of this section) the documents creating the securitization require retention of an economic interest in the credit risk of the financial assets in accordance with the requirements of the Section 15G regulations as though such regulations were then in effect.

* * * * *

Dated at Washington, DC, this 22nd day of October, 2015.

By order of the Board of Directors.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2015–29822 Filed 11–23–15; 8:45 am]

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FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1238

RIN 2590–AA74

Stress Testing of Regulated Entities

AGENCY: Federal Housing Finance Agency.

ACTION: Final rule.

SUMMARY: The Federal Housing Finance Agency (FHFA) is adopting a final rule amending its stress testing rule adopted in 2013 to implement section 165(i) of the Dodd-Frank Wall Street Reform and Consumer Protection Act. FHFA received no comments to its proposed amendments, published for comment in an August 21, 2015 Notice of Proposed Rule. These amendments adopt the proposed amendments without change to modify: The start date of the stress test cycles from October 1 of a calendar year to January 1 of the following calendar year; the dates for FHFA to issue scenarios for the upcoming cycle; the dates for the regulated entities to report the results of their stress tests to FHFA; and the dates for the regulated entities to publicly disclose a summary of their stress test results for the severely adverse scenario. These amendments align FHFA's rule with rules adopted by other financial institution regulators that implement the Dodd-Frank stress testing requirements.

DATES: Effective January 1, 2016.

FOR FURTHER INFORMATION CONTACT: Naa Awaa Tagoe, Senior Associate Director, Office of Financial Analysis, Modeling and Simulations, (202) 649–3140, *naaawaa.tagoe@fhfa.gov;* Stefan Szilagyi, Examination Manager, FHLBank Modeling, FHLBank Risk Modeling Branch (202) 649–3515, *stefan.szilagy@fhfa.gov;* Karen Heidel, Senior Counsel, Office of General Counsel, (202) 649–3073, *karen.heidel@fhfa.gov;* or Mark D. Laponsky, Deputy General Counsel, Office of General Counsel, (202) 649–3054, *mark.laponsky@fhfa.gov.* The telephone number for the Telecommunications Device for the Hearing Impaired is (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

FHFA is an independent agency of the federal government established to regulate and oversee the Federal National Mortgage Association (Fannie Mae), the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively, the Enterprises), and the Federal Home Loan Banks (Bank(s)) (collectively, the regulated entities).[1] FHFA is the primary federal financial regulator of each regulated entity. FHFA's regulatory mission is to ensure, among other things, that each of the regulated entities ''operates in a safe and sound manner'' and that their ''operations and activities . . . foster liquid, efficient, competitive, and resilient national housing finance markets.'' [2]

On September 26, 2013, FHFA published a final rule implementing section 165(i)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act),[3] which requires certain financial companies with total consolidated assets of more than $10 billion to conduct annual stress tests to determine whether the companies have the capital necessary to absorb losses as a result of adverse economic conditions. Each regulated entity is covered by this Dodd-Frank Act requirement. FHFA's regulation, located at 12 CFR part 1238, requires each regulated entity to conduct an annual stress test based on scenarios provided by FHFA and consistent with FHFA prescribed methodologies and practices. The rule requires the annual stress test period to begin October 1 of one year and end September 30 of the next year, which coincided with the testing period established by Federal Reserve Board (FRB) regulations for its Dodd-Frank Act stress testing.

FHFA's regulation also requires that the Agency issue to the regulated entities stress test scenarios that are generally consistent with and comparable to those developed by the FRB not later than 15 days after the FRB publishes its scenarios.[4] Each regulated entity is required to report the stress test results to FHFA and the FRB and publicly disclose a summary of the stress test results for the severely adverse scenario. The reporting date for the Enterprises is on or before February 5, and for the Banks it is on or before April 30.[5] The date for each Enterprise

[1] Federal Housing Enterprises Financial Safety and Soundness Act of 1992, as amended by the Housing and Economic Recovery Act of 2008, 12 U.S.C. 4501, *et seq.*

[2] 12 U.S.C. 4513(a)(1)(B).

[3] 78 FR 59219 (September 26, 2013).

[4] 12 CFR 1238.3(b).

[5] 12 CFR 1238.5(a).

to publicly disclose its results from the severely adverse scenario of the stress test is the period between April 15 and April 30.[6] The Banks are required to disclose their summaries between July 15 and July 30.[7] Maintaining consistency with the FRB testing rules, these dates were established by measuring forward from the corresponding dates in the FRB regulation, after accounting for differences in the business models of the regulated entities from those of the institutions regulated by the FRB.

On October 27, 2014, the FRB published a final rule amending several dates relevant to its rule and from which FHFA measured to determine appropriate dates for stress testing cycles, scenario issuance, test reporting, and summary test disclosures.[8] The effect of the rule change shifts the date for scenario issuance by approximately three months. The FRB's new rule establishes January 1 of each year as the beginning of the stress testing cycle (changed from October 1) and the following December 31 as the date as of which the regulated entity is to identify and use data for testing.[9] The new FRB rule requires large bank holding companies with $50 billion or more in total consolidated assets to report their test results not later than April 5 [10] and publicly disclose their summary results by mid-July.[11] The new FRB rule also requires U.S. banking institutions with total consolidated assets over $10 billion and less than $50 billion to report their test results by July 31 and publicly disclose their results during the period beginning October 15 and ending October 31.[12] Since FHFA measured several of its regulatory dates from corresponding dates in the FRB regulation, FHFA is amending its regulation to maintain consistency and comparability in stress testing regimes.

The final rule realigns FHFA's stress testing rule with those of the FRB, Federal Deposit Insurance Corporation (FDIC) and the Office of the Comptroller of the Currency (OCC) by modifying: (1) The start date of the stress test cycles from October 1 of a calendar year to January 1 of the following calendar year; (2) the dates regulated entities are required to report stress test results to FHFA and the FRB; (3) the dates by which the regulated entities are required to publicly disclose summaries of the results for the severely adverse scenario; and (4) the date by which FHFA is required to issue stress testing scenarios to its regulated entities.

As a result of FHFA's experience through two stress test cycles, these amendments also lengthen the time between FRB's issuance of its scenarios and FHFA's issuance. The original rule's 15 day period after FRB's issuance has proven to be too short to allow appropriate analysis, stakeholder input, and adjustment of the scenarios to account for the differences in business models between the Enterprises and Banks as compared with other regulated institutions conducting Dodd-Frank stress tests under their regulators' rules. Consequently, FHFA is extending the time by which it is required to issue its scenarios to 30 calendar days following FRB's issuance of its final element of the supervisory scenarios.

II. Discussion of Public Comments

On August 21, 2015, FHFA published in the **Federal Register** proposed amendments to the Dodd-Frank stress testing requirements for the regulated entities. The comment period closed on September 21, 2015. FHFA did not receive any comments. Therefore, FHFA is adopting as its final rule the same rule proposed on August 21, 2015, without any change.

III. Summary of the Final Rule

Annual Stress Test—§ 1238.3

Section 1238.3 of the rule changes the ''as of'' date for the data used for stress testing from September 30 of that calendar year to December 31 of the previous calendar year. As a result of the shift, the stress test cycles would begin on January 1, based on data as of December 31 of the preceding calendar year. This cycle matches the cycle recently adopted by the other Dodd-Frank stress testing regulators.

Section 1238.3(b) lengthens the amount of time by which FHFA commits to providing a description of the baseline, adverse, and severely adverse scenarios to all regulated entities from within 15 calendar days to within 30 calendar days after the FRB publishes its scenarios. This will provide additional time for FHFA to analyze and adjust the scenarios it issues to the Enterprises and Banks.

Required Report to FHFA and the FRB of Stress Test Results and Related Information—§ 1238.5

Section 1238.5 changes the date by which stress test results are required to be reported to the FRB and FHFA. Instead of February 5 of each year, reports are required on or before May 20 for the Enterprises. Instead of April 30 of each year, reports are required on or before August 31 for the Banks. These changes reflect the shift in the stress test cycle and corresponding reporting dates adopted by the FRB and other regulators.

Publication of Results by Regulated Entities—§ 1238.7

Section 1238.7 specifies a two week period within which the mandatory publication of a summary of the stress test results for the severely adverse scenario must occur. Instead of requiring publication between April 15 and April 30, the Enterprises must publish between August 1 and August 15 of each year. Instead of requiring publication between July 15 and July 30, the Banks must publish between November 15 and November 30 of each year. These changes reflect the shift in the stress test cycle and corresponding publication dates adopted by the FRB and other regulators.

IV. Coordination With the FRB and the Federal Insurance Office

In accordance with section 165(i)(2)(C) of the Dodd-Frank Act, (12 U.S.C. 5365(i)(2)(C)), FHFA has coordinated with both the FRB and the Federal Insurance Office (FIO). On October 27, 2014, the FRB published a final rule covering ''bank holding compan[ies] with total consolidated assets of greater than $10 billion but less than $50 billion and savings and loan holding companies and state member banks with total consolidated assets of greater than $10 billion,'' [13] and large bank holding companies and non-bank financial companies, also known as ''covered companies'' [14]; the FDIC issued its final rule on November 21, 2014,[15] and the OCC issued its final rule on December 3, 2014.[16] Although FHFA's final rule would not be identical to those of the FRB, the FDIC, and the OCC, it is consistent and comparable with them.

[6] 12 CFR 1238.7(a).

[7] 12 CFR 1238.7(a).

[8] 79 FR 64025 (October 27, 2014), codified at12 CFR part 252.

[9] 12 CFR 252.12(t)(2), *See* 79 FR at 64046.

[10] 12 CFR 252.57(a)(1), *See* 79 FR at 64054.

[11] 12 CFR 252.58(a)(1)(i), requires companies to publicly disclose a summary of the stress test results within 15 calendar days after the FRB discloses the results of its supervisory stress test. The FRB will publicly disclose a summary of the supervisory stress test results by June 30 pursuant to 12 CFR 252.46(b)(1). *See* 79 FR at 64054.

[12] 12 CFR 252.17(a)(3)(iii), *See* 79 FR at 64049.

[13] 12 CFR part 252, subpart B, *See* 79 FR at 64045.

[14] 12 CFR part 252, subpart F, *See* 79 FR at 64051.

[15] 79 FR 69365 (November 21, 2014), codified at 12 CFR part 325.

[16] 79 FR 71630 (December 3, 2014), codified at 12 CFR part 46.

V. Differences Between the Banks and the Enterprises

Section 1313(f) of the Safety and Soundness Act requires the Director to consider the differences between the Banks and the Enterprises whenever promulgating regulations that affect the Banks. In developing the amendments to this rule, FHFA considered the differences between the Banks and the Enterprises, but also adhered to the statutory mandate that the regulation be ''consistent and comparable'' with the regulations of the other agencies. In implementing the regulation, FHFA will define scenarios for the regulated entities, bearing in mind the key risk exposures at each regulated entity.

In the final rule, FHFA requires different timeframes for reporting stress test results for the Enterprises versus the Banks. For the Enterprises, FHFA sets the dates for reporting stress test results to the regulator, the FRB, and the public in proximity to similar dates in the other agencies' rules for institutions with over $50 billion in assets. Reporting dates for all the Banks, regardless of size, are set in proximity to similar dates for institutions with less than $50 billion in assets. As a result, the Banks have over three additional months to report results to FHFA, the FRB, and the public.

VI. Paperwork Reduction Act

The final rule does not contain any collections of information pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*). Therefore, FHFA has not submitted any information to the Office of Management and Budget for review.

VII. Regulatory Flexibility Act

The final rule applies only to the regulated entities, which do not come within the meaning of small entities as defined in the Regulatory Flexibility Act (see 5 U.S.C. 601(6)). Therefore, in accordance with section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the General Counsel of FHFA certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 12 CFR Part 1238

Administrative practice and procedure, Capital, Federal Home Loan Banks, Government-sponsored enterprises, Regulated entities, Reporting and recordkeeping requirements, Stress test.

Authority and Issuance

For the reasons stated in the preamble, and under the authority of 12 U.S.C. 4513, 4526, and 5365(i), FHFA amends part 1238 of title 12 of the Code of Federal Regulations as follows:

PART 1238—STRESS TESTING OF REGULATED ENTITIES

■ 1. The authority citation for part 1238 continues to read as follows:

Authority: 12 U.S.C. 5365(i); 12 U.S.C. 4513, 4526, 4612; and 12 U.S.C. 1426.

■ 2. Amend § 1238.3 by revising paragraphs (a)(1) and (b) to read as follows:

§ 1238.3 Annual stress test.

(a) * * *

(1) Shall complete an annual stress test of itself based on its data as of December 31 of the preceding calendar year;

* * * * *

(b) *Scenarios provided by FHFA.* In conducting its annual stress tests under this section, each regulated entity must use scenarios provided by FHFA, which shall be generally consistent with and comparable to those established by the FRB, that reflect a minimum of three sets of economic and financial conditions, including a baseline, adverse, and severely adverse scenario. Not later than 30 days after the FRB publishes its scenarios, FHFA will issue to all regulated entities a description of the baseline, adverse, and severely adverse scenarios that each regulated entity shall use to conduct its annual stress tests under this part.

■ 3. Amend § 1238.5 by revising paragraph (a) to read as follows:

§ 1238.5 Required report to FHFA and the FRB of stress test results and related information.

(a) *Report required for stress tests.* On or before May 20 of each year, the Enterprises must report the results of the stress tests required under § 1238.3 to FHFA, and to the FRB, in accordance with paragraph (b) of this section; and on or before August 31 of each year, the Banks must report the results of the stress tests required under § 1238.3 to FHFA, and to the FRB, in accordance with paragraph (b) of this section;

* * * * *

■ 4. Amend § 1238.7 by revising paragraph (a) to read as follows:

§ 1238.7 Publication of results by regulated entities.

(a) *Public disclosure of results required for stress tests of regulated entities.* The Enterprises must disclose publicly a summary of the stress test results for the severely adverse scenario not earlier than August 1 and not later than August 15 of each year. Each Bank must disclose publicly a summary of the stress test results for the severely adverse scenario not earlier than November 15 and not later than November 30 of each year. The summary may be published on the regulated entity's Web site or in any other form that is reasonably accessible to the public;

* * * * *

Dated: November 11, 2015.

Melvin L. Watt,

Director, Federal Housing Finance Agency.

[FR Doc. 2015–29861 Filed 11–23–15; 8:45 am]

BILLING CODE 8070–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–0490; Directorate Identifier 2014–NM–018–AD; Amendment 39–18322; AD 2015–23–06]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2008–22–20 for certain Airbus Model A330–200, A330–300, and A340–300 series airplanes. AD 2008–22–20 required repetitive high frequency eddy current (HFEC) inspections for cracking, repair if necessary, and modification of the upper shell structure of the fuselage. This new AD shortens certain compliance times. This AD was prompted by a determination from a fatigue and damage tolerance evaluation that the compliance times must be reduced. We are issuing this AD to prevent fatigue cracking of the upper shell structure of the fuselage, which could result in reduced structural integrity of the airplane.

DATES: This AD becomes effective December 29, 2015.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 29, 2015.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of December 17, 2008 (73 FR 66747, November 12, 2008).

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;*

D=FAA-2015-0490; or in person at the Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *airworthiness.A330–A340@airbus.com;* Internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0490.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1138; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2008–22–20, Amendment 39–15717 (73 FR 66747, November 12, 2008). AD 2008–22–20 applied to certain Airbus Model A330–200, A330–300, and A340–300 series airplanes. The NPRM published in the **Federal Register** on March 17, 2015 (80 FR 13799). The NPRM was prompted by a determination from a fatigue and damage tolerance evaluation that the compliance times must be reduced. The NPRM also proposed to shorten certain compliance times. We are issuing this AD to prevent fatigue cracking of the upper shell structure of the fuselage, which could result in reduced structural integrity of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014–0012R1, dated January 24, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus Model A330–200, A330–300, and A340–300 series airplanes. The MCAI states:

> During fatigue tests (EF3) on the A340–600, damage was found in the longitudinal doubler at the Vertical Tail Plane (VTP) attachment cut out between Frame (FR) 80 and FR86. This damage occurred between 58,341 and 72,891 simulated flight cycles (FC).
>
> Due to the higher Design Service Goal and different design of the affected structural area (*e.g.* doubler thickness) for A330–200/–300 and A340–300 airplane series, the damage assessment concluded that these airplanes may be also potentially affected.
>
> This condition, if not detected and corrected, could affect the structural integrity of the upper shell structure between FR80 and FR86.
>
> Prompted by these findings, EASA issued AD 2007–0284 [(*http://ad.easa.europa.eu/blob/easa_ad_2007_0284_superseded.pdf/AD_2007-0284_1*)] to require implementation of an inspection programme of this structural area using a high frequency eddy current (HFEC) method and a modification to improve the upper shell structure.
>
> Since that [EASA] AD was issued, in the frame of a new fatigue and damage tolerance evaluation, taking into account the airplane utilisation, the inspection threshold and intervals have been reassessed and the conclusion was that the thresholds and intervals for inspection, as well as the threshold for modifying the airplane, must be reduced.
>
> For the reason described above, this [EASA] AD retains the requirements of EASA AD 2007–0284, which is superseded and introduces redefined thresholds and intervals.
>
> This [EASA] AD is revised to clarify that, under some conditions, accomplishment of a repair constitutes terminating action for the repetitive inspections. One of the outcome of this clarification is the deletion of paragraph (5) of this [EASA] AD.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2015-0490-0002.*

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (80 FR 13799, March 17, 2015) and the FAA's response to each comment.

Support for the NPRM (80 FR 13799, March 17, 2015)

An anonymous commenter agreed with the safety benefit provided by the NPRM (80 FR 13799, March 17, 2015).

Request for Revise Cost

Delta requested that we revise the NPRM (80 FR 13799, March 17, 2015) to relay the heavy impact of accomplishing Airbus Service Bulletin A330–53–3160, Revision 03, dated January 6, 2012. Delta explained that the modification specified in Airbus Service Bulletin A330–53–3160, Revision 03, dated January 6, 2012, requires removal of the vertical stabilizer and the aft galley, which can heavily impact the operation. Delta reasoned that it has consulted with its maintenance organization and it is estimated to take 400 work-hours instead of 208 work-hours.

We disagree with the request to revise this AD. We made the cost estimate based on the information provided in Airbus Service Bulletin A330–53–3160, Revision 03, dated January 6, 2012. The required work-hours defined in Airbus Service Bulletin A330–53–3160, Revision 03, dated January 6, 2012, are based on the direct labor cost to do the work. The need to remove and reinstall the aft galley depends on the airplane interior configuration and may differ from operator to operator. We are unable to determine all possible interior configurations and thus determine the maximum work-hours which may be required for any specific configuration. This estimate assumes that the work will be done by experienced personnel, and may need to be revised upwards to suit an operator's circumstances. The estimate does not include the time to prepare, plan, or inspect the work. We have made no changes to this AD in this regard.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (80 FR 13799, March 17, 2015) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (80 FR 13799, March 17, 2015).

Related Service Information Under 1 CFR Part 51

Airbus has issued the following service information.

- Airbus Service Bulletin A330–53–3159, Revision 02, dated March 29, 2010, describes procedures for a modification of the fuselage, which includes inspections (*e.g.,* eddy current rotating probe test of fastener holes for cracking, high frequency eddy current (HFEC) inspections for cracking of the upper shell structure of the fuselage, and checks of the fastener position for clearance) and applicable corrective actions (*e.g.,* repair and rework).
- Airbus Service Bulletin A330–53–3160, Revision 03, dated January 6, 2012, describes procedures for applicable actions, including an eddy current rotating probe test for cracking of the fastener holes and an HFEC inspection for cracks in the upper shell

of the fuselage (and including checks of the fastener position for clearance and applicable corrective actions (*e.g.,* repair and rework)), and a modification of the airplane upper shell structure of the fuselage between FR80 and FR86.

- Airbus Service Bulletin A330–53–3168, Revision 02, dated December 21, 2011, describes procedures for a HFEC inspection for cracking of the upper shell structure of the fuselage between FR80 and FR86.
- Airbus Service Bulletin A340–53–4165, Revision 02, dated March 29, 2010, describes procedures for a modification of the fuselage, which includes inspections (*e.g.,* eddy current rotating probe test of fastener holes for cracking, HFEC inspections for cracking of the upper shell structure of the fuselage, and checks of the fastener position for clearance) and applicable corrective actions (*e.g.,* repair and rework).
- Airbus Service Bulletin A340–53–4172, Revision 01, dated July 8, 2009, describes procedures for inspections (*e.g.,* rototest inspections of fastener holes for cracking, HFEC inspections for cracking of the upper shell structure of the fuselage, and checks of the fastener position for clearance) and modification of the airplane upper shell structure between FR80 and FR86 (including applicable corrective actions (*e.g.,* repair and rework).
- Airbus Service Bulletin A340–53–4174, Revision 02, dated December 21, 2011, describes procedures for a HFEC inspection for cracking of the upper shell structure of the fuselage between FR80 and FR86.

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

Costs of Compliance

We estimate that this AD affects 26 airplanes of U.S. registry. We also estimate that it will take about 208 work-hours per product to comply with the basic requirements (inspection and modification) of this AD. The average labor rate is $85 per work-hour. Required parts will cost about $28,360 per product. Based on these figures, we estimate the cost of this AD on U.S. operators to be $1,197,040, or $46,040 per product.

We have received no definitive data that will enable us to provide cost estimates for the on-condition actions specified in this AD.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

3. Will not affect intrastate aviation in Alaska; and

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2015-0490;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2008–22–20, Amendment 39–15717 (73 FR 66747, November 12, 2008), and adding the following new AD:

2015–23–06 Airbus: Amendment 39–18322. Docket No. FAA–2015–0490; Directorate Identifier 2014–NM–018–AD.

(a) Effective Date

This AD becomes effective December 29, 2015.

(b) Affected ADs

This AD replaces AD 2008–22–20, Amendment 39–15717 (73 FR 66747, November 12, 2008).

(c) Applicability

This AD applies to Airbus Model A330–201, –202, –203, –223, –243, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes; and Model A340–311, –312, and –313 airplanes; certificated in any category; all manufacturer serial numbers on which Airbus Modification 44205 has been embodied in production, except those on which Airbus Modification 52974 or 53223 has been embodied in production.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Reason

This AD was prompted by the results of a fatigue and damage tolerance evaluation that concluded existing compliance times must be reduced. We are issuing this AD to prevent fatigue cracking of the upper shell structure of the fuselage, which could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Inspection for Airbus Model A330–300 and A340–300 Airplanes, Except Model A340–300 Weight Variant (WV) 027 Airplanes

For Model A330–300 and A340–300 airplanes, except Model A340–300 WV 027 airplanes: At the applicable time specified in paragraph (g)(1) or (g)(2) of this AD, do a high frequency eddy current (HFEC) inspection for cracking of the upper shell structure between frame (FR) 80 and FR86, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–53–3168, Revision 02, dated December 21, 2011; or Airbus Service Bulletin A340–53–4174, Revision 02, dated December 21, 2011; as applicable. Repeat the inspection thereafter at the applicable time specified in paragraph 1.E., ''COMPLIANCE,'' of Airbus Service Bulletin A330–53–3168, Revision 02, dated December 21, 2011; or Airbus Service Bulletin A340–53–4174, Revision 02, dated December 21, 2011; as applicable.

(1) For airplanes that, as of the effective date of this AD, have not been inspected in accordance with Airbus Service Bulletin A330–53–3168; or Airbus Service Bulletin A340–53–4174; as applicable: Inspect at the later of the times specified in paragraphs (g)(1)(i) and (g)(1)(ii) of this AD.

(i) Before reaching the applicable threshold specified in paragraph 1.E., ''COMPLIANCE,'' of Airbus Service Bulletin A330–53–3168, Revision 02, dated December 21, 2011; or Airbus Service Bulletin A340–53–4174, Revision 02, dated December 21, 2011; as applicable for airplane model, configuration, and utilization, since the airplane's first flight.

(ii) Within the threshold defined in paragraph 1.E, ''COMPLIANCE,'' of Airbus Service Bulletin A330–53–3168, Revision 01, dated February 15, 2008; or Airbus Service Bulletin A340–53–4174, Revision 01, dated February 15, 2008; as applicable for airplane model, configuration, and utilization since the airplane's first flight; or within 12 months after the effective date of this AD; whichever occurs first.

(2) For airplanes that, as of the effective date of this AD, have been inspected in accordance with Airbus Service Bulletin A330–53–3168; or Airbus Service Bulletin A340–53–4174; as applicable: Inspect at the later of the times specified in paragraphs (g)(2)(i) and (g)(2)(ii) of this AD.

(i) Within the applicable interval specified in paragraph 1.E., ''COMPLIANCE,'' of Airbus Service Bulletin A330–53–3168, Revision 02, dated December 21, 2011; or Airbus Service Bulletin A340–53–4174, Revision 02, dated December 21, 2011; as applicable; to be counted from the last inspection.

(ii) Within 12 months after the effective date of this AD without exceeding the intervals defined in paragraph 1.E, ''COMPLIANCE,'' of Airbus Service Bulletin A330–53–3168, Revision 01, dated February 15, 2008; or Airbus Service Bulletin A340–53–4174, Revision 01, dated February 15, 2008; as applicable for airplane model, configuration, and utilization to be counted from the last inspection.

(h) Corrective Action for Airbus Model A330–300 and A340–300 Airplanes, Except Model A340–300 WV 027 Airplanes

If any crack is detected during any HFEC inspection required by the introductory text to paragraph (g) of this AD: Before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). Accomplishment of a repair for a specific area, as required by this paragraph, is terminating action for the repetitive HFEC inspections required by the introductory text to paragraph (g) of this AD, as applicable, for that specific repaired area only. The need and definition of subsequent repetitive inspections (if any) for that specific repaired area will be defined in the applicable repair method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA) or Airbus's EASA Design Organization Approval (DOA).

(i) Optional Terminating Action

For Airbus Model A330–300 and A340–300 airplanes, except Model A340–300 WV 027 airplanes: Modification, which includes inspections and applicable corrective actions, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–53–3159, Revision 02, dated March 29, 2010; or Airbus Service Bulletin A340–53–4165, Revision 02, dated March 29, 2010; as applicable; terminates the repetitive HFEC inspections required by the introductory text to paragraph (g) of this AD, except where Airbus Service Bulletin A330–53–3159, Revision 02, dated March 29, 2010; or Airbus Service Bulletin A340–53–4165, Revision 02, dated March 29, 2010; as applicable; specifies to contact the manufacturer, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA; or Airbus's EASA DOA.

(j) Inspection and Modification for Airbus Model A330–200 Airplanes

Within the compliance times specified in paragraph (j)(1) or (j)(2) of this AD, whichever occurs later: Do all applicable actions, including an eddy current rotating probe test and an HFEC inspection for cracks, and modify the airplane upper shell structure between FR80 and FR86; in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–53–3160, Revision 03, dated January 6, 2012.

(1) Within the compliance times identified in paragraph 1.E., ''COMPLIANCE,'' of Airbus Service Bulletin A330–53–3160, Revision 03, dated January 6, 2012, as applicable for airplane configuration and utilization since the airplane's first flight.

(2) Within 12 months after the effective date of this AD without exceeding the threshold defined in paragraph 1.E, ''COMPLIANCE,'' of Airbus Service Bulletin A330–53–3160, Revision 02, dated March 29, 2010, since the airplane's first flight.

(k) Inspection and Modification for Airbus Model A340–300 Airplanes, Only WV 027

For Model A340–300 airplanes, WV 027 only: Before the accumulation of 14,200 total flight cycles from the airplane's first flight, do all applicable inspections and modify the airplane upper shell structure between FR80 and FR86; in accordance with the Accomplishment Instructions of Airbus Service Bulletin A340–53–4172, Revision 01, dated July 8, 2009.

(l) Corrective Action for Airbus Model A330–200 Airplanes; and Model A340–300 Airplanes, only WV 027

If any crack is detected during the inspection required by the introductory text to paragraph (j) of this AD, or paragraph (k) of this AD, before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA; or Airbus's EASA DOA; concurrently with modification required by paragraph the introductory text to paragraph (j) of this AD, or paragraph (k) of this AD.

(m) Definition of ''Threshold'' and ''Interval''

(1) For the purposes of this AD, the term ''Threshold,'' as used in paragraph 1.E., ''COMPLIANCE,'' of the service information specified in paragraphs (m)(2)(i) through (m)(2)(vi) of this AD means the total flight cycles or flight hours accumulated since the airplane's first flight.

(2) For the purposes of this AD, the term ''Interval'' as used in paragraph 1.E., ''COMPLIANCE,'' of the service information specified in paragraphs (m)(2)(i) through (m)(2)(vi) of this AD means the total flight cycles or flight hours accumulated since the last inspection, as applicable.

(i) Airbus Service Bulletin A330–53–3168, dated September 19, 2007.

(ii) Airbus Service Bulletin A330–53–3168, Revision 01, dated February 15, 2008.

(iii) Airbus Service Bulletin A330–53–3168, Revision 02, dated December 21, 2011.

(iv) Airbus Service Bulletin A340–53–4174, dated September 19, 2007.

(v) Airbus Service Bulletin A340–53–4174, Revision 01, dated February 15, 2008.

(vi) Airbus Service Bulletin A340–53–4174, Revision 02, dated December 21, 2011.

(n) Credit for Previous Actions

(1) For Model A330–300 and A340–300 airplanes, except Model A340–300 WV 027 airplanes: This paragraph provides credit for the modification specified in paragraph (i) of this AD, if those actions were performed before the effective date of this AD using the service information identified in paragraph (n)(1)(i), (n)(1)(ii), (n)(1)(iii), or (n)(1)(iv) of this AD, as applicable. This service information is not incorporated by reference in this AD.

(i) Airbus Service Bulletin A330–53–3159, dated September 19, 2007.

(ii) Airbus Service Bulletin A330–53–3159, Revision 01, dated June 15, 2009.

(iii) Airbus Service Bulletin A340–53–4165, dated September 19, 2007.

(iv) Airbus Service Bulletin A340–53–4165, Revision 01, dated June 17, 2009.

(2) For Model A330–200 airplanes: This paragraph provides credit for the inspection

and modification required by the introductory text to paragraph (j) of this AD, if those actions were performed before the effective date of this AD using the service information identified in paragraph (n)(2)(i), (n)(2)(ii), or (n)(2)(iii) of this AD, as applicable.

(i) Airbus Service Bulletin A330–53–3160, dated July 9, 2007, which was incorporated by reference in AD 2008–22–20, Amendment 39–15717 (73 FR 66747, November 12, 2008).

(ii) Airbus Service Bulletin A330–53–3160, Revision 01, dated April 28, 2009, which is not incorporated by reference in this AD.

(iii) Airbus Service Bulletin A330–53–3160, Revision 02, dated March 29, 2010, which is not incorporated by reference in this AD.

(3) For Model A340–300 airplanes, WV 027 only: This paragraph provides credit for the inspection and modification required by paragraph (k) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A340–53–4172, dated July 10, 2007, which is was incorporated by reference in AD 2008–22–20, Amendment 39–15717 (73 FR 66747, November 12, 2008).

(o) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1138; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

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

(p) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014–0012R1, dated January 24, 2014, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0490.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (q)(3) and (q)(4) of this AD.

(q) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on December 29, 2015.

(i) Airbus Service Bulletin A330–53–3159, Revision 02, dated March 29, 2010.

(ii) Airbus Service Bulletin A330–53–3160, Revision 03, dated January 6, 2012.

(iii) Airbus Service Bulletin A330–53–3168, Revision 02, dated December 21, 2011.

(iv) Airbus Service Bulletin A340–53–4165, Revision 02, dated March 29, 2010.

(v) Airbus Service Bulletin A340–53–4172, Revision 01, dated July 8, 2009.

(vi) Airbus Service Bulletin A340–53–4174, Revision 02, dated December 21, 2011.

(4) The following service information was approved for IBR on December 17, 2008 (73 FR 66747, November 12, 2008).

(i) Airbus Service Bulletin A330–53–3168, Revision 01, dated February 15, 2008.

(ii) Airbus Service Bulletin A340–53–4174, Revision 01, dated February 15, 2008.

(5) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *airworthiness.A330-A340@airbus.com;* Internet *http://www.airbus.com.*

(6) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on October 30, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–28886 Filed 11–23–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–0682; Directorate Identifier 2014–NM–074–AD; Amendment 39–18329; AD 2015–23–12]

RIN 2120–AA64

Airworthiness Directives; ATR—GIE Avions de Transport Régional Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all ATR—GIE Avions de Transport Régional Model ATR42 and ATR72 airplanes. This AD was prompted by new occurrences of certain cracked main landing gear (MLG) rear hinge pins. This AD requires identifying the serial number and part number of the MLG rear hinge pins, and replacing pins or the MLG if necessary. We are issuing this AD to detect and correct cracked rear hinge pins, which could lead to MLG structural failure, possibly resulting in collapse of the MLG and consequent injury to the occupants of the airplane.

DATES: This AD becomes effective December 29, 2015. The Director of the **Federal Register** approved the incorporation by reference of certain publications listed in this AD as of December 29, 2015.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2015-0682;* or in person at the Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

For service information identified in this AD, contact ATR—GIE Avions de Transport Régional, 1, Allée Pierre Nadot, 31712 Blagnac Cedex, France; telephone +33 (0) 5 62 21 62 21; fax +33 (0) 5 62 21 67 18; email *continued.airworthiness@atr.fr;* Internet *http://www.aerochain.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for

and locating Docket No. FAA–2015–0682.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1137; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all ATR—GIE Avions de Transport Régional Model ATR42 and ATR72 airplanes. The NPRM published in the **Federal Register** on April 10, 2015 (80 FR 19246).

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014–0074, dated March 21, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all ATR—GIE Avions de Transport Régional Model ATR42 and ATR72 airplanes. The MCAI states:

> Prompted by cases of rupture of Main Landing Gear (MLG) rear hinge pin part number (P/N) D61000 encountered in service in 1994 and 1996, DGAC France issued [an] AD * * * for ATR 42 aeroplanes and [another]AD * * * for ATR 72 aeroplanes to require inspection and, depending on findings, corrective action.
>
> Since those [French] ADs were issued, new occurrences of cracked rear hinge pin P/N D61000 were reported on ATR72 MLG.
>
> The result of subsequent investigation revealed that the affected pins were subjected to a non-detected thermal abuse done in production during grinding process. Analysis also showed that other MLG pin P/N's could be affected by the same nonconformity.
>
> This condition, if not detected and corrected, could lead to MLG structural failure, possibly resulting in collapse of the MLG and consequently injury to the occupants of the aeroplane.
>
> For the reasons described above, this [EASA] AD requires inspection and, depending on findings, replacement of affected pins.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2015-0682-0002.*

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (80 FR 19246, April 10, 2015) or on the determination of the cost to the public.

Conclusion

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

- Are consistent with the intent that was proposed in the NPRM (80 FR 19246, April 10, 2015) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (80 FR 19246, April 10, 2015).

Related Service Information Under 1 CFR Part 51

Messier-Bugatti-Dowty has issued the following service information, which describes procedures for inspecting the MLG hinge pin.

- Service Bulletin 631–32–213, dated December 16, 2013.
- Service Bulletin 631–32–214, dated January 13, 2014.
- Service Bulletin 631–32–215, dated January 13, 2014.
- Service Bulletin 631–32–216, Revision 1, dated December 17, 2013.
- Service Bulletin 631–32–219, dated March 3, 2014.
- Service Bulletin 631–32–220, dated March 3, 2014.

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

Costs of Compliance

We estimate that this AD affects 81 airplanes of U.S. registry.

We also estimate that it will take about 8 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Required parts will cost about $16,000 per product. Based on these figures, we estimate the cost of this AD on U.S. operators to be $1,351,080, or $16,680 per product.

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

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator.

''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

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

Regulatory Findings

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

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

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2015-0682;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2015–23–12 ATR—GIE Avions de Transport Régional: Amendment 39–18329. Docket No. FAA–2015–0682; Directorate Identifier 2014–NM–074–AD.

(a) Effective Date

This AD becomes effective December 29, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to ATR—GIE Avions de Transport Régional Model ATR42–200, –300, –320, and –500 airplanes; and Model ATR72–101, –201, –102, –202, –211, –212, and –212A airplanes; certificated in any category; all certified models; all manufacturer serial numbers.

(d) Subject

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

(e) Reason

This AD was prompted by new occurrences of certain cracked main landing gear (MLG) rear hinge pins. We are issuing this AD to detect and correct cracked rear hinge pins, which could lead to MLG structural failure, possibly resulting in collapse of the MLG and consequent injury to the occupants of the airplane.

(f) Compliance

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

(g) Hinge Pin Identification and Replacement for Model ATR72 Airplanes

For Model ATR72 airplanes: Within 12 months after the effective date of this AD, inspect for the serial number of the left-hand (LH) and right-hand (RH) MLG rear hinge pins having part number (P/N) D61000. A review of airplane maintenance records is acceptable in lieu of this identification if the part number and serial number of the LH and RH MLG rear hinge pins can be conclusively determined from that review. If a rear hinge pin having P/N D61000 has a serial number listed in Messier-Bugatti-Dowty Service Bulletin 631–32–213, dated December 16, 2013; or Messier-Bugatti-Dowty Service Bulletin 631–32–216, Revision 1, dated December 17, 2013; as applicable: Within 12 months after the effective date of this AD, replace the pin with a serviceable part as identified in paragraph (h) of this AD, in accordance with the Accomplishment Instructions of Messier-Bugatti-Dowty Service Bulletin 631–32–213, dated December 16, 2013; or Messier-Bugatti-Dowty Service Bulletin 631–32–216, Revision 1, dated December 17, 2013; as applicable.

(h) Definition of Serviceable Hinge Pin for Model ATR72 Airplanes

For Model ATR72 airplanes: For purposes of paragraph (g) of this AD, a serviceable MLG rear hinge pin is a pin that is specified in paragraph (h)(1) or (h)(2) of this AD.

(1) A hinge pin that is not identified in Messier-Bugatti-Dowty Service Bulletin 631–32–213, dated December 16, 2013; or Messier-Bugatti-Dowty Service Bulletin 631–32–216, Revision 1, dated December 17, 2013; as applicable.

(2) A hinge pin that has been inspected and reconditioned, in accordance with the Accomplishment Instructions of Messier-Bugatti-Dowty Service Bulletin 631–32–213, dated December 16, 2013; or Messier-Bugatti-Dowty Service Bulletin 631–32–216, Revision 1, dated December 17, 2013; as applicable.

(i) MLG Pin Identification and Replacement for Model ATR72 Airplanes

For Model ATR72 airplanes: At the earlier of the times specified in paragraphs (i)(1) and (i)(2) of this AD, inspect all LH and RH MLG pins for a part number and serial number listed in Messier-Bugatti-Dowty Service Bulletin 631–32–214, dated January 13, 2014; or Messier-Bugatti-Dowty Service Bulletin 631–32–219, dated March 3, 2014; as applicable. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number and serial number of the LH and RH MLG pin can be conclusively determined from that review. If any affected MLG pin is found: At the earlier of the compliance times specified in paragraphs (i)(1) and (i)(2) of this AD, replace the MLG with a serviceable MLG as identified in paragraph (j) of this AD, using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or ATR—GIE Avions de Transport Régional's EASA Design Organization Approval (DOA).

(1) No later than the next MLG overhaul scheduled after the effective date of this AD.

(2) Within 20,000 flight cycles or 9 years, whichever occurs first, accumulated since installation of the MLG on an airplane since new or since last overhaul, as applicable.

(j) Definition of Serviceable MLG for Model ATR72 Airplanes

For Model ATR72 airplanes: For purposes of paragraph (i) of this AD, a serviceable MLG is one that incorporates pins specified in paragraph (j)(1) or (j)(2) of this AD.

(1) Pins that are not identified in Messier-Bugatti-Dowty Service Bulletin 631–32–214, dated January 13, 2014; or Messier-Bugatti-Dowty Service Bulletin 631–32–219, dated March 3, 2014; as applicable.

(2) Pins that have been inspected and reconditioned in accordance with the Accomplishment Instructions of Messier-Bugatti-Dowty Service Bulletin 631–32–214, dated January 13, 2014; or Messier-Bugatti-Dowty Service Bulletin 631–32–219, dated March 3, 2014; as applicable.

(k) MLG Pin Identification and Replacement for Model ATR42 Airplanes

(1) For Model ATR42 airplanes: Within the compliance time identified in paragraph (k)(1)(i) or (k)(1)(ii) of this AD, whichever occurs first, inspect for any LH and RH MLG pins having a part number and serial number listed in Messier-Bugatti-Dowty Service Bulletin 631–32–215, dated January 13, 2014; or Messier-Bugatti-Dowty Service Bulletin 631–32–220, dated March 3, 2014; as applicable. A review of airplane maintenance records is acceptable in lieu of this identification if the part number and serial number of the LH and RH MLG pin can be conclusively determined from that review.

(i) No later than the next MLG overhaul scheduled after the effective date of this AD.

(ii) Within 20,000 flight cycles or 9 years, whichever occurs first, accumulated since installation of the MLG on an airplane since new or since last overhaul, as applicable.

(2) If the MLG pin having a part number and serial number listed in Messier-Bugatti-Dowty Service Bulletin 631–32–215, dated January 13, 2014; or Messier-Bugatti-Dowty Service Bulletin 631–32–220, dated March 3, 2014; as applicable; is found to be installed during the identification required by paragraph (k)(1) of this AD, within the compliance time identified in paragraph (k)(1) of this AD, replace the MLG with a serviceable MLG, using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA; or ATR—GIE Avions de Transport Régional's EASA DOA. A serviceable MLG is a part that has pins as identified in paragraph (k)(2)(i) or (k)(2)(ii) of this AD.

(i) Pins that are not listed in Messier-Bugatti-Dowty Service Bulletin 631–32–215, dated January 13, 2014; or Messier-Bugatti-Dowty Service Bulletin 631–32–220, dated March 3, 2014; as applicable.

(ii) Pins that have been inspected and reconditioned, in accordance with the Accomplishment Instructions of Messier-Bugatti-Dowty Service Bulletin 631–32–215, dated January 13, 2014; or Messier-Bugatti-Dowty Service Bulletin 631–32–220, dated March 3, 2014; as applicable.

(l) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Messier-Bugatti-Dowty Service Bulletin 631–32–216, dated October 30, 2013, which is not incorporated by reference in this AD.

(m) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Tom Rodriguez, Aerospace Engineer,

International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1137; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA; or ATR—GIE Avions de Transport Régional's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(n) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014–0074, dated March 21, 2014, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2015-0682-0002.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (o)(3) and (o)(4) of this AD.

(o) Material Incorporated by Reference

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

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

(i) Messier-Bugatti-Dowty Service Bulletin 631–32–213, dated December 16, 2013.

(ii) Messier-Bugatti-Dowty Service Bulletin 631–32–214, dated January 13, 2014.

(iii) Messier-Bugatti-Dowty Service Bulletin 631–32–215, dated January 13, 2014.

(iv) Messier-Bugatti-Dowty Service Bulletin 631–32–216, Revision 1, dated December 17, 2013. Pages 4, 5, and 8 of this service bulletin are the original issue and are dated October 30, 2013.

(v) Messier-Bugatti-Dowty Service Bulletin 631–32–219, dated March 3, 2014.

(vi) Messier-Bugatti-Dowty Service Bulletin 631–32–220, dated March 3, 2014.

(3) For service information identified in this AD, contact ATR—GIE Avions de Transport Régional, 1, Allée Pierre Nadot, 31712 Blagnac Cedex, France; telephone +33 (0) 5 62 21 62 21; fax +33 (0) 5 62 21 67 18; email *continued.airworthiness@atr.fr;* Internet *http://www.aerochain.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on November 12, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–29682 Filed 11–23–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–0251; Directorate Identifier 2014–NM–200–AD; Amendment 39–18330; AD 2015–23–13]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Airbus Model A318, A319, A320, and A321 series airplanes. This AD was prompted by a determination that, in specific flight conditions, the allowable load limits on the vertical tail plane could be reached and possibly exceeded. Exceeding allowable load could result in detachment of the vertical tail plane. This AD requires modification of the pin programming flight warning computer (FWC) to activate the stop rudder input warning (SRIW) logic; and an inspection to determine the part numbers of the FWC and the flight augmentation computer (FAC), and replacement of the FWC and FAC if necessary. We are issuing this AD to prevent detachment of the vertical tail plane and consequent loss of control of the airplane.

DATES: This AD becomes effective December 29, 2015.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 29, 2015.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2015-0251;* or in person at the Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0251.

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

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus Model A318, A319, A320, and A321 series airplanes. The NPRM published in the **Federal Register** on March 5, 2015 (80 FR 11960). The NPRM was prompted by a determination that, in specific flight conditions, the allowable load limits on the vertical tail plane could be reached and possibly exceeded. Exceeding allowable load could result in detachment of the vertical tail plane. The NPRM proposed to require modification of the pin programming of the FWC to activate the SRIW logic; and an inspection to determine the part numbers of the FWC and the FAC, and replacement of the FWC and FAC if necessary. We are issuing this AD to prevent detachment of the vertical tail plane and consequent loss of control of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014–0217R1, dated February 26, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition. The MCAI states:

> During design reviews that were conducted following safety recommendations related to in-service incidents and one accident on another aircraft type, it has been determined that, in specific flight conditions, the allowable load limits on the vertical tail plane could be reached and possibly exceeded.
>
> This condition, if not corrected, could lead, in the worst case, to detachment of the

vertical tail plane in flight and consequent loss of the aeroplane.

To prevent such a possibility, Airbus has developed modifications within the flight augmentation computer (FAC) to reduce the vertical tail plane stress and to activate a conditional aural warning within the flight warning computer (FWC) to further protect against pilot induced rudder doublets.

Consequently, EASA issued AD 2014–0217 (ad.easa.europa.eu/blob/easa_ad_2014_0217.pdf/AD_2014–0217_1) to require installation and activation of the stop rudder input warning (SRIW) logic. In addition, that [EASA] AD required, prior to or concurrent with modification of an aeroplane with the activation of the SRIW, upgrades of the FAC and FWC, to introduce the SRIW logic and SRIW aural capability, respectively. After modification, the [EASA] AD prohibited installation of certain Part Number (P/N) FWC and FAC.

Since that [EASA] AD was issued, an additional previously-published Airbus Service Bulletin (SB) was identified, and a new SB was published, for the concurrent requirement to replace the FAC with a unit having a P/N as listed in Table 3 of Appendix 1 of the AD.

For the reasons described above, this [EASA] AD is revised to amend paragraph (2), adding references to additional Airbus SBs.

In addition, this AD requires, prior to or concurrent with modification of an airplane with the activation of the SRIW, upgrades of the FAC and FWC to introduce the SRIW logic and SRIW aural capability, respectively. After modification, this AD prohibits installation of FWCs and FACs having certain part numbers. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2015-0251-0003.*

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (80 FR 11960, March 5, 2015) and the FAA's response to each comment.

Request To Refer to Revised Service Information

Airbus requested that we refer to revised service information.

We agree with the Airbus request to refer to revised service information. No additional work is required by the revised service information. We have revised paragraph (g) of this AD to refer to Airbus Service Bulletin A320–22–1480, Revision 02, dated March 30, 2015. We have added new paragraph (m)(1) of this AD to provide credit for the actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–22–1480, dated July 9, 2014; or Airbus Service Bulletin A320–22–1480, Revision 01, dated February 6, 2015.

We have revised paragraph (i) of this AD to refer in part to the following service information.

- Airbus Service Bulletin A320–22–1427, Revision 05, including Appendix 01, dated November 24, 2014 (FAC 622 hard B).
- Airbus Service Bulletin A320–22–1447, Revision 03, dated April 21, 2015 (FAC CAA02 hard C).
- Airbus Service Bulletin A320–22–1454, dated February 12, 2014 (FAC CAA02).
- Airbus Service Bulletin A320–22–1461, Revision 07, including Appendix 01, dated March 23, 2015 (FAC B623 hard B).
- Airbus Service Bulletin A320–22–1502, dated November 14, 2014 (FAC CAA02).

We have redesignated paragraph (m) of the proposed AD (80 FR 11960, March 5, 2015) as new paragraph (m)(2) of this AD to provide credit for the actions required by paragraph (i) of this AD, if those actions were performed before the effective date of this AD using the following additional service information.

- Airbus Service Bulletin A320–22–1427, Revision 04, dated February 11, 2014.
- Airbus Service Bulletin A320–22–1447, Revision 01, dated September 18, 2014.
- Airbus Service Bulletin A320–22–1447, Revision 02, dated December 2, 2014.
- Airbus Service Bulletin A320–22–1461, Revision 04, dated September 15, 2014.
- Airbus Service Bulletin A320–22–1461, Revision 05, dated November 13, 2014.
- Airbus Service Bulletin A320–22–1461, Revision 06, dated January 21, 2015.

Request To Clarify Approved Parts

United Airlines (UAL) requested that we split paragraph (h)(3)(iv) of the proposed AD (80 FR 11960, March 5, 2015) into two paragraphs to clarify the approved parts. UAL stated that paragraphs (h)(3)(i), (h)(3)(ii), and (h)(3)(iii) of the proposed AD clearly denote three of the four possible standards of FAC, but paragraph (h)(3)(iv) of the proposed AD leads one to believe that a FAC CAA02 hard C is required regardless of the airplane configuration.

We agree with UAL's request to clarify the FWCs and FACs having the part numbers that are compatible with SRIW activation required by paragraph (g) of this AD. We have revised paragraph (h)(3)(iv) of the AD to state that for all airplanes configured with an FAC standard CAA01, an FAC having soft P/N G2856AAA02 installed on hard P/N C13206AA00 (CAA02 hard C) are compatible with SRIW activation required by paragraph (g) of this AD. We have added new paragraph (h)(3)(v) of this AD to state that for all airplane configurations, an FWC having P/N 350E053021212 (H2–F7) are compatible with SRIW activation required by paragraph (g) of this AD.

Request for Additional Details and Clarification Regarding SRIW Changes

The National Transportation Safety Board (NTSB) stated that there are differences between the Airbus Model A300/A310 series airplane SRIW system and the Airbus Model A320 series airplane SRIW system. The NTSB explained that the Model A300/A310 series airplane SRIW contains a red warning light on the glareshield, which lights when the SRIW is activated; however, the NPRM (80 FR 11960, March 5, 2015) did not mention the warning light as part of the Model A320 series airplane SRIW. The NTSB also stated that details associated with the modifications of the FAC and FWC are not stated in the NPRM (80 FR 11960, March 5, 2015). The NTSB stated that without details regarding the changes associated with the Model A320 series airplane SRIW it cannot fully assess the FAA response for the Model A320 series airplanes to NTSB safety recommendations A–04–56 (*http://www.ntsb.gov/safety/safety-recs/recletters/A04_56_62.pdf*) and A–04–57 (*http://www.ntsb.gov/safety/safety-recs/recletters/A04_56_62.pdf*). The NTSB also wanted the FAA to clarify whether the Model A320 series airplane SRIW has more comprehensive protections compared with the Model A300 series airplane SRIW.

We agree with the NTSB that there are differences between the Airbus Model A300/A310 series airplane and Model A318/A319/A320/A321 series airplane SRIW systems, such as, the latter does not include a light on the glareshield in front of each pilot; instead it includes a red master caution warning in addition to the aural synthetic voice warning to prevent pilots from making any further reversals. In addition, the Model Airbus A318/A319/A320/A321 series airplane SRIW modification includes a rudder travel limiter unit (RTLU) modification in the FAC that minimizes the available deflections for all the possible combinations of altitude and speed. This will ensure that after one full rudder pedal reversal, the vertical tail

plane (VTP) loads remain within the safe limits. After reviewing the design, analyses, and simulator demonstrations, the FAA has concluded that these warnings will prevent the flightcrew from continuing the inappropriate rudder inputs prior to exceeding the ultimate design loads that could result in failure of the vertical tail plane. We have determined that details associated with our disposition to NTSB safety recommendations A–04–56 and A–04–57 are outside the context of this AD. We will provide those details directly to the NTSB in our response to the safety recommendations. We have not changed this final rule in this regard.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (80 FR 11960, March 5, 2015) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (80 FR 11960, March 5, 2015).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

Airbus has issued Service Bulletin A320–22–1480, Revision 02, dated March 30, 2015. This service information describes procedures for modifying the pin programming to activate the SRIW logic.

Airbus has also issued the following service information. The service information describes procedures for replacing FWCs and FACs.

- Airbus Service Bulletin A320–22–1375, dated January 15, 2014.
- Airbus Service Bulletin A320–22–1427, Revision 05, dated November 24, 2014.
- Airbus Service Bulletin A320–22–1447, Revision 03, dated April 21, 2015.
- Airbus Service Bulletin A320–22–1454, dated February 12, 2014.
- Airbus Service Bulletin A320–22–1461, Revision 07, dated March 23, 2015.
- Airbus Service Bulletin A320–22–1502, dated November 14, 2014.
- Airbus Service Bulletin A320–31–1414, Revision 03, dated September 15, 2014.

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

Costs of Compliance

We estimate that this AD affects 953 airplanes of U.S. registry.

We also estimate that it will take about 3 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this AD on U.S. operators to be $243,015, or $255 per product.

In addition, we estimate that any necessary follow-on actions will take about 6 work-hours (3 work-hours for an FWC and 3 work-hours for an FAC), for a cost of up to $510 per product. We have received no definitive data that will enable us to provide part cost estimates for the on-condition actions specified in this AD. We have no way of determining the number of aircraft that might need these actions.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

3. Will not affect intrastate aviation in Alaska; and

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2015-0251;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2015–23–13 Airbus: Amendment 39–18330. Docket No. FAA–2015–0251; Directorate Identifier 2014–NM–200–AD.

(a) Effective Date

This AD becomes effective December 29, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1) through (c)(4) of this AD, certificated in any category, all manufacturer serial numbers.

(1) Airbus Model A318–111, –112, –121, and –122 airplanes.

(2) Airbus Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(3) Airbus Model A320–211, –212, –214, –231, –232, and –233 airplanes.

(4) Airbus Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 22, Auto Flight; 31, Instruments.

(e) Reason

This AD was prompted by a determination that, in specific flight conditions, the allowable load limits on the vertical tail plane could be reached and possibly exceeded. Exceeding allowable load could result in detachment of the vertical tail plane. We are issuing this AD to prevent detachment of the vertical tail plane and consequent loss of control of the airplane.

(f) Compliance

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

(g) Pin Programming Modification

Within 48 months after the effective date of this AD, modify the pin programming to activate the stop rudder input warning (SRIW) logic, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–22–1480, Revision 02, dated March 30, 2015.

(h) Inspection To Determine Part Numbers (P/Ns), Flight Warning Computer (FWC) and Flight Augmentation Computer (FAC) Replacement

Prior to or concurrently with the actions required by paragraph (g) of this AD: Inspect the part numbers of the FWC and the FAC installed on the airplane. If any FWC or FAC having a part number identified in paragraph (h)(1) or (h)(2) of this AD, as applicable, is installed on an airplane, prior to or concurrently with the actions required by paragraph (g) of this AD, replace all affected FWCs and FACs with a unit having a part number identified in paragraph (h)(3) of this AD, in accordance with the Accomplishment Instructions of the applicable Airbus service information specified in paragraph (i) of this AD.

(1) Paragraphs (h)(1)(i) through (h)(1)(xvii) of this AD identify FWCs having part numbers that are non-compatible with the SRIW activation required by paragraph (g) of this AD.

(i) 350E017238484 (H1D1).
(ii) 350E053020303 (H2E3).
(iii) 350E016187171 (C5).
(iv) 350E053020404 (H2E4).
(v) 350E017248685 (H1D2).
(vi) 350E053020606 (H2F2).
(vii) 350E017251414 (H1E1).
(viii) 350E053020707 (H2F3).
(ix) 350E017271616 (H1E2).
(x) 350E053021010 (H2F3P).
(xi) 350E018291818 (H1E3CJ).
(xii) 350E053020808 (H2F4).
(xiii) 350E018301919 (H1E3P).
(xiv) 350E053020909 (H2–F5).
(xv) 350E018312020 (H1E3Q).
(xvi) 350E053021111 (H2–F6).
(xvii) 350E053020202 (H2E2).

(2) Paragraphs (h)(2)(i) through (h)(2)(xxxiv) of this AD identify FACs having part numbers that are non-compatible with the SRIW activation required by paragraph (g) of this AD.

(i) B397AAM0202.
(ii) B397BAM0101.
(iii) B397BAM0512.
(iv) B397AAM0301.
(v) B397BAM0202.
(vi) B397BAM0513.
(vii) B397AAM0302.
(viii) B397BAM0203.
(ix) B397BAM0514.
(x) B397AAM0303.
(xi) B397BAM0305.
(xii) B397BAM0515.
(xiii) B397AAM0404.
(xiv) B397BAM0406.
(xv) B397BAM0616.
(xvi) B397AAM0405.
(xvii) B397BAM0407.
(xviii) B397BAM0617.
(xix) B397AAM0506.
(xx) B397BAM0507.
(xxi) B397BAM0618.
(xxii) B397AAM0507.
(xxiii) B397BAM0508.
(xxiv) B397BAM0619.
(xxv) B397AAM0508.
(xxvi) B397BAM0509.
(xxvii) B397BAM0620.
(xxviii) B397AAM0509.
(xxix) B397BAM0510.
(xxx) B397CAM0101.
(xxxi) B397AAM0510.
(xxxii) B397BAM0511.
(xxxiii) B397CAM0102.
(xxxiv) Soft P/N G2856AAA01 installed on hard P/N C13206AA00.

(3) Paragraphs (h)(3)(i) through (h)(3)(v) of this AD identify the FWCs and FACs having the part numbers that are compatible with SRIW activation required by paragraph (g) of this AD.

(i) For airplane configurations with no sharklet, an FAC having P/N B397BAM0621 (621 hard B).

(ii) For airplanes configured with sharklet A320 and A319, an FAC having P/N B397BAM0622 (622 hard B).

(iii) For airplanes configured with sharklet A321, an FAC having P/N B397BAM0623 (623 hard B).

(iv) For all airplanes configured with an FAC standard CAA01, an FAC having soft P/N G2856AAA02 installed on hard P/N C13206AA00 (CAA02 hard C).

(v) For all airplane configurations, an FWC having P/N 350E053021212 (H2–F7).

(i) Service Information for Actions Required by Paragraph (h) of This AD

Do the actions required by paragraph (h) of this AD in accordance with the Accomplishment Instructions of the applicable Airbus service information specified in paragraphs (i)(1) through (i)(7) of this AD.

(1) Airbus Service Bulletin A320–22–1375, dated January 15, 2014 (FAC 621 hard B).

(2) Airbus Service Bulletin A320–22–1427, Revision 05, including Appendix 01, dated November 24, 2014 (FAC 622 hard B).

(3) Airbus Service Bulletin A320–22–1447, Revision 03, dated April 21, 2015 (FAC CAA02 hard C).

(4) Airbus Service Bulletin A320–22–1454, dated February 12, 2014 (FAC CAA02).

(5) Airbus Service Bulletin A320–22–1461, Revision 07, including Appendix 01, dated March 23, 2015 (FAC 623 hard B).

(6) Airbus Service Bulletin A320–22–1502, dated November 14, 2014 (FAC CAA02).

(7) Airbus Service Bulletin A320–31–1414, Revision 03, dated September 15, 2014 (FWC H–F7).

(j) Exclusion From Actions Required by Paragraphs (g) and (h) of This AD

An airplane on which Airbus Modification 154473 has been embodied in production is excluded from the requirements of paragraphs (g) and (h) of this AD, provided that within 30 days after the effective date of this AD, an inspection of the part numbers of the FWC and the FAC installed on the airplane is done to determine that no FWC having a part number listed in paragraph (h)(1) of this AD, and no FAC having a part number listed in paragraph (h)(2) of this AD, has been installed on that airplane since date of manufacture. A review of airplane maintenance records is acceptable in lieu of this inspection if the part numbers of the FWC and FAC can be conclusively determined from that review. If any FWC or FAC having a part number identified in paragraph (h)(1) or (h)(2) of this AD, as applicable, is installed on a post-Airbus Modification 154473 airplane: Within 30 days after the effective date of this AD, do the replacement required by paragraph (h) of this AD.

(k) Parts Installation Prohibitions

After modification of an airplane as required by paragraphs (g), (h), and (j) of this AD: Do not install on that airplane any FWC having a part number listed in paragraph (h)(1) of this AD or any FAC having a part number listed in paragraph (h)(2) of this AD.

(l) Later Approved Parts

Installation of a version (part number) of the FWC or FAC approved after the effective date of this AD is an approved method of compliance with the requirements of paragraph (h) or (j) of this AD, provided the requirements specified in paragraphs (l)(1) and (l)(2) of this AD are met.

(1) The version (part number) must be approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA).

(2) The installation must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA; or Airbus's EASA DOA.

(m) Credit for Previous Actions

(1) This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–22–1480, dated July 9, 2014; or Airbus Service Bulletin A320–22–1480, Revision 01, dated February 6, 2015. This service information is not incorporated by reference in this AD.

(2) This paragraph provides credit for actions required by paragraph (i) of this AD, if those actions were performed before the effective date of this AD using the applicable Airbus service information identified in paragraphs (m)(2)(i) through (m)(2)(xviii) of

this AD. This service information is not incorporated by reference in this AD.

(i) Airbus Service Bulletin A320–22–1427, dated January 25, 2013.

(ii) Airbus Service Bulletin A320–22–1427, Revision 01, dated July 30, 2013.

(iii) Airbus Service Bulletin A320–22–1427, Revision 02, dated October 14, 2013.

(iv) Airbus Service Bulletin A320–22–1427, Revision 03, dated November 8, 2013.

(v) Airbus Service Bulletin A320–22–1427, Revision 04, dated February 11, 2014.

(vi) Airbus Service Bulletin A320–22–1447, dated October 18, 2013.

(vii) Airbus Service Bulletin A320–22–1447, Revision 01, dated September 18, 2014.

(viii) Airbus Service Bulletin A320–22–1447, Revision 02, dated December 2, 2014.

(ix) Airbus Service Bulletin A320–22–1461, dated October 31, 2013.

(x) Airbus Service Bulletin A320–22–1461, Revision 01, dated February 25, 2014.

(xi) Airbus Service Bulletin A320–22–1461, Revision 02, dated April 30, 2014.

(xii) Airbus Service Bulletin A320–22–1461, Revision 03, dated July 17, 2014.

(xiii) Airbus Service Bulletin A320–22–1461, Revision 04, dated September 15, 2014.

(xiv) Airbus Service Bulletin A320–22–1461, Revision 05, dated November 13, 2014.

(xv) Airbus Service Bulletin A320–22–1461, Revision 06, dated January 21, 2015.

(xvi) Airbus Service Bulletin A320–31–1414, dated December 19, 2012.

(xvii) Airbus Service Bulletin A320–31–1414, Revision 01, dated March 21, 2013.

(xviii) Airbus Service Bulletin A320–31–1414, Revision 02, dated July 30, 2013.

(n) Other FAA AD Provisions

The following provisions also apply to this AD:

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

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

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

(o) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014–0217R1, dated February 26, 2015, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2015-0251-0003.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (p)(3) and (p(4) of this AD.

(p) Material Incorporated by Reference

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

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

(i) Airbus Service Bulletin A320–22–1375, dated January 15, 2014.

(ii) Airbus Service Bulletin A320–22–1427, Revision 05, including Appendix 01, dated November 24, 2014.

(iii) Airbus Service Bulletin A320–22–1447, Revision 03, dated April 21, 2015.

(iv) Airbus Service Bulletin A320–22–1454, dated February 12, 2014.

(v) Airbus Service Bulletin A320–22–1461, Revision 07, including Appendix 01, dated March 23, 2015.

(vi) Airbus Service Bulletin A320–22–1480, Revision 02, dated March 30, 2015.

(vii) Airbus Service Bulletin A320–22–1502, dated November 14, 2014.

(viii) Airbus Service Bulletin A320–31–1414, Revision 03, dated September 15, 2014.

(3) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on November 9, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–29702 Filed 11–23–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2015–1869; Airspace Docket No. 15–AGL–9]

Establishment of Class E Airspace; Newberry, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects an error in the legal description of a final rule published in the **Federal Register** of September 24, 2015, that establishes Class E airspace at the Newberry VHF Omni-Directional Range/Distance Measuring Equipment (VOR/DME), Newberry, MI. The legal description noted exclusionary language for Federal airways and Canadian airspace not required for this airspace.

DATES: Effective date: 0901 UTC, December 10, 2015. The Director of the Federal Register approves this incorporation by reference action under 1 Code of Federal Regulations, Part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Raul Garza, Jr., Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 10101 Hillwood Parkway., Fort Worth, TX 76177; telephone 817–222–5874.

SUPPLEMENTARY INFORMATION:

History

On September 24, 2015, a final rule was published in the **Federal Register** establishing Class E airspace at the Newberry VOR/DME, Newberry, MI (80 FR 57522) Docket No. FAA–2015–1869. Subsequent to publication, the FAA found that the exclusionary language for Federal airways and Canadian airspace noted in the airspace description is not required and, therefore, is removed.

Final Rule Correction

Accordingly, pursuant to the authority delegated to me, in the **Federal Register** of September 24, 2015, (80 FR 57522) FR Doc. 2015–23987, on

page 57523, column 2, beginning on line 26, remove '', excluding that airspace within Federal airways and within Canadian airspace''.

Issued in Fort Worth, TX, on November 10, 2015.

Robert W. Beck,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2015–29704 Filed 11–23–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 528

[Docket No. FDA–2015–N–0002]

New Animal Drugs in Genetically Engineered Animals; opAFP–GHc2 Recombinant Deoxyribonucleic Acid Construct

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency) is amending the animal drug regulations to reflect the approval of a new animal drug application (NADA) filed by AquaBounty Technologies, Inc. The NADA provides for use of a recombinant deoxyribonucleic acid (rDNA) gene construct in a lineage of genetically engineered Atlantic salmon.

DATES: This rule is effective November 24, 2015.

FOR FURTHER INFORMATION CONTACT: Larisa Rudenko, Center for Veterinary Medicine (HFV–2), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8247, email: *abig@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: AquaBounty Technologies, Inc., Two Clock Tower Pl., suite 395, Maynard, MA 01754 filed NADA 141–454 for an *opAFP–GHc2* rDNA construct at the α-locus in the EO–1α lineage triploid, hemizygous, all-female Atlantic salmon (*Salmo salar*) known as AQUADVANTAGE Salmon. Significantly more of these Atlantic salmon grow to at least 100 grams within 2,700 Celsius degree-days than their comparators. The NADA is approved as of November 19, 2015, and the regulations are amended in 21 CFR part 528 to reflect the approval.

In addition, AquaBounty Technologies, Inc., is not currently listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to add entries for this firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application (FOI Summary) may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The Agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact (FONSI) and the evidence supporting that finding, contained in an environmental assessment (EA), may be seen in the Division of Dockets Management (address in the previous paragraph) between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to the Internet may obtain the FOI Summary, EA, and FONSI at the Center for Veterinary Medicine FOIA Electronic Reading Room: *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.* Patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.*

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 528

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 528 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for ''AquaBounty Technologies, Inc.'' and in the table in paragraph (c)(2), numerically add an entry for ''086053'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
AquaBounty Technologies, Inc., Two Clock Tower Pl., suite 395, Maynard, MA 01754	086053
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* *	* * * *
086053	AquaBounty Technologies, Inc., Two Clock Tower Pl., suite 395, Maynard, MA 01754 * * *
* *	* * * *

PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

■ 3. The authority citation for 21 CFR part 528 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 4. Add § 528.1092 to read as follows:

§ 528.1092 opAFP–GHc2 recombinant deoxyribonucleic acid construct.

(a) *Specifications.* A single copy of the α-form of the *opAFP–GHc2* recombinant deoxyribonucleic acid (rDNA) construct at the α-locus in the EO–1 α lineage of triploid, hemizygous, all-female Atlantic salmon (*Salmo salar*).

(b) *Sponsor.* See No. 086053 in § 510.600 of this chapter.

(c) *Indications for use.* Significantly more of these Atlantic salmon grow to at least 100 grams within 2,700 Celsius degree-days than their comparators.

(d) *Limitations.* These Atlantic salmon are produced as eyed-eggs and grown-out only in physically-contained, freshwater culture facilities specified in an FDA-approved application.

Dated: November 19, 2015.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2015–29902 Filed 11–23–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 151

[Docket No. USCG–2012–0924]

RIN 1625–AB68

Ballast Water Management Reporting and Recordkeeping

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: This final rule amends the Coast Guard's ballast water management reporting and recordkeeping requirements. Upon the effective date of this rule, the Coast Guard will require vessels with ballast tanks operating exclusively on voyages between ports or places within a single Captain of the Port Zone to submit an annual report of their ballast water management practices. This rule also simplifies and streamlines the ballast water report form. Finally, this rule will allow most vessels to submit ballast water reports after arrival at a port or place of destination, instead of requiring submission of such reports prior to arrival. This rule will reduce the administrative burden on the regulated population, while still providing the Coast Guard with the information necessary to analyze and understand ballast water management practices.

DATES: This final rule is effective February 22, 2016, except for the amendments to 33 CFR 151.2060(b) through (f) and 151.2070, which contain collection of information requirements that have not yet been approved by the Office of Management and Budget (OMB). The Coast Guard will publish a document in the **Federal Register** announcing the effective date of those sections.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2012–0924 and are available on the Internet by going to *http://www.regulations.gov,* inserting USCG–2010–0924 in the ''Keyword'' box, and then clicking ''Search.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Ms. Regina Bergner, Environmental Standards Division (CG–OES–3), Coast Guard; telephone 202–372–1431, email *Regina.R.Bergner@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

I. Abbreviations

BWM Ballast Water Management
CFR Code of Federal Regulations
COTP Captain of the Port
EPA Environmental Protection Agency
EEZ Exclusive Economic Zone
FR Federal Register
IMO International Maritime Organization
MISLE Marine Information for Safety and Law Enforcement
NANPCA Non-Indigenous Aquatic Nuisance Prevention and Control Act of 1990
NBIC National Ballast Information Clearinghouse
NISA National Invasive Species Act of 1996
OMB Office of Management and Budget
Pub. L. Public Law
RFA Regulatory Flexibility Act
SANS Ship Arrival Notification System
U.S.C. United States Code

II. Background

A vessel brings water into its ballast tanks to control or maintain trim, draft, stability or stress of the vessel when it is fully or partially empty of cargo. Generally, the vessel will discharge ballast water when it loads cargo, often at another port of call. Vessels discharge more than 80 million tons of ballast water annually into U.S. waters.[1]

Many invasive species have been introduced into U.S. waters through ballast water discharge because ballast water often contains organisms indigenous to the area where it was loaded. These organisms can become invasive species when they are discharged in a new location, often with damaging results.[2]

The Great Lakes provide many examples of the damage invasive species can inflict on an environment. According to the U.S. Environmental Protection Agency (EPA),[3] no fewer than 25 invasive species of fish have entered the Great Lakes. Invasive filter-feeders such as zebra mussels have caused severe problems at power plants and municipal water supplies, clogging intake screens, pipes, and cooling systems. Fast-growing invasive plants have displaced native plant populations that support wildlife habitat and prevent erosion. The prevalence of these invasive plant species has also hindered commercial and recreational activities. Similar problems with invasive species have occurred in U.S. waters throughout the country.[4]

III. Basis and Purpose

A. Legal Authority

The Non-Indigenous Aquatic Nuisance Prevention and Control Act of 1990 (NANPCA, Pub. L. 101–646), as amended by the National Invasive Species Act of 1996 (NISA), (Pub. L. 104–332), requires the Secretary of Homeland Security (Secretary) to ensure, to the maximum extent practicable, that aquatic nuisance species are not discharged into U.S. waters from vessels (16 U.S.C. 4701 *et seq.*). These statutes also direct the Secretary to issue regulations and collect records regarding vessel ballasting practices as a means for determining vessel compliance with the

[1] See the American Association of Port Authorities Web site at *http://www.aapa-ports.org/Issues/USGovRelDetail.cfm?itemnumber=880.*

[2] For a list of examples of aquatic bio-invasions causing major impact internationally, see the International Maritime Organization's Web site at: *http://www.imo.org/OurWork/Environment/BallastWaterManagement/Pages/AquaticInvasiveSpecies(AIS).aspx.*

[3] See the EPA's Web site at *http://www.epa.gov/glnpo/invasive.*

[4] The U.S. Geological Survey maintains an online database of non-indigenous aquatic species at *http://nas.er.usgs.gov.* The database is searchable by several variables, including by state and species.

ballast water management (BWM) program (16 U.S.C. 4711(c) and (f)).

The Secretary has delegated the regulatory functions and authorities in 16 U.S.C. 4711 to the Commandant of the Coast Guard (Department of Homeland Security Delegation No. 0170.1 (II.) 57). Coast Guard regulations regarding BWM are located in 33 CFR part 151, subparts C and D. With limited exceptions, these regulations apply to all vessels, U.S. and foreign, equipped with ballast tanks, that operate in U.S. waters. (*see* 33 CFR 151.2005, 151.2010, 151.2015, and 151.2025).

This final rule revises the regulatory provisions that deal with BWM reporting and recordkeeping requirements. A full discussion of the statutory and regulatory history of the Coast Guard's broader actions to implement both NANPCA and NISA may be found in the preamble to the final rule entitled ''Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters,'' published on March 23, 2012 (77 FR 17254).

B. Purposes of This Regulatory Action

This regulatory action implements provisions of NANPCA and NISA by requiring the collection of records on vessel BWM practices. The Coast Guard will now require vessels with ballast tanks operating exclusively on voyages between ports or places within a single Captain of the Port (COTP) Zone to submit an annual report of their BWM practices. This rule also allows most vessels to submit ballast water reports after arrival at a port or place of destination, instead of requiring submission of such reports prior to arrival. Additionally, this rule simplifies and streamlines the ballast water report form. This rule will reduce reporting redundancies affecting the regulated population, while still providing the Coast Guard with the information necessary to analyze and understand BWM practices. By doing so, this rule is intended to improve the Coast Guard's knowledge about such practices, which will enable us to reduce the discharge of aquatic nuisance species into U.S. waters from vessels and to reduce future damage caused by such discharges.

Efficient and effective BWM data collection is essential to the Coast Guard's ability to evaluate the availability of BWM technologies for the range of vessels operating in waters of the U.S. These important data directly inform the Coast Guard's decision making efforts to ensure, to the maximum extent practicable, that aquatic nuisance species are not discharged into waters of the U.S.

IV. Regulatory History

On June 5, 2013, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled ''Ballast Water Management Reporting and Recordkeeping'' in the **Federal Register** (78 FR 33774). No public meeting was requested for this rulemaking and none was held. A summary of the proposals in the NPRM is provided below.

The Coast Guard proposed a three-year requirement applicable to vessels equipped with ballast tanks and operating exclusively on voyages between ports and places within a single COTP Zone to submit an annual summary report of their BWM practices. Historically, the Coast Guard has not collected extensive information about the BWM practices of this segment of the vessel population because it seemed unlikely that vessels operating within a single COTP Zone would introduce invasive species from place to place within the COTP Zone. Public comments received in response to the most recent Coast Guard rulemaking on ballast water [5] correctly indicated that COTP Zones are administrative in nature, and are not established based on any ecological or biological bases. Therefore, COTP Zones may not necessarily be appropriate boundaries for assessing invasive species. The Coast Guard proposed this new three-year annual reporting requirement to improve the breadth and quality of BWM data so it can make the most informed programmatic and regulatory decisions. Additionally, collecting this information advances the Coast Guard's efforts to meet the statutory requirement to maintain a clearinghouse of national ballast water data (16 U.S.C. 4712(f)).

The Coast Guard also proposed to simplify ballast water reporting for all vessels by revising the report form and encouraging electronic report submission. We proposed to streamline the reporting process and to revise the report to include only data that are essential to understanding and analyzing BWM practices.

Finally, the Coast Guard proposed to allow vessels bound for a port or destination outside of the Great Lakes or the Hudson River north of the George Washington Bridge to submit ballast water reports either no later than six hours after arrival, or prior to departure, whichever is earlier. Prior to this rulemaking, the regulations required certain vessels to submit ballast water reports before arriving at the port or destination. As a practical matter, vessels often discovered information after arrival that necessitated amending the reports. Accordingly, the Coast Guard proposed the change in submission requirements to reduce the need for amended reports.

[5] Notice of proposed rulemaking entitled ''Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters'' (74 FR 44632; August 28, 2009). The docket for that rulemaking is available for viewing online at *www.regulations.gov,* Docket Number USCG–2001–10486.

V. Discussion of NPRM Comments and Changes

In response to the NPRM, the Coast Guard received 6 public comment letters containing a total of 13 separate comments. The comments are available for viewing in the public docket for this rulemaking, where indicated above under **ADDRESSES**.

This section contains a description of each comment, followed by the Coast Guard's response. Since several of the letters raised similar issues, this section is organized by comment topic. Except for the changes identified in this section, the Coast Guard adopts the regulations as proposed in the NPRM without change.

A. Three-Year Annual Reporting Requirement for Vessels Operating Exclusively Within a Single COTP Zone

One commenter supported the proposal to require vessels operating within a single COTP zone to submit annual reports for three years. The commenter stated that annual reporting would provide data that is useful to the Coast Guard for making regulatory decisions affecting these vessels. The Coast Guard agrees.

One commenter opposed the proposal to require vessels operating within a single COTP zone to submit annual reports, arguing that the burden of the reporting requirement is not justified due to the low risk of introduction of aquatic invasive species within a single COTP zone. The Coast Guard disagrees. An annual report, limited to three years, presents a minimal burden, but will provide the essential data for the Coast Guard to determine whether vessels that operate solely in a single COTP zone should be subject to the same or similar BWM regulations as those applicable to vessels operating in multiple COTP zones.

The commenter also suggested the Coast Guard could obtain all necessary ballast water operation information from advisory committees and trade associations instead of introducing new reporting requirements. The Coast Guard disagrees. Data from such sources would be limited because not all vessel owners and operators are members of trade associations or represented in advisory committee studies.

Furthermore, reports to such trade associations and advisory committees would be voluntary instead of legally required, which would limit the amount of data. For these reasons, a streamlined, annual report is the more effective approach for collecting accurate data.

B. Revisions to the Ballast Water Reporting Form

Two commenters supported the Coast Guard's proposal to streamline and simplify the ballast water reporting form. In this final rule, the Coast Guard is taking an additional step to simplify the regulations in §§ 151.2060 (Reporting requirements) and 151.2070 (Recordkeeping requirements). The Coast Guard intends to align the information required for reporting and recordkeeping purposes as much as possible because the information required to satisfy both requirements is almost identical. The NPRM, however, listed the information required for reporting purposes under § 151.2060, and separately listed similar information required for recordkeeping purposes in § 151.2070. Upon further review of the NPRM, the Coast Guard wishes to avoid any confusion or misunderstanding regarding the lists of information required for reporting and recordkeeping. Specifically, the Coast Guard wishes to avoid a misunderstanding that there is one set of information required under § 151.2060 for reporting purposes, and a separate set of information required under § 151.2070 for recordkeeping purposes. Accordingly, for regulatory clarity, this final rule now lists the information required for reporting purposes in § 151.2060. Instead of repeating that list of information for recordkeeping, § 151.2070(a) simply states that there is a requirement to maintain records of all the information required to be reported under § 151.2060. Also in § 151.2070, there is an additional recordkeeping requirement regarding sediment discharge. Sediment discharge is the one data point which is subject to the recordkeeping requirement, but is not subject to the reporting requirement.

Another commenter requested an additional change to the form that would enable a reporting officer to sign the form electronically. The Coast Guard is granting this request. Ballast water reporting forms are submitted to the National Ballast Information Clearinghouse (NBIC) using any of the methods on the NBIC Web site.[6] Reporters may complete the form by filling out the fields on NBIC's online click-thru web-based version of the form. At the end of the web-based form, reporters will be asked to electronically certify the accuracy of the information provided. This certification satisfies the Coast Guard's signature requirement in § 151.2070 for recordkeeping purposes.

One commenter requested an additional change to the form that would enable reporters to highlight an entire column and fill it out with one entry that stays constant (or near-constant) throughout the body of the report. The Coast Guard wishes to clarify that while we manage the content of the form, NBIC manages the functionality of the form. The Coast Guard communicated the commenter's request to NBIC for its consideration. NBIC advised against the commenter's request, noting that it implemented this option into an earlier test version of the form and found that it resulted in too many errors. Specifically, the ease of use of auto-fill columns was outweighed by the tendency of reporters to not enter data in these columns accurately. As form technology evolves, NBIC will consider adding an auto-fill function pending availability of a system that is better at identifying and eliminating errors.

One commenter requested that the Coast Guard continue to allow all vessel operators the choice of reporting ballast water capacities and discharge volumes in gallons or metric tons. The Coast Guard communicated the commenter's request to NBIC for its consideration. NBIC has agreed to change the form to include a drop-down menu that enables reporters to choose gallons or cubic meters as their preferred unit of measurement. Because the form will now allow reporters to choose which volumetric unit to use, we have removed the specific reference to cubic meters from the regulatory text in 33 CFR 151.2060.

One commenter noted that the form requires reporters to provide the vessel's International Maritime Organization (IMO) number, though many U.S.-flagged vessels are not issued IMO numbers. The commenter recommended an amendment to the form to specify another acceptable identification number for such vessels. In response, the Ballast Water Reporting form will be updated to offer an option for inputting either the IMO number or other documentation number.

C. Timing of Report Submission

Three commenters supported the Coast Guard's proposal to allow vessels to submit ballast water reports after arrival at a port or place of destination. The Coast Guard adopts the proposal without change. For purposes of clarity, we note that Coast Guard regulations in 33 CFR 151.2005 define the phrase ''[p]ort or place of destination'' to mean ''. . . any port or place to which a vessel is bound to anchor or moor.'' The Coast Guard provides further guidance on the practical application of the phrase ''port or place of destination'' for ballast water reporting purposes in Navigation and Vessel Inspection Circular NVIC 07–04, Change 1 (Oct. 29, 2004).[7] For example, for barges equipped with ballast tanks, reports must be submitted only for stops where cargo operations are conducted. For towing vessels equipped with ballast tanks, reports must be submitted when the vessel conducts fueling operations. In both cases, reports are not required when the vessel stops for fleeting, waits for locks, or purposes other than cargo or fueling operations.

One commenter requested a change to the regulations to emphasize that vessels operating on the Great Lakes are covered under the new provision permitting report submission within six hours after arrival at a port or place of destination. While the Coast Guard agrees that the vessels in question are covered under this provision, we are not granting the commenter's request to change the regulatory text because the language in 33 CFR 151.2060 is sufficiently clear on this point, and it is unnecessary to add specific language solely for Great Lakes vessels.

One commenter suggested 2 alternatives for when the 6-hour post-arrival submission window should start in order to further reduce the need for amended reports. The commenter suggested that the 6-hour window should start when the vessel's cargo operations commence, even if this is some time after the vessel arrives at berth. Alternatively, the commenter suggested that the 6-hour window should start when the vessel arrives at berth. The Coast Guard rejects the commenter's preferred approach because it would mean different timing for different vessels, causing inconsistency in applying and enforcing the 6-hour submission window. Regarding the commenter's alternative approach, the Coast Guard expects that the 6-hour submission window starting upon arrival at the ''port or place of destination'' as discussed above will give the vessel crew ample time to submit an accurate ballast water report, without the need for an amended report

[6] Forms are submitted through NBIC's Web site at *http://invasions.si.edu/nbic/submit.html.*

[7] NVIC 07–04 may be viewed online at: *http://www.uscg.mil/hq/cg5/nvic/pdf/2004/NVIC_07-04_CH-1.pdf.*

in most instances. The Coast Guard will, however, continue to enable vessels to submit an amended report when necessary.

D. Other Comments and Changes

One commenter requested that the Coast Guard provide a definition of the term ''trip'' for reporting purposes on operations exclusively within a single COTP Zone. We agree that the term ''trip'' is ambiguous. To clarify, the Coast Guard is not seeking reported information on each and every vessel movement. Instead, we are seeking reported information on the number of ballast water discharges, if any. The Coast Guard has modified the regulatory text by removing the term ''trip'' to more clearly reflect the Coast Guard's intention.

Two commenters questioned the utility of BWM data to the Coast Guard, and requested that we consider eliminating BWM reporting and recordkeeping requirements altogether. For the reasons discussed below, the Coast Guard cannot grant this request.

The Coast Guard requires vessels to report and to maintain records of BWM practices and activities pursuant to a statutory mandate (16 U.S.C. 4711(f)). More specifically, this information enables us to assess the rate of effective compliance with established BWM requirements and guidelines. The information provides important data on volumes of ballast water discharged by different types of vessels, patterns of ballast water transport (*i.e.,* locations where ballast water is loaded and discharged), patterns of BWM by different types of vessels, and safety and practicability issues that affect the ability of different types of vessels to implement specific BWM practices.

Additionally, the Coast Guard uses the reported information to track patterns of BWM and delivery in the U.S. over time. These data provide information on the relative amounts of ballast water that different types of vessels must manage, as well as the circumstances (*e.g.,* voyage lengths and routes) that necessitate BWM. These data are also essential in evaluating the availability of BWM technologies for the range of vessels operating in waters of the U.S. These important data directly inform the Coast Guard's decision making efforts to ensure, to the maximum extent practicable, that aquatic nuisance species are not discharged into waters of the U.S.

One commenter questioned whether this rulemaking applies to vessels that operate outside of U.S. waters (*i.e.,* beyond 12 nautical miles of shore), but still within the Exclusive Economic Zone (EEZ), which generally extends 200 nautical miles from the territorial sea baseline.[8] The Coast Guard confirms that this rulemaking does not apply to vessels operating exclusively outside of U.S. waters. In accordance with the applicability provision in 33 CFR 151.2010, this rulemaking ''applies to all non-recreational vessels, U.S. and foreign, that are equipped with ballast tanks and operate in the waters of the United States, except as expressly provided in § 151.2015 or § 151.2020 of [33 CFR part 151 subpart D].''

Two commenters requested exemptions from the ballast water reporting requirements for certain vessels, including those that do not discharge ballast water from their tanks and those that use potable water for ballast. The Coast Guard is not granting these requests for blanket exemptions. The controlling statutory provisions in 46 U.S.C. 4711(c) and (f) require the Coast Guard to apply these regulations to ''. . . all vessels equipped with ballast water tanks that operate in the waters of the United States.'' It is the presence of a ballast water tank that triggers the applicable reporting requirement, not the discharge of ballast water. When a vessel is equipped with a ballast water tank, the non-discharge of ballast water or the use of potable water for ballast is a BWM practice, and the reporting requirement provides useful information regarding the effectiveness of these measures in preventing the introduction or spread of invasive species. The purpose of the reported information is to assist the Coast Guard in evaluating BWM practices in general, regardless of whether a vessel discharges ballast water. However, we remind owners and operators that 33 CFR 151.2065 provides relief under certain circumstances (*i.e.,* where compliance with 33 CFR 151.2060 is economically or physically impractical) to submit a request for the Coast Guard to approve an alternative equivalent reporting method.

[8] *See* 33 CFR 2.30.

We are revising the text in 33 CFR 151.2015 in several places to refer to a ''single'' COTP zone instead of ''one'' COTP zone for clarity and consistency with the rest of that section. Additionally, we are revising the text in 33 CFR 151.2060(b)(1)(ii) to reflect the accurate name of the ''St. Lawrence Seaway Ballast Water Reporting Form.'' These are non-substantive technical changes.

VI. Regulatory Analyses

We developed this final rule after considering numerous statutes and executive orders related to rulemaking. Below, we summarize our analyses based on these statutes or executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 (''Regulatory Planning and Review'') and 13563 (''Improving Regulation and Regulatory Review'') 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 (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 final rule has not been designated a ''significant regulatory action'' under section 3(f) of Executive Order 12866, ''Regulatory Planning and Review,'' as supplemented by Executive Order 13563, ''Improving Regulation and Regulatory Review,'' and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. Accordingly, the final rule has not been reviewed by the Office of Management and Budget (OMB).

We received no public comments that affect the Regulatory Assessment (RA); nor have we identified any new information or data that would require us to reassess the RA in the NPRM. We, therefore, adopt the NPRM's Regulatory Assessment as the final assessment to this final rule. A final Regulatory Assessment is provided as follows:

Table 1 presents a summary of the economic impact of this final rule. A detailed description of the estimates is presented in the next sections.

TABLE 1—SUMMARY OF REGULATORY ECONOMIC IMPACTS

Changes	Description	Affected population	Costs (7% discount rate)		Benefits
			Annualized	Total	
1. Require vessels operating exclusively on voyages between ports and places within a single COTP Zone to report BWM practices.	Owners or operators of vessels with ballast tanks and operating exclusively on voyages between ports or places within a single COTP Zone would be required to submit an annual summary of their BWM practices. This information collection requirement would be for a 3 year period.	400 owners or operators of 1,280 vessels operating in a single COTP Zone.	$22,110	$155,292	Improve the breadth and quality of BWM data, enabling the Coast Guard and others to make the most informed programmatic and regulatory actions to prevent non-indigenous species invasions in U.S. waters.
2. Update current ballast water report requirements.	Update current ballast water report. Vessels already complying with 33 CFR 151.2070 requirements would not incur additional burden due to the updates.	Vessels currently reporting BWM activities under 33 CFR 151.2070.	$0	$0	Concise reporting and inclusion of only essential data on BWM practices.
3. Allow vessel owners or operators to submit ballast water reports after arrival to the port or place of destination.	Currently, vessels are required to submit reports 24 hours prior to arrival. Allowing vessels to report after arrival—when their ballasting activities are complete—should greatly reduce the need for post-arrival amendments.	Vessels currently reporting BWM activities under 33 CFR 151.2070.	($184,868) Cost savings.	($1,298,437) Cost savings.	Reduce the administrative burden on the regulated population. We estimate that this final rule will eliminate an average of 10,717 post-arrival reports per year.
4. Change the format of electronic report..	Standardize the data format and add pull down menus to reduce data entry errors..	Vessels currently reporting BWM activities under 33 CFR 151.2070.	$0	$0	Facilitate electronic report submission and improve efficiency in data handling and analysis.

This final rule would modify and amend the following recordkeeping requirements and procedures:

1. Require Vessels Operating in a Single COTP Zone To Report BWM Practices

In this final rule, the Coast Guard requires owners or operators of vessels with ballast tanks operating exclusively on voyages between ports or places within a single COTP Zone to submit an annual summary report of their BWM practices for a period of 3 years.

Based on data from the Coast Guard Marine Information for Safety and Law Enforcement (MISLE) and the Ship Arrival Notification System (SANS), we estimate that the final rule will have an annual affect on 1,280 U.S.-flagged vessels that operate exclusively between ports or places within a single COTP Zone. Table 2 presents the vessel types affected by this requirement. These vessels are currently exempt from the ballast water reporting requirements under 33 CFR 151.2070. Owners or operators of these vessels will be required to submit an annual summary report of their BWM practices to the Coast Guard for a period of 3 years.

TABLE 2—U.S. FLAG VESSELS OPERATING EXCLUSIVELY BETWEEN PORTS OR PLACES WITHIN A SINGLE COTP ZONE

Vessel type	Affected population
Commercial Fishing Vessel ..	117
Fish Processing Vessel	4
Freight Ship	117
Industrial Vessel	28
Mobile Offshore Drilling Unit	5
Offshore Supply Vessel	175
Oil Recovery	6
Passenger (inspected)	154
Passenger (uninspected)	3
Research Vessel	11
Tank Ship	29
Towing Vessel	604
Other Vessels[9]	27
Total	1,280

Source: MISLE and SANS data.

[9] Includes permanently moored vessels, school ships, and vessels with unspecified vessel type.

For the purposes of the cost analysis, we assume that all vessels discharge ballast water. We estimate the total annual burden hours required to complete the report will be approximately 40 minutes per vessel per year. We anticipate vessel owners or operators will need 15 minutes to complete and submit their annual ballasting report. Most of the information required is well known by the vessel owner or operator and does not require additional document consultation. The information that does not require additional document consultation includes: Vessel name, identification number, type, operator, tonnage, call sign, COTP Zone of operation, number of ballast water tanks, total ballast water capacity, and primary port of ballast water loading and discharge.

The remaining 25 minutes accounts for the total time allocated (over the entire year) for vessel operators to assemble and review information to determine the number of times ballast water is discharged and the volume of

discharge released during such vessel operations. We also recognize that vessels that do not discharge ballast water will only be burdened with the 15 minutes to fill out and submit the annual form.

We assume that the vessel owner or operator, with an estimated wage rate of $69/hr [10], will be in charge of this reporting. The annual cost per vessel is $46.23 (.67 hrs × $69/hr) and the total cost per vessel for the 3-year period is $139. The estimated annual cost of the new reporting requirement for the 1,280 vessels, operating exclusively between ports or places within a single COTP Zone, is, $59,174 (1,280 vessels × .67 hrs × $69 hr) (undiscounted). The total cost for a 3-year reporting period is $177,522 (undiscounted) or $155,291 (at seven percent discount rate). Table 3 presents the reporting costs for vessels operating exclusively between ports or places within a single COTP Zone.

TABLE 3—ANNUAL AND TOTAL COST OF REPORTING (IN US$) FOR VESSELS OPERATING EXCLUSIVELY BETWEEN PORTS OR PLACES WITHIN A SINGLE COTP ZONE

Year [11]	Cost		
	Undiscounted	At 7 percent discount rate	At 3 percent discount rate
1	$59,174	$55,303	$57,450
2	59,174	51,685	55,777
3	59,174	48,304	54,153
4–10	0	0	0
Total	177,523	155,292	167,380
Annualized		22,110	19,622

This final rule will collect information on ballast water operations from vessels operating exclusively between ports or places within a single COTP Zone, a segment of the industry for which the Coast Guard has limited information. Therefore, the Coast Guard seeks to improve the breadth and quality of its BWM data so it can make the most informed programmatic and regulatory decisions.

The Coast Guard considered several alternatives for collecting the needed information on the ballast practices for vessels operating exclusively between ports or places within a single COTP Zone. One alternative would require these vessels to complete a full ballast water reporting form (33 CFR 151.2060) upon each entry into port, similar to existing requirements for other vessels operating outside a single COTP Zone. The Coast Guard instead chose the alternative that requires only an annual summary report of ballast activities with a limited number of required data elements. The Coast Guard will also collect this data for only 3 years. The Coast Guard believes that the annual summary report for 3 years provides enough information to characterize BWM practices for vessels operating exclusively between ports or places within a single COTP Zone, while minimizing the reporting burden to these entities.

2. Update Current Ballast Water Report Requirements (33 CFR 151.2060)

The Coast Guard is updating the ballast water reporting form to make it more concise and include only essential data on BWM practices. Current recordkeeping requirements in 33 CFR 151.2070 are amended to include only data fields essential for understanding and analyzing BWM practices of vessels operating in waters of the U.S.

Vessel owners or operators who currently submit ballast water reports to comply with 33 CFR 151.2060 requirements will not incur additional burden due to the reporting updates. Updates to the report form will make questions more clear and concise. The most time consuming section of the report (section 5, ''Ballast Water History'') will be restructured, but the content will be maintained. We do not expect that changes to the reporting form will affect the amount of burden time necessary to fill-out the form. Currently, vessels equipped with ballast water tanks bound for ports or places within the U.S. or those entering U.S. waters are required to submit a ballast water report. According to the Coast Guard's estimate in OMB collection of information Control Number 1625–0069, it takes approximately 40 minutes to complete and submit the report. The CFR at 33 CFR 151.2060 and 151.2070 presents detailed information on reporting and recordkeeping requirements.

In addition, updating the current reporting form will improve the utility of the data provided by the vessel population to the Coast Guard.

3. Allow Vessels To Submit Ballast Water Reports After Arrival to the Port or Place of Destination

Prior to this final rule, 33 CFR 151.2060 required vessels to predict their ballasting operations and submit reports on BWM 24 hours before arrival at port. Often, vessel owners and operators would revise their reports with the actual ballasting information and resubmit them to NBIC. NBIC estimates that approximately 40 percent of the amended reports it receives are due to the timing of the report submission. Allowing those vessels travelling from outside of the EEZ that are not bound for the Great Lakes or the Hudson River north of the George Washington Bridge to submit ballast water reports after arrival to the port or place of destination greatly reduces the need for amended reports. We estimate that an average of 10,717 reports [12] are amended and resubmitted every year due to the timing of submission. We estimate that it would take the vessel owner or operator approximately 15 minutes to amend and resend the reports. Therefore, we expect that this amendment will result in an annual reduction of burden by approximately 2,679 hours (10,717 reports × 0.25 hours [13]), representing a cost savings of

[10] Fully loaded wage rate for GS–12 (equivalent) out-of-govt., obtained from Enclosure (2) to COMDTINST 7310.1M and validated based on the Bureau of Labor Statistics (BLS) subcategory Managers (Occupation Code 11–9199) using a base average form years 2010–2011 data and a load factor of 1.4.

[11] The Coast Guard anticipates the information collection requirement would lapse after the completion of 3 years.

[12] The estimate is based on data provided by NBIC on superseded reports for 2006 to 2012.

[13] Estimation based on time reported in the OMB 1625–0069 from vessel operators currently

$184,868 (2,679 hours × $69/hr [14]) per year to the industry. The total cost savings (Table 4) that results from allowing report submittal after arrival at a port for a 10-year period is $1,298,437 (at 7 percent discount rate).

TABLE 4—ANNUAL AND TOTAL COST SAVINGS OF CHANGING THE TIME OF THE REPORT

Year	Cost savings		
	Undiscounted	At 7 percent discount rate	At 3 percent discount rate
1	($184,868)	($172,774)	($179,484)
2	(184,868)	(161,471)	(174,256)
3	(184,868)	(150,908)	(169,181)
4	(184,868)	(141,035)	(164,253)
5	(184,868)	(131,809)	(159,469)
6	(184,868)	(123,186)	(154,824)
7	(184,868)	(115,127)	(150,315)
8	(184,868)	(107,595)	(145,937)
9	(184,868)	(100,556)	(141,686)
10	(184,868)	(93,978)	(137,559)
Total	(1,848,683)	(1,298,437)	(1,576,964)
Annualized		(184,868)	(184,868)

4. Change the Format of Electronic Reports

The Coast Guard expects reporting efficiency and data handling will improve by changing the format of the electronic report that can be found in Information Collection Request (ICR), OMB Control number 1625–0069. The Coast Guard will standardize the data formats and add pull down menus. Since the pull down menu will make the reporting form simpler and will reduce response variability, we do not anticipate any significant change in the reporting burden. These efficiencies will not result in cost savings. Therefore, we do not expect additional costs or cost savings to the industry. According to NBIC data from the past 6 years, approximately 99 percent of reports have been submitted electronically. Within the last 2 years, 100 percent of the reports have been submitted electronically. Standardized data entry will improve data quality and, as a result, data analyses will be easier and less time consuming.

5. Summary of Economic Impacts of Final Rule

This final rule will impact the industry for a limited time only (3 years). During this time, we estimate a total annual non-discounted cost savings of $125,694 and a total 10-year non-discounted cost savings of $1,671,160. We also estimate an annualized cost savings of $162,758, with a discounted ten-year saving of $1,443,145 both respectively discounted at 7 percent for a 10-year period of analysis. These estimates are developed and shown in Table 5.

TABLE 5—ANNUAL AND TOTAL ECONOMIC IMPACT OF FINAL RULE

[At 7 percent discount rate]

Year	1. Report from vessels operating exclusively in a single COTP Zone (cost)	2. Update current ballast water report	3. Allow vessels to submit reports after arrival (cost savings)	4. Require reports be submitted electronically	Economic impact of final rule
1	$55,303	$0	($172,774)	$0	($117,471)
2	51,685	0	(161,471)	0	(109,786)
3	48,304	0	(150,908)	0	(102,604)
4		0	(141,035)	0	(141,035)
5		0	(131,809)	0	(131,809)
6		0	(123,186)	0	(123,186)
7		0	(115,127)	0	(115,127)
8		0	(107,595)	0	(107,595)
9		0	(100,556)	0	(100,556)
10		0	(93,978)	0	(93,978)
Total	155,292	0	(1,298,437)	0	(1,143,145)
Annualized	22,110	0	(184,868)	0	(162,758)

Note: Totals may not add due to rounding.

B. Small Entities

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), we have considered whether this final rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are

completing ballast water management reports to comply with 33 CFR 151.2070.

[14] Wage rate obtained from Enclosure (2) to COMDTINST 7310.1M and validated based on the BLS subcategory Managers (Occupation Code 11–9199).

independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

As described in the ''Regulatory Analyses'' section, we expect costs per vessel (an annual cost of $46.23 for a 3-year period) to owners or operators of vessels operating exclusively between ports or places within a single COTP Zone. Based on available data, we estimate that about 74 percent of entities affected by this final rule are small under the RFA and the Small Business Administration's size standards. The economic impact of the 3-year reporting requirement is less than 1 percent of revenue for 100 percent of the small entities. We determine that each entity, on average, manages a total of 3 vessels with an estimated annual cost of $139 (3 * $46.23) (non-discounted). We have estimated that for this rule to have a revenue impact of greater than 1 percent, total annual revenue for small entities must be less than $13,900. Therefore, we anticipate that this final rule will not have a significant economic impact on small entities. Through this final rule, the Coast Guard will obtain information on ballast water operations from a segment of the industry for which there is limited information, and improve the utility of the data provided to Coast Guard.

Owners and operators of applicable vessels already reporting BWM practices under 33 CFR 151.2060 would incur a cost savings as a result of the elimination of post-arrival amendments due to time of the reporting.

Therefore, the Coast Guard certifies that under 5 U.S.C. 605(b), this final rule will not have a significant economic impact on a substantial number of small entities.

C. Assistance for Small Entities

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 final rule so that they can better evaluate its effects on them and participate in the rulemaking. If the final rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult Ms. Regina Bergner, Environmental Standards Division, U.S. Coast Guard (CG–OES–3); telephone 202–372–1431, email, *Regina.r.bergner@uscg.mil*. 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.

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).

D. Collection of Information

This final rule modifies an existing collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). As defined in 5 CFR 1320.3(c), ''collection of information'' comprises reporting, recordkeeping, monitoring, posting, labeling, and other, similar actions. The title and description of the information collection, a description of those who must collect the information, and an estimate of the total annual burden follow. The burden-hour estimates cover the time for reviewing instructions, searching existing sources of data, gathering and maintaining the data needed, and completing and reviewing the collection.

Title: Ballast Water Management Reporting and Recordkeeping.

OMB Control Number: 1625–0069.

Summary of the Collection of Information: This final rule modifies the existing BWM recordkeeping requirements in 33 CFR 151.2070 and amends the ballast water report. In this final rule, the Coast Guard requires vessels with ballast tanks that operate exclusively on voyages between ports or places within a single COTP Zone to submit an annual summary report of their BWM practices for 3 years. The Coast Guard is also updating the ballast water report to include only data that are essential to understanding and analyzing BWM practices. These updates will not result in changes to current industry burden. The final rule also allows most vessels to submit ballast water reports after arrival at the port or place of destination.

Need for Information: It is essential for the Coast Guard to improve the breadth and quality of its BWM data so it can make the most informed programmatic and regulatory decisions on how to prevent the introduction of non-indigenous aquatic species in U.S. waters. Limited information is available for vessels operating exclusively between ports or places within a single COTP Zone, since most of these vessels are exempt from the reporting requirements of 33 CFR 151.2060.

Use of Information: BWM data from a segment of the industry for which the Coast Guard has limited information will improve the utility of the data provided by the currently-regulated vessel population.

Description of the Respondents: The respondents are:

(a) Owners and operators of vessels with ballast water tanks operating exclusively on voyages between ports or places within a single COTP Zone.

(b) Owners and operators of vessels currently reporting BWM activities under 33 CFR 151.2060.

Number of Respondents: The current number of respondents is 8,383. The requirements of this final rule will add 1,280 respondents from vessels with ballast water tanks operating exclusively on voyages between ports or places within a single COTP Zone. Therefore, the total number of respondents would increase by 1,280 to 9,663 (8,383 current respondents + 1,280 new respondents).

Frequency of Response: Current respondents under 33 CFR 151.2060 will continue to submit their reports upon arrival to U.S. ports. New respondents (owners and operators of vessels operating exclusively on voyages between ports or places within a single COTP Zone) will report once a year for a period of 3 years. After the 3 year period, the Coast Guard will have a base understanding of ballast water practices for these vessels, and reporting requirements will no longer be necessary.

Burden of Response: We estimate that the response would take approximately 40 minutes per report for vessels with ballast water tanks operating exclusively on voyages between ports or places within a single COTP Zone.

Estimate of Total Annual Burden: The annual burden is estimated as follows:

(a) *Annual burden for new reporting requirement for vessels operating within a single COTP Zone:* This rule would create a new burden of 858 hours (1,280 vessels × .67 hours) [15] for the private sector.

(b) *Annual burden for current reporting requirements:*

This final rule will result in a total annual burden increase of 858 hours due to the new requirement for vessels

[15] The estimation based on time required for reporting. Most information is well known by the vessel manager and does not require additional document or consultation. The questions are: Vessel name, number, identification number, type, operator, tonnage, call sign, COTP Zone of operation, number of ballast water tanks, total ballast water capacity, primary port of ballast water loading and discharge, estimated number of times ballast water is discharged and volume.

operating exclusively on voyages between ports or places within a single COTP Zone. We estimate the total annual cost burden to be $59,174 (non-discounted).

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we will submit a copy of this final rule to the Office of Management and Budget (OMB) for its review of the collection of information.

E. Federalism

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. Our analysis is explained below.

This rule revises the Coast Guard's BWM reporting and recordkeeping requirements promulgated under the authority of NANPCA, as amended by NISA. NANPCA, as amended by NISA, contains a ''savings provision'' that saves to States their authority to ''adopt or enforce control measures for aquatic nuisance species, [and nothing in the Act would] diminish or affect the jurisdiction of any State over species of fish and wildlife'' (16 U.S.C. 4725). This type of BWM reporting and recordkeeping is a ''control measure'' saved to States under the savings provision and would not be preempted unless State law makes compliance with this rule's requirements impossible or frustrates the purpose of Congress. No such State law has been identified. Additionally, the Coast Guard has long interpreted this savings provision to be a congressional mandate for a Federal-State cooperative regime in which federal preemption under NANPCA, as amended by NISA, would be unlikely.

F. 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 would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

G. Taking of Private Property

This rule would not cause a taking of private property or otherwise have taking implications under Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights.''

H. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

I. Protection of Children

We have analyzed this rule under Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks.'' This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

J. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

K. Energy Effects

We have analyzed this rule under Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.'' We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

L. Technical Standards

The National Technology Transfer and Advancement Act (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

M. 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 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. A final environmental analysis checklist supporting this determination is available in the docket where indicated under the ''Addresses'' section of this preamble. This rule involves regulations that are editorial and procedural, and falls under section 2.B.2, figure 2–1, paragraph (34)(a) of the Instruction.

List of Subjects in 33 CFR Part 151

Administrative practice and procedure, Ballast water management, Oil pollution, Penalties, Reporting and recordkeeping requirements, Water pollution control.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 151 as follows:

PART 151—VESSELS CARRYING OIL, NOXIOUS LIQUID SUBSTANCES, GARBAGE, MUNICIPAL OR COMMERCIAL WASTE, AND BALLAST WATER

Subpart C—Ballast Water Management for Control of Non-Indigenous Species in the Great Lakes and Hudson River

■ 1. The authority citation for subpart C continues to read as follows:

Authority: 16 U.S.C. 4711; Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 151.1516, revise paragraph (a) introductory text to read as follows:

§ 151.1516 Compliance monitoring.

(a) The master of each vessel equipped with ballast tanks must provide the following information, in written form, to the Captain of the Port (COTP):

* * * * *

Subpart D—Ballast Water Management for Control of Non-Indigenous Species in Waters of the United States

■ 3. The authority citation for subpart D continues to read as follows:

Authority: 16 U.S.C. 4711; Department of Homeland Security Delegation No. 0170.1.

■ 4. Amend § 151.2015 as follows:
■ a. Revise paragraph (b);
■ b. Redesignate paragraph (c) as paragraph (d);
■ c. Add new paragraph (c);
■ d. Revise newly redesignated paragraphs (d)(1) and (3); and
■ e. Add Table 1 to § 151.2015.

The revisions and addition read as follows:

§ 151.2015 Exemptions.

* * * * *

(b) Crude oil tankers engaged in coastwise trade are exempt from the requirements of §§ 151.2025 (ballast water management (BWM) requirements), 151.2060 (reporting), and 151.2070 (recordkeeping) of this subpart.

(c) Vessels that operate exclusively on voyages between ports or places within a single COTP Zone are exempt from the requirements of §§ 151.2025 (ballast water management (BWM) requirements), and 151.2070 (recordkeeping) of this subpart.

(d) * * *

(1) Seagoing vessels that operate in more than a single COTP Zone, do not operate outside of the EEZ, and are less than or equal to 1,600 gross register tons or less than or equal to 3,000 gross tons (International Convention on Tonnage Measurement of Ships, 1969).

* * * * *

(3) Vessels that operate in more than a single COTP Zone and take on and discharge ballast water exclusively in a single COTP Zone.

TABLE 1 TO § 151.2015—TABLE OF 33 CFR 151.2015 SPECIFIC EXEMPTIONS FOR TYPES OF VESSELS

	151.2025 (Management)	151.2060 (Reporting)	151.2070 (Recordkeeping)
Department of Defense or Coast Guard vessel subject to 46 U.S.C. 4713.	Exempt	Exempt	Exempt.
Vessel of the Armed Forces subject to the "Uniform National Discharge Standards for Vessels of the Armed Forces" (33 U.S.C. 1322(n)).	Exempt	Exempt	Exempt.
Crude oil tankers engaged in coastwise trade	Exempt	Exempt	Exempt.
Vessel operates exclusively on voyages between ports or places within a single COTP Zone.	Exempt	Applicable	Exempt.
Seagoing vessel operates on voyages between ports or places in more than a single COTP Zone, does not operate outside of EEZ, and ≤1600 gross register tons or ≤3000 gross tons (ITC).	Exempt	Applicable	Applicable.
Non-seagoing vessel	Exempt	Applicable	Applicable (unless operating exclusively on voyages between ports or places within a single COTP Zone).
Vessel operates between ports or places in more than a single COTP Zone and takes on and discharges ballast water exclusively in a single COTP Zone.	Exempt	Applicable	Applicable.

■ 5. Amend § 151.2060 by revising paragraphs (b) and (c) and adding paragraphs (d) through (f) to read as follows:

§ 151.2060 Reporting requirements.

* * * * *

(b) Unless operating exclusively on voyages between ports or places within a single COTP Zone, the master, owner, operator, agent, or person in charge of a vessel subject to this subpart and this section must submit a ballast water report to the National Ballast Information Clearinghouse (NBIC) by electronic ballast water report format using methods specified at NBIC's Web site at *http://invasions.si.edu/nbic/submit.html*. The ballast water report will include the information listed in paragraph (c) of this section and must be submitted as follows:

(1) *For any vessel bound for the Great Lakes from outside the EEZ.* (i) Submit a ballast water report at least 24 hours before the vessel arrives in Montreal, Quebec.

(ii) Non-U.S. and non-Canadian flag vessels may complete the St. Lawrence Seaway Ballast Water Reporting Form and submit it in accordance with the applicable Seaway notice as an alternative to this requirement.

(2) *For any vessel bound for the Hudson River north of the George Washington Bridge entering from outside the EEZ:* Submit the ballast water report at least 24 hours before the vessel enters New York, NY.

(3) *For any vessel that is equipped with ballast water tanks and bound for ports or places in the United States and not addressed in paragraphs (b)(1) and (2) of this section:* Submit the ballast water report no later than 6 hours after arrival at the port or place of destination, or prior to departure from that port or place of destination, whichever is earlier.

(c) The ballast water report required by paragraph (b) of this section must include the following information:

(1) *Vessel information.* This includes the vessel's name, International Maritime Organization (IMO) number or other vessel identification number if an IMO number is not issued, country of registry, owner or operator, type and tonnage.

(2) *Voyage information.* This includes the port and date of arrival, name and contact information of the person submitting the form, last port and country of call, and next port and country of call.

(3) *Ballast water information.* This includes the vessel's total ballast water capacity, total number of ballast water tanks, total volume of ballast water onboard, total number of ballast water tanks in ballast, and the identification of ballast water management method used.

(4) *Information on ballast water tanks that are to be discharged into the waters of the United States or to a reception facility.* Include the following for each tank discharged:

(i) The numerical designation, type and capacity of the ballast tank.

(ii) The source of the ballast water. This includes date(s), location(s), and volume(s). If a tank has undergone ballast water exchange, provide the

loading port of the ballast water that was discharged during the exchange.

(iii) The date(s), starting location(s), ending location(s), volume(s), and method(s) of ballast water management.

(iv) The date(s), location(s), and volume(s) of any ballast water discharged into the waters of the United States or to a reception facility.

(5) *Certificate of accurate information.* Include the name and title of the individual (*i.e.,* master, owner, operator, agent, person in charge) attesting to the accuracy of the information provided and that the activities were in accordance with the ballast water management plan required by § 151.2050(g). If exceptional circumstances required deviation from the plan, the details surrounding the need for deviation and associated actions must be explained.

(d) If the information submitted in accordance with paragraph (c) of this section changes, the master, owner, operator, agent, or person in charge of the vessel must submit an amended report before the vessel departs the waters of the United States or not later than 24 hours after departure from the port or place, whichever is earlier.

(e) The master, owner, operator, agent, or person in charge of a vessel operating on voyages exclusively between ports or places within a single COTP Zone, and subject to this subpart and this section, must submit the information required by paragraph (f) of this section to NBIC by electronic Annual Ballast Water Summary Report format using methods specified at NBIC's Web site at *http://invasions.si.edu/nbic/submit.html*. The Annual Ballast Water Summary Report is required for a period of three years on the following schedule:

(1) Report on the vessel's ballasting practices for calendar year 2016 due no later than March 31, 2017.

(2) Report on the vessel's ballasting practices for calendar year 2017 due no later than March 31, 2018.

(3) Report on the vessel's ballasting practices for calendar year 2018 due no later than March 31, 2019.

(f) The Annual Ballast Water Summary Report will include the following information:

(1) *Vessel information.* This includes name, identification number, vessel type, operator, tonnage, call sign and COTP Zone of operation.

(2) *Ballast information.* This includes the number of ballast tanks and total ballast water capacity.

(3) *Operational information.* This includes the estimated number of times ballast water is discharged, estimated volume of ballast water discharged each time, primary port of ballast water loading, primary port of ballast water discharge, and certification of compliance with § 151.2050.

■ 6. Revise § 151.2070 to read as follows:

§ 151.2070 Recordkeeping requirements.

(a) The master, owner, operator, agent, or person in charge of a vessel bound for a port or place in the United States, unless specifically exempted by § 151.2015 of this subpart, must ensure the maintenance of written or digital records that include the information required to be reported by § 151.2060 of this subpart and the sediment information in paragraph (a)(1) of this section.

(1) *Discharge of sediment.* If sediment was discharged within the jurisdiction of the United States, include the name and location of the facility where sediment disposal took place.

(2) *Certification of accurate information.* Include the master, owner, operator, agent, person in charge, or responsible officer's printed name, title, and signature attesting to the accuracy of the information provided and that the activities were in accordance with the ballast water management plan required by § 151.2050(g). If exceptional circumstances required deviation from the plan, the details surrounding the need for deviation and associated actions must be explained. The signature requirement may be satisfied by affirming the certification portion of the electronic ballast water report.

(b) The master, owner, operator, agent, or person in charge of a vessel subject to this section must retain a signed copy of this information onboard the vessel for 2 years.

(c) The recordkeeping requirements in this section may be met by maintaining a copy of the reporting form completed pursuant to § 151.2060 of this subpart, in addition to maintaining a record of the sediment information in paragraph (a)(1) of this section. These records may be stored on digital media but must be readily viewable by the Coast Guard during an inspection.

(d) The master, owner, operator, agent, or person in charge of a vessel subject to this section must retain the monitoring records required in 46 CFR 162.060–20(b) for 2 years. These records may be stored on digital media but must be readily viewable by the Coast Guard during an inspection.

Dated: November 18, 2015.

F.J. Sturm,

Acting Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. 2015–29848 Filed 11–23–15; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2015–1032]

RIN 1625–AA00

Safety Zone, Delaware River; New Castle, DE

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters encompassing Pea Patch Island Anchorage No. 5 and the upper portion of Reedy Point South Anchorage No. 3 to facilitate dredging in New Castle Range in the Delaware River. This regulation is necessary to provide for the safety of life on the navigable waters of the Delaware River in the vicinity of Pea Patch Island Anchorage No. 5 and Reedy Point South Anchorage No. 3. These closures are intended to restrict vessel anchoring to protect mariners from the hazards associated with ongoing pipe-laying and dredging operations.

DATES: This rule is effective without actual notice from November 24, 2015 through December 31, 2015. For purposes of enforcement, actual notice will be used from November 20, 2015 through November 24, 2015.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2015–1032 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 Brennan Dougherty, U.S. Coast Guard, Sector Delaware Bay, Chief Waterways Management Division, Coast Guard; telephone (215) 271–4851, email *Brennan.P.Dougherty@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
E.O. Executive order
FR Federal Register
Pub. L. Public Law
§ Section
U.S.C. United States Code
COTP Captain of the Port

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 impractical given that the final details for the dredging operation were not received until November 12, 2015. Vessels attempting to enter the waters of either Pea Patch Island Anchorage No. 5 or the upper portion of Reedy Point South Anchorage No. 3 during pipe-laying or dredging operations may be at risk. Delaying this rule to wait for a notice and comment period to run would be contrary to the public interest as it would inhibit the Coast Guard's ability to protect the public from the hazards associated with pipe-laying and dredging operations. We are issuing this rule, and, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register** because allowing this dredging and pipe laying operation to go forward without a safety zone in place would expose mariners and the public to unnecessary dangers.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231; 33 CFR 1.05–1 and 160.5; and Department of Homeland Security Delegation No. 0170.1. The Captain of the Port, Delaware Bay, has determined that potential hazards associated with dredging and pipe laying operations starting November 20, 2015, will be a safety concern for anyone attempting to transit in the Delaware River, along New Castle Range, in the vicinity of Pea Patch Island Anchorage No. 5, the upper portion of Reedy Point South Anchorage No. 3, and near the entrance to the C & D Canal. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while dredging is being conducted.

IV. Discussion of the Rule

The Coast Guard Captain of the Port is temporarily establishing a safety zone on the waters of Pea Patch Island Anchorage No. 5 and the upper portion of Reedy Point South Anchorage No. 3 from November 20, 2015 to December 31, 2015, unless cancelled earlier by the Captain of the Port. The safety zone will include all waters within the boundaries of Pea Patch Island Anchorage No. 5 and all waters within a portion of Reedy Point South Anchorage No. 3 north of a line drawn between positions 39°33′7.5″ N., 75°33′2.0″ W. and 39°33′8.8″ N., 75°32′31.8″ W., as charted on NOAA chart 12311. The waters of the anchorages are described in 33 CFR 110.157. Entry into, transiting, or anchoring within the safety zone is prohibited unless vessels obtain permission from the Captain of the Port (COTP) or make satisfactory passing arrangements with the dredge ESSEX per this rule and the Rules of the Road (33 CFR chapter I, subchapter E).

The Captain of the Port will terminate the safety zone once all submerged pipeline has been recovered and dredging operations are complete. Notice of the implementation and the termination of the safety zone will be made per 33 CFR 165.7.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

E.O.s 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. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a ''significant regulatory action,'' under E.O. 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, and duration of the safety zone. Although this regulation will restrict access to the regulated area, the effect of this rule will not be significant because Pea Patch Island Anchorage No. 5 and Reedy Point Anchorage No. 3 are not frequently used anchorages for vessels in the Delaware River, especially during the period of the closure, and there are a number of alternate anchorages available for vessels to anchor. Furthermore, vessels may be permitted to transit through the safety zone with the permission of the Captain of the Port or upon making satisfactory passing arrangements with the dredge. Extensive notification of the safety zone to the maritime public will be made via maritime advisories allowing mariners to alter their plans accordingly.

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 E.O. 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 E.O. 13132.

Also, this rule does not have tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. 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 a safety zone in force from November 20, 2015 to December 31, 2015, that prohibits entry of vessels in Pea Patch Island Anchorage No. 5 and the upper portion of Reed Point Anchorage No. 3. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add temporary § 165.T05–1032, to read as follows:

§ 165.T05–1032 Safety Zone, Delaware River; New Castle, DE

(a) *Location:* The safety zone will include all waters within the boundaries of Pea Patch Island Anchorage No. 5 (as defined in 33 CFR 110.157(a)(6)) and all waters within a portion of Reedy Point South Anchorage No. 3 (as defined in 33 CFR 110.157(a)(4)) north of a line drawn between positions 39°33′7.5″ N, 75°33′2.0″ W and 39°33′8.8″ N, 75°32′31.8″ W, as charted on NOAA chart 12311. These coordinates are based upon North American Datum 83 (NAD 83).

(b) Definitions.—(1) *The Captain of the Port* means the Commander of Sector Delaware Bay or any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port to act on his behalf.

(2) *Designated representative* means any Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port, Delaware Bay, to assist in enforcing the safety zone described in paragraph (a) of this section.

(c) *Regulations:* The general safety zone regulations found in 33 CFR part 165 subpart C apply to the safety zone created by this section.

(1) Entry into, transiting, or anchoring within the safety zone is prohibited unless vessels obtain permission from the Captain of the Port (COTP) or make satisfactory passing arrangements, via VHF–FM channel 16, with the dredge ESSEX per this rule and the Rules of the Road (33 CFR chapter I, subchapter E).

(2) To seek permission to transit the safety zone, the Captain of the Port's representative can be contact via VHF–FM channel 16.

(3) Vessels granted permission to transit the safety zone must do so in accordance with the directions provided by the Captain of the Port or his designated representative.

(4) No person or vessel may enter or remain in a safety zone without permission from the Captain of the Port;

(5) Each person and vessel in a safety zone shall obey any direction or order of the Captain of the Port or his designated representative.

(6) At least one side of the main navigational channel will be clear for safe passage of vessels in the vicinity of the safety zone. At no time will the main navigational channel be closed for vessel traffic. Vessels are advised to ensure safety passage by contacting the dredge ESSEX on VHF–FM channel 16 one hour prior to arrival.

(7) This section applies to all vessels wishing to transit through the safety zone except vessels that are engaged in the following operations: enforcing laws; servicing aids to navigation, and emergency response vessels.

(d) *Enforcement officials.* The U.S. Coast Guard may be assisted by Federal, State, and local agencies in the patrol and enforcement of the zone.

(e) *Enforcement period.* This rule will be enforced from November 20, 2015, to December 31, 2015, unless cancelled earlier by the Captain of the Port.

Dated: November 18, 2015.

B.A. Cooper,

Captain, U.S. Coast Guard, Captain of the Port Delaware Bay.

[FR Doc. 2015–29835 Filed 11–23–15; 8:45 am]

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LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 381

[Docket No. 15–CRB–0013–NCEBR–COLA (2016)]

Cost of Living Adjustment for Performance of Musical Compositions by Colleges and Universities

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Final rule.

SUMMARY: The Copyright Royalty Judges announce a cost of living adjustment (COLA) of 2% in the royalty rates that colleges, universities, and other educational institutions not affiliated with National Public Radio pay for the use of published nondramatic musical compositions in the SESAC repertory for the statutory license under the Copyright Act for noncommercial broadcasting.

DATES: *Effective Date:* December 24, 2015.

FOR FURTHER INFORMATION CONTACT: LaKeshia Keys, CRB Program Specialist, by telephone at (202) 707–7658 or by email at *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: Section 118 of the Copyright Act, title 17 of the United States Code, creates a statutory license for the use of published nondramatic musical works and published pictorial, graphic, and sculptural works in connection with noncommercial broadcasting.

On November 29, 2012, the Copyright Royalty Judges (Judges) adopted final regulations governing the rates and terms of copyright royalty payments under section 118 of the Copyright Act for the license period 2013–2017. *See* 77 FR 71104. Pursuant to these regulations, on or before December 1 of each year, the Judges shall publish in the **Federal Register** a notice of the change in the cost of living for the rate codified at § 381.5(c)(3) relating to compositions in the repertory of SESAC. The adjustment, fixed to the nearest dollar, shall be the greater of ''the change in the cost of living as determined by the Consumer Price Index (all consumers, all items) [CPI–U] * * * during the period from the most recent index published prior to the previous notice to the most recent index published prior to December 1, of that year,'' or 2%. 37 CFR 381.10.

The change in the cost of living as determined by the CPI–U during the period from the most recent index published before December 1, 2014, to the most recent index published before December 1, 2015, is .2%.[1] In accordance with 37 CFR 381.10(b), the Judges announce that COLA for calendar year 2016 shall be 2%. Application of the 2% COLA to the current rate for the performance of published nondramatic musical compositions in the repertory of SESAC—$146 per station—results in an adjusted rate of $149 per station.

List of Subjects in 37 CFR Part 381

Copyright, Music, Radio, Television, Rates.

Final Regulations

In consideration of the foregoing, the Judges amend part 381 of title 37 of the Code of Federal Regulations as follows:

PART 381—USE OF CERTAIN COPYRIGHTED WORKS IN CONNECTION WITH NONCOMMERCIAL EDUCATIONAL BROADCASTING

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

Authority: 17 U.S.C. 118, 801(b)(1), and 803.

■ 2. Section 381.5 is amended by revising paragraph (c)(3)(iv) to read as follows:

§ 381.5 Performance of musical compositions by public broadcasting entities licensed to colleges and universities.

* * * * *

(c) * * *

(3) * * *

(iv) 2016: $149 per station.

* * * * *

Dated: November 18, 2015.

Suzanne M. Barnett,

Chief Copyright Royalty Judge.

[FR Doc. 2015–29862 Filed 11–23–15; 8:45 am]

BILLING CODE 1410–72–P

LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 386

[Docket No. 15–CRB–0014–SA–COLA (2016)]

Cost of Living Adjustment to Satellite Carrier Compulsory License Royalty Rates

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Final rule.

SUMMARY: The Copyright Royalty Judges announce a cost of living adjustment (COLA) of 0% in the royalty rates satellite carriers pay for a compulsory license under the Copyright Act. The COLA is based on the change in the Consumer Price Index from October 2014 to October 2015.

DATES: *Effective Date:* January 1, 2016. *Applicability Dates:* These rates are applicable to the period January 1, 2016, through December 31, 2016.

FOR FURTHER INFORMATION CONTACT: LaKeshia Keys, CRB Program Specialist, by telephone at (202) 707–7658 or by email at *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: The satellite carrier compulsory license establishes a statutory copyright licensing scheme for the retransmission of distant television programming by satellite carriers. 17 U.S.C. 119. Congress created the license in 1988 and has reauthorized the license for additional five-year periods, most recently with the passage of the STELA Reauthorization Act of 2014, Public Law 113–200.

On August 31, 2010, the Copyright Royalty Judges (Judges) adopted rates for the section 119 compulsory license for the 2010–2014 term. *See* 75 FR 53198. The rates were proposed by Copyright Owners and Satellite Carriers [1] and were unopposed. *Id.* Section 119(c)(2) of the Copyright Act provides that, effective January 1 of each year, the Judges shall adjust the royalty fee payable under Section 119(b)(1)(B) ''to reflect any changes occurring in the cost of living as determined by the most recent Consumer Price Index (for all consumers and for all items) [CPI–U] published by the Secretary of Labor before December 1 of the preceding year.'' Section 119 also requires that ''[n]otification of the adjusted fees shall be published in the **Federal Register** at least 25 days before January 1.'' 17 U.S.C. 119(c)(2).

The change in the cost of living as determined by the CPI–U during the period from the most recent index published before December 1, 2014, to the most recent index published before December 1, 2015, is .2%.[2] Application of the .2% COLA to the current rate for the secondary transmission of broadcast stations by satellite carriers for private home viewing—27 cents per subscriber per month—results in an unchanged rate of 27 cents per subscriber per month (rounded to the nearest cent). *See* 37 CFR 386.2(b)(1). Application of the .2% COLA to the current rate for viewing in commercial establishments—56 cents per subscriber per month—results in an unchanged rate of 56 cents per subscriber per month (rounded to

[1] On November 17, 2015, the Bureau of Labor Statistics announced that the CPI–U increased .2% over the last 12 months.

[1] Program Suppliers and Joint Sports Claimants comprised the Copyright Owners while DIRECTV, Inc., DISH Network, LLC, and National Programming Service, LLC, comprised the Satellite Carriers.

[2] On November 17, 2015, the Bureau of Labor Statistics announced that the CPI–U increased .2% over the last 12 months.

the nearest cent). *See* 37 CFR 386.2(b)(2).

List of Subjects in 37 CFR Part 386

Copyright, Satellite, Television.

Final Regulations

In consideration of the foregoing, the Judges amend part 386 of title 37 of the Code of Federal Regulations as follows:

PART 386—ADJUSTMENT OF ROYALTY FEES FOR SECONDARY TRANSMISSIONS BY SATELLITE CARRIERS

■ 1. The authority citation for part 386 continues to read as follows:

Authority: 17 U.S.C. 119(c), 801(b)(1).

■ 2. Section 386.2 is amended by adding paragraphs (b)(1)(vii) and (b)(2)(vii), and footnotes 3 and 4, to read as follows:

§ 386.2 Royalty fee for secondary transmission by satellite carriers.

* * * * *

(b) * * *

(1) * * *

(vii) 2016: 27 cents per subscriber per month (for each month of 2016).[3]

(2) * * *

(vii) 2016: 56 cents per subscriber per month (for each month of 2016).[4]

Dated: November 18, 2015.

Suzanne M. Barnett,

Chief Copyright Royalty Judge.

[FR Doc. 2015–29863 Filed 11–23–15; 8:45 am]

BILLING CODE 1410–72–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2015–0593; A–1–FRL–9939–24–Region 1]

Air Plan Approval; ME; Repeal of the Maine's General Conformity Provision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted by the State of Maine. This revision removes State Regulation Chapter 141—Conformity of General Federal Actions from the SIP. The intended effect of this action is to remove the repealed State Regulation and leave the Federal General Conformity provisions in place to demonstrate conformity with the applicable SIP as required by section 176(c) of the Clean Air Act. This action is being taken in accordance with the Clean Air Act.

DATES: This direct final rule will be effective January 25, 2016, unless EPA receives adverse comments by December 24, 2015. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R01–OAR–2015–0593 by one of the following methods:

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

2. *Email: arnold.anne@epa.gov*.

3. *Fax:* (617) 918–0047.

4. *Mail:* ''Docket Identification Number EPA–R01–OAR–2015–0593'', Anne Arnold, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912.

5. *Hand Delivery or Courier.* Deliver your comments to: Anne Arnold, Manager, Air Quality Planning Unit, Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R01–OAR–2015–0593. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *http://www.regulations.gov,* or email, information that you consider to be CBI or otherwise protected. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *http://www.regulations.gov* or at U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

In addition, copies of the state submittal and EPA's technical support document are also available for public inspection during normal business hours, by appointment at the State Air Agency; the Bureau of Air Quality Control, Department of Environmental Protection, First Floor of the Tyson Building, Augusta Mental Health Institute Complex, Augusta, ME 04333–0017.

FOR FURTHER INFORMATION CONTACT: Ariel Garcia, Air Quality Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912, telephone number (617) 918–1660, fax number (617) 918–0660, email *garcia.ariel@epa.gov*.

[3] This is the 2015 rate adjusted for the amount of inflation as measured by the change in the Consumer Price Index for All Urban Consumers All Items from October 2014 to October 2015.

[4] This is the 2015 rate adjusted for the amount of inflation as measured by the change in the Consumer Price Index for All Urban Consumers All Items from October 2014 to October 2015.

SUPPLEMENTARY INFORMATION:

Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

Organization of this document. The following outline is provided to aid in locating information in this preamble.

I. Background and Purpose

Section 176(c) of the Clean Air Act, as amended (the Act), prohibits Federal entities from taking actions in nonattainment or maintenance areas which do not conform to the State Implementation Plan (SIP) for the attainment and maintenance of the national ambient air quality standards (NAAQS). Therefore, the purpose of conformity is to: (1) Ensure Federal activities do not interfere with the emission budgets in the SIPs; (2) ensure actions do not cause or contribute to new violations; and (3) ensure attainment and maintenance of the NAAQS. Section 176(c) of the Act also requires EPA to promulgate criteria and procedures for demonstrating and ensuring conformity of Federal actions to an applicable implementation plan developed pursuant to Section 110 and Part D of the Act. EPA promulgated a final rulemaking on November 30, 1993 consisting of 40 CFR part 93, subpart B ''Determining Conformity of General Federal Actions to State or Federal Implementation Plans,'' which applied to Federal agencies immediately (hereafter referred to as the General Conformity rule); and 40 CFR part 51, subpart W ''Determining conformity of general Federal Actions to State or Federal Implementation Plans'' which established requirements for States in submitting SIPs. The general conformity rules, except for the 40 CFR 51.851(a) language requiring State submission of a SIP revision, were repeated at 40 CFR part 93, subpart B. The General Conformity rule establishes the criteria and procedures governing the determination of conformity for all Federal actions, except Federal highway and transit actions.[1]

The General Conformity rule also establishes the criteria for EPA approval of SIPs. See 40 CFR 51.851 and 93.151. These criteria provide that the state provisions must be at least as stringent as the requirements specified in EPA's General Conformity rule, and that they can be more stringent only if they apply equally to Federal and non-Federal entities (§§ 51.851(b)). Following EPA approval of the State conformity provisions in a SIP revision, the approved State criteria and procedures would govern conformity determinations and the Federal conformity regulations contained in 40 CFR part 51 and part 93 would apply only for the portion, if any, of the State's conformity provisions that is not approved by EPA. Finally, all SIP-approved requirements relating to general conformity remain enforceable until the State revises its SIP to specifically remove them from the SIP and that revision is approved by EPA.

On October 11, 1996, the State of Maine submitted a formal revision to its SIP. The SIP revision consisted of incorporating-by-reference 40 CFR 51.850 through 51.860 (with the exception of § 51.851) thereby establishing general conformity criteria and procedures in the Maine SIP no more stringent than the Federal rule and not imposing any additional controls on non-Federal entities. EPA approved Maine's General Conformity SIP through a direct final rule published in the **Federal Register** on September 23, 1997, (62 FR 49608–49611) and effective November 24, 1997.

On June 29, 2007, the State of Maine submitted a second revision to its General Conformity SIP. This SIP revision consists of incorporating by reference 40 CFR 51.852 (Definitions), and 51.853 (Applicability), of 40 CFR part 51, subpart W, ''Determining Conformity of General Federal Actions to State or Federal Implementation Plans,'' as amended on July 17, 2006 in the **Federal Register** (71 FR 40420–40426). By incorporating by reference the amended General Conformity rule, Maine's Chapter 141 ''Conformity of General Federal Actions,'' is no more stringent than the Federal rule and does not impose any additional controls on non-Federal entities. EPA approved Maine's revision to its General Conformity SIP through a direct final rule published in the **Federal Register** on February 20, 2008 (73 FR 9203–9206) and effective on April 21, 2008.

On April 5, 2010, EPA revisited the Federal General Conformity Requirements Rule to clarify the conformity process, authorize innovative and flexible compliance approaches, remove outdated or unnecessary requirements, reduce the paperwork burden, provide transition tools for implementing new standards, address issues raised by Federal agencies affected by the rules, and provide a better explanation of conformity regulations and policies. EPA's April 2010 revised rule simplified state SIP requirements for general conformity, eliminating duplicative general conformity provisions codified at 40 CFR part 93, subpart B and 40 CFR part 51, subpart W by removing section 51.850, and sections 51.852 through 51.860. Finally, the April 2010 revision updated the Federal General Conformity Requirements Rule to reflect changes to governing laws passed by Congress since EPA's 1993 rule.

The ''Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users,'' (SAFETEA–LU) passed by Congress in 1995 contains a provision eliminating the Clean Air Act requirement for states to adopt general conformity SIPs. As a result of SAFETEA–LU, EPA's April 2010 General Conformity rule eliminated the Federal regulatory requirement for states to adopt and submit general conformity SIPs, instead making submission of a general conformity SIP a state option.

The 2010 General Conformity amendments (Sections 51.851(c) as well as section 93.151) restated the requirement that in the absence of an EPA approved General Conformity SIP, Federal agencies shall use the provisions of 40 CFR part 93, subpart B to demonstrate conformity with the applicable implementation plan as required by section 176(c) of the Clean Air Act (42 U.S.C. 7506).

II. State Submittal

On August 18, 2015, the Maine Department of Environmental Protection submitted a formal SIP revision to remove Chapter 141–Conformity of General Federal Actions. Maine's Chapter 141 regulation incorporated-by-reference 40 CFR part 51, subpart W ''Determining Conformity of General Federal Actions to State or Federal Implementation Plans'' as published in the November 30, 1993, **Federal Register** (58 FR 63247–63253) and amended in the July 17, 2006 **Federal Register**, (71 FR 40420–40426). As stated above all of the general conformity provisions referenced in Maine's General Conformity regulation were deleted as duplicative on April 5, 2010. At the time they were approved into the SIP, provisions of Maine's General Conformity SIP were no less stringent then the Federal General Conformity regulations, nor did the SIP establish more stringent conformity criteria and procedures applying equally to non-Federal as well as Federal entities.

As the State of Maine did not revise its SIP-approved Chapter 141—

[1] Conformity to State or Federal Implementation Plans of transportation plans, programs, and projects which are developed, funded or approved under Title 23 U.S.C. or the Federal Transit Laws are implemented under 40 CFR part 51, subpart T, and 40 CFR part 93, subpart A.

Conformity of General Federal Actions following EPA's April 5, 2010 General Conformity amendments, the current State rule with a state effective date of April 19, 2007, does not provide any flexibility, or relaxation to the general conformity criteria and procedures as allowed by the amendments.

Maine Department of Environmental Protection repealed Chapter 141 in July 2015 after public notice and opportunity for public hearing. The removal of Chapter 141—Conformity of General Federal Actions from the SIP will leave the Federal General Conformity Regulations at 40 CFR 93.150 through 93.165 as well as 40 CFR 51.851, in place for administrative and enforcement purposes. Once EPA approves the removal of Chapter 141 from Maine's SIP, Federal actions can take advantage of the flexibility provided by the Federal General Conformity Rule. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

III. Final Action

EPA is approving Maine's August 18, 2015, SIP revision to remove Chapter 141—Conformity of General Federal Actions from the SIP. EPA has evaluated this SIP revision and has determined that the State has complied with its administrative procedures to repeal Chapter 141. The appropriate public participation and comprehensive interagency consultations have been undertaken during development and adoption of this SIP revision. Finally, EPA has determined that removing Chapter 141 from the Maine SIP will result in Federal agencies using the provisions of 40 CFR part 93, subpart B to demonstrate conformity with the applicable implementation plan as required by section 176(c) of the Clean Air Act (42 U.S.C. 7506). Federal actions can take advantage of the flexibility provided by the Federal General Conformity Rule which includes EPA's April 2010 General Conformity Amendments.

EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should relevant adverse comments be filed. This rule will be effective January 25, 2016 without further notice unless the Agency receives relevant adverse comments by December 24, 2015.

If EPA receives such comments, then EPA will publish a notice withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on the proposed rule. All parties interested in commenting on the proposed rule should do so at this time. If no such comments are received, the public is advised that this rule will be effective on January 25, 2016 and no further action will be taken on the proposed rule. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

IV. Statutory and Executive Order Reviews

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

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

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 25, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of

proposed rulemaking for this action published in the proposed rules section of the **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: November 5, 2015.

H. Curtis Spalding,

Regional Administrator, EPA New England.

Part 52 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart U—Maine

§ 52.1020 [Amended]

■ 2. In § 52.1020(c), the table is amended by removing the entry for Chapter 141, ''Conformity of General Federal Actions.''

[FR Doc. 2015–29825 Filed 11–23–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Parts 240 and 242

[Docket No. FRA–2015–0123]

Best Practices for Designing Vision Field Tests for Locomotive Engineers or Conductors

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Interim interpretation with request for comments.

SUMMARY: FRA is issuing this interim interpretation to clarify provisions in its locomotive engineer and conductor qualification and certification regulations with respect to vision standards and testing. In particular, this document addresses further evaluation of persons who do not meet the vision threshold criteria provided for in those regulations, and provides best practices guidance for designing valid, reliable, and comparable vision field tests for assessing whether persons who do not meet those thresholds can perform safely as locomotive engineers and conductors.

DATES: Written comments on the interpretation must be received on or before January 25, 2016. Comments received after that date will be considered to the extent possible without incurring additional expense or delay.

ADDRESSES: Comments related to Docket No. FRA–2015–0123 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.

Instructions: All submissions must include the agency name and docket number. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Privacy Act: Anyone is able to 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.*). *See http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov or interested parties may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477).

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* at any time or to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays. Anyone is able to 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.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy. See* also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov.

FOR FURTHER INFORMATION CONTACT: Dr. B.J. Arseneau, Medical Director, FRA, 1200 New Jersey Avenue SE., Washington, DC 20590, (202) 493–6232; Alan Nagler, Senior Trial Attorney, FRA, Office of Chief Counsel, Mail Stop 10, 1200 New Jersey Avenue SE., Washington, DC 20590, (202) 493–6049; or Joseph D. Riley, Railroad Safety Specialist, FRA, Mail Stop 25, 1200 New Jersey Avenue SE., Washington, DC 20590, (202) 493–6318.

SUPPLEMENTARY INFORMATION:

I. Background

FRA is issuing this interim interpretation to clarify provisions in its locomotive engineer and conductor qualification and certification regulations related to further evaluation of persons who do not meet the vision threshold criteria in Title 49 Code of Federal Regulations (CFR) 240.121(c) and 242.117(h), and to provide best-practices guidance for designing valid, reliable, and comparable vision field tests, in response to: (1) The fatal railroad accident that occurred near Goodwell, OK, on June 24, 2012; (2) inquiries FRA has received requesting clarification of the applicable regulatory provisions; and (3) numerous requests for FRA review, under the locomotive engineer and conductor certification regulations, when individuals have been denied recertification by a railroad based on a color vision or monocular vision deficiency.

A. Railroad Accident Near Goodwell, OK

The fatal accident that occurred near Goodwell, in which two Union Pacific Railroad (UP) trains collided head-on, exemplifies how important it is to railroad safety that each railroad establish valid, reliable, and comparable procedures to evaluate persons who do not meet the vision thresholds in 49 CFR 240.121(c) or 242.117(h), and to strictly adhere to those procedures. The

locomotive engineer and conductor of the eastbound train and the engineer of the westbound train were killed. Three locomotives and 24 cars of the eastbound train and 2 locomotives and 8 cars of the westbound train derailed. Several fuel tanks from the derailed locomotives were ruptured, releasing diesel fuel that ignited and burned. Damage was estimated at $14.8 million. The National Transportation Safety Board (NTSB) determined that one of several probable causes of the accident was the eastbound engineer's inability to visually detect and recognize the approach and stop signal aspects of wayside railroad signals due to color vision deficiency and distant visual acuity impairment the engineer had acquired as a result of a number of chronic, progressive eye conditions and visual disturbances.[1]

During its investigation of the Goodwell accident, the NTSB found that: (1) The eastbound engineer last underwent vision testing required for recertification in 2009; (2) during that testing, the eastbound engineer failed an initial color vision test (*i.e.,* the Ishihara Color Vision Test [2]) that UP selected from the list of color vision test protocols in 49 CFR part 240, Appendix F, and did not meet the distant visual acuity threshold (corrected) in 49 CFR 240.121(c); (3) UP relied on a vision field test of unknown validity, reliability, and comparability [3] in further evaluating the engineer and did not adhere to UP's field test protocol; (4) UP relied on a telephonic report of distant visual acuity testing from the engineer's optometrist in recertifying the engineer, and did not adhere to UP's own policy which required UP to obtain written documentation from the engineer's optometrist to confirm the telephonic report; and (5) UP failed to reevaluate the engineer's vision within one year of his 2009 recertification despite the UP medical examiner's written determination that it was necessary to reevaluate the engineer's vision within one year, rather than triennially, due to the engineer's chronic, progressive eye conditions. The NTSB concluded that had the engineer been reevaluated by UP the following year or when he self-reported his test results, the collision might have been avoided.

B. Color Vision Deficiency, Monocular Vision and Other Eye Conditions and Visual Disturbance

As indicated in the NTSB's report on the Goodwell accident, there are numerous eye conditions, including color vision deficiency and monocular vision, which can affect a person's ability to safely perform as a locomotive engineer or conductor. The American Optometric Association defines ''color vision deficiency'' as the inability to distinguish certain shades of color, or in more severe cases, see colors at all. The term ''color blindness'' is also used to describe this visual condition, but very few people are completely color-blind. People who have complete color-blindness, a condition called achromatopsia, can only see things as black and white or in shades of gray. The severity of color vision deficiency can range from mild to severe. ''Red-green'' is the most common deficiency. Another form of color deficiency is ''blue-yellow.'' The latter is a rare and more severe form of color vision deficiency since persons with blue-yellow deficiency frequently have red-green deficiency too. Color vision deficiency can be inherited. About 8 percent of Caucasian males are born with some degree of color deficiency. Women are typically asymptomatic if they are carriers of the color deficient gene (*i.e.,* women are carriers of the gene without suffering with color vision deficiency), though approximately 0.5 percent of women have color vision deficiency. People can also acquire a color vision deficiency as a result of certain types of medical conditions, a side-effect of certain medications, and certain eye injuries. Examples of eye conditions that can cause an acquired color-vision deficiency include, but are not limited to, diabetes, glaucoma, macular degeneration, multiple sclerosis, chronic alcoholism, leukemia, sickle cell anemia, syphilis, or other conditions resulting in optic nerve damage or inflammation. Examples of medications that can sometimes cause adverse effects that result in color-vision deficiency include, but are not limited to, certain medications used to treat heart problems, high blood pressure, infections, and nervous disorders.

There are many other eye conditions and visual disturbances other than color-vision deficiency. Examples of these problems and disturbances include halos, blurred vision (*i.e.,* the loss of sharpness of vision and the inability to see fine details), and blind spots or scotomas (*i.e.,* dark ''holes'' in the vision in which nothing can be seen, and loss of use of one eye, commonly called ''monocular vision''). The degree to which these conditions and disturbances can affect a person's ability to perform safely varies by individual, depending on the specific job duties a person performs as a certified locomotive engineer or conductor, the nature and severity of the condition, the degree to which the visual disturbance is corrected with treatment, and in certain cases, the degree to which a person can compensate for the disturbance. Persons with monocular vision can sometimes, on a case-by-case basis, compensate for a limited degree of peripheral vision field loss by head turning.

II. FRA's Interpretation

A. Requirement for Further Evaluation by the Railroad's Medical Examiner

FRA's locomotive engineer and conductor qualification and certification rules do not require railroads to categorically disqualify or decertify individuals who do not meet the vision thresholds in 49 CFR 240.121(c) or 242.117(h) because they may have a color-vision, sub-threshold distance visual acuity, or field of vision (*e.g.,* monocular vision) deficiency, if they are otherwise qualified. To the contrary, 49 CFR 240.121(e) and 242.117(e) require railroads to subject, upon request, persons who do not meet those thresholds to further medical evaluation by the railroad's medical examiner to determine whether the person can safely perform as a locomotive engineer or conductor. FRA's longstanding view is that there are some people who, despite not meeting the vision threshold in 49 CFR 240.121(c) and 242.117(h), have sufficient residual visual capacity to safely perform as a locomotive engineer or conductor.

The Railway Association of Canada (RAC) has published medical guidelines that are applicable to qualification and certification of locomotive engineers in Canada.[4] FRA allows railroads to adopt the monocular vision criteria in the RAC's guidelines under the railroad's own authority.

B. Vision Requirements to Safely Perform as a Locomotive Engineer or a Conductor

Depending on their assigned responsibilities, a person generally must have sufficient distant visual acuity and

[1] National Transportation Safety Board Railroad Accident Report NTSB/RAR–13–02 (adopted June 18, 2013). Head-On Collision of Two Union Pacific Railroad Freight Trains Near Goodwell, Oklahoma, June 24, 2012. Retrieved from *http://www.ntsb.gov/investigations/AccidentReports/Reports/RAR1302.pdf* on Dec. 2, 2014.

[2] S. Ishihara, Tests for colour-blindness (Handaya, Tokyo, Hongo Harukicho, 1917).

[3] The NTSB did not define the terms ''validity,'' ''reliability,'' and ''comparability'' or indicate what might constitute a valid, reliable, and comparable field test.

[4] Railway Association of Canada (2013), Canadian Medical Rules Handbook, pages 38, 43, 44, and 51. Retrieved from *http://www.railcan.ca/publications/rule_handbook* on March 24, 2015.

field of vision to see railroad signals and stationary and moving objects such as other locomotives, workers, and railroad equipment on or near the track, to perform safely as a locomotive engineer or conductor. Should a person perform as a locomotive engineer or conductor on portions of the railroad system on which colors of railroad signals convey information about speed, routing, or obstructions or other hazards, a person with that responsibility must additionally have sufficient color vision to safely perform.

FRA recognizes that railroads may assign some employees the responsibility to recognize and distinguish color light railroad signals, but not other employees. For example, some passenger conductors may not have responsibility to recognize and distinguish between colors of railroad signals. FRA also recognizes that some locomotive engineers and conductors only perform service in unsignalled (*i.e.,* dark) territory or in territories where they do not have responsibility to recognize and distinguish between one or more types of colored railroad signals (*e.g.,* wayside color light signals, color-position light signals, and blue flag signals). Although FRA's certification regulations require that both locomotive engineers and conductors be vision-tested, including color-vision, regardless of the actual operating or working conditions, a railroad's medical examiner should be cognizant of whether a person with a color-vision deficiency already works or could work safely in dark territory. Medical examiners should also keep in mind that even though a person may only work in dark territory, that person may still need to be able to identify colored items such as blue signals or roadway worker flags.

C. Use of Valid, Reliable, and Comparable Vision Tests

There are many types of eye conditions and visual disturbances ranging in severity from very mild to severe and many types and designs of railroad signals and railroad operating rules. Accordingly, FRA's locomotive engineer and conductor qualification and certification rules grant railroad medical examiners discretion in determining the methods and procedures the medical examiner will use to further evaluate persons who do not meet the vision thresholds in 49 CFR 240.121(c) and 242.117(h). In the 1991 final locomotive engineer certification rule, FRA stated that ''[m]edical discretion will allow railroads to respond appropriately when they encounter individuals who fail to meet FRA-prescribed acuity levels, but demonstrate that they can compensate to a sufficient degree for their diminished acuity level.'' 56 FR 28228, 28235; June 19, 1991. FRA granted railroad medical examiners similar discretion in further evaluating persons for the purposes of conductor qualification and certification. FRA states in its locomotive engineer and conductor certification rules that, should a person not meet specific vision thresholds, appropriate further evaluation may include optometric or ophthalmologic referral, or (secondary) testing with a field or other practical or scientific screening test. Although FRA's rules grant discretion to railroads in selecting a test protocol, FRA's longstanding interpretation of this provision is that the test offered by a railroad must be a valid, reliable, and comparable test for assessing whether a person who fails an initial vision test can safely perform as a locomotive engineer or conductor.

1. Field Tests

A ''practical test,'' more commonly known as a ''field test'' within the railroad community, is a test performed outdoors under test conditions that reasonably match actual operating or working conditions. A railroad is permitted to conduct field testing on a moving train, positioned in a stationary locomotive, or standing on the ground at distances from a signal or other object that the person must see and recognize to perform safely as a locomotive engineer or conductor.

Before issuing this interpretation, FRA contacted several organizations to collect information that would help in the development of recommended best practices for field tests, and FRA has captured that feedback in memoranda and documents it has placed in the docket. First, FRA wants to thank the American Academy of Ophthalmology and the American Optometric Association for providing expert medical information regarding testing and evaluating color perception during six conference calls held with FRA personnel. Second, FRA wants to thank the Brotherhood of Locomotive Engineers and Trainmen (BLET) and United Transportation Union-SMART Transportation Division for providing information and concerns regarding the strengths and weaknesses of current field testing practices, and asking that FRA find a way to encourage each railroad to conduct such field testing, during a conference call with FRA personnel. Third, FRA wants to thank the Association of American Railroads (AAR) for providing a written overview of the different practices currently used by various Class I railroads. AAR stated, in a July 14, 2015, Discussion on Color Vision Field Testing that field ''testing is, at the moment, the preferred way of determining whether an individual's unique set of deficits actually impacts performance.'' FRA provides best practices for designing valid, reliable, and comparable vision field tests in Section III, ''Best Industry Practices for Conducting Color Vision Field Testing'' of this interpretation.

2. Scientific Tests

A scientific vision test is a test instrument that, based on the results of a rigorous scientific study published in a peer-reviewed scientific or medical journal or other publication, is a valid, reliable, and comparable test for assessing whether a person has sufficient distance visual acuity, field of vision, or color vision, which, for purposes or railroad operations, allows the person to safely perform as a locomotive engineer or conductor. Examples of such scientific screening tests include, but are not limited to, a simulator, the Ishihara test and other color plate tests, a perimetry test (*i.e.,* a test of field of vision), and a Snellen or equivalent distance visual acuity test. Should a railroad offer a scientific test to further evaluate persons who fail an initial test, FRA expects the test to be a valid, reliable, and comparable test for assessing whether the person can safely perform as a locomotive engineer or conductor despite not meeting the specific vision threshold (*i.e.,* distance visual acuity, field of vision, or color perception) in 240.121(c) or 242.117(h). That means the railroad must be able to cite a rigorous scientific study published in a peer-reviewed scientific or medical publication that demonstrates the scientific test is a valid, reliable, and comparable test for that visual capacity. For example, Hovis and Oliphant, in 2000, published a validation test of a lantern test that they designed, the CNLAN lantern test. The authors rigorously validated the CNLAN lantern test in a peer-reviewed journal against a simulated field test with a high degree of content validity to show the CNLAN lantern test has a high degree of validity and reliability for assessing the ability to recognize and distinguish between aspects of color light railroad signals in Canada.[5] Two major railroads in Canada use the CNLAN lantern test. Interested parties should note, however, that simply showing a person a lantern

[5] Hovis, J.K., and Oliphant, D., A Lantern Color Vision Test for the Rail Industry. American Journal of Internal Medicine, 38:681–696 (2000).

with different colored lights displayed is certainly not the same as the CNLAN lantern test, which is a scientifically validated test.

3. Determining the Validity, Reliability, and Comparability of a Vision Test

Validity means the degree to which a test actually measures what the test is intended to measure. For example, a color vision field test is valid to the degree that it assesses whether a person can recognize and distinguish between colors of the types of railroad signals in the yard or on all portions of railroad systems on which the person must perform safely, depending on the person's responsibilities. One way to estimate the validity of a test is to assess its degree of job-relatedness (content validity). The degree to which a field test's conditions match actual operating conditions determines, to a large extent, its validity.

Reliability means the degree of reproducibility of the test results. In this case, reproducibility means an examinee that is repeatedly administered the same test would demonstrate the same number of correct responses and missed signal responses each time the test is administered.

Comparability means the testing procedures are fairly administered and the test results are uniformly recorded. When tests have comparability, it is fair to compare test results between individuals regardless of whether different testing officers, or different railroads, administered the test. Additionally, for a test to be comparable, the testing officer must administer the test without any bias or prejudice.

D. Optometric and Ophthalmologic Referral

In addition to field and scientific tests, FRA's locomotive engineer qualification and certification regulations also permit optometric or ophthalmologic referral which can provide important information about the nature and severity of a person's eye condition or visual disturbance. The referral can also provide information about whether the vision condition is stable or should be monitored more frequently than triennially by the railroad's medical examiner because it is likely to worsen to a level that would make it unsafe to perform service prior to a certified employee's next triennial recertification evaluation.

E. Special Conditions of Certification (Restrictions)

Sections 240.121(e) and 242.117(e) permit railroads to conditionally certify a person as a locomotive engineer or conductor if the railroad's medical examiner determines in writing that a special condition of certification is necessary on the basis of findings elicited on further evaluation of the person's vision. Examples of special conditions of certification include: (1) More frequent evaluation of an eye condition or visual disturbance by a railroad's medical examiner that will likely deteriorate prior to the person's next required triennial recertification examination to a level that the person may not be able to safely perform; (2) required use of corrective lenses (*i.e.,* glasses or contact lenses) to correct distant visual acuity to a level that the person can safely perform as a locomotive engineer or conductor; (3) restriction to perform service only in unsignalled (dark) territory should a person be otherwise qualified but not have the ability to recognize and distinguish between colors of wayside railroad color light or color-position light signals; (4) restriction of service to unsignalled (dark) territory, or marking up for service only at night when there is greater brightness contrast between signals and the remainder of the operating environment, should a person demonstrate the ability to perform safely only under those operating conditions; or (5) restriction of service to performance in a yard or on portions of railroad systems where locomotives move at slower speeds, should a person be able to recognize and distinguish between colors of railroad signals at those slower speeds. There is research evidence that some individuals with color vision deficiency may be able to detect and recognize signal aspects at shorter sighting distance that exist in the yard or on portions of the railroad where locomotives move at slower speed to perform safely.[6]

F. Chromatic Lenses

FRA's locomotive engineer and conductor certification rules do not permit examinees to use chromatic lenses when taking an initial test the railroad selects from the list of accepted color vision test protocols in the appendices to parts 240 and 242. Although examinees may not use chromatic lenses during an initial color vision test, FRA grants each railroad the discretion to determine whether it will permit examinees to use chromatic lenses during a secondary field or other practical or scientific test offered by a railroad to further evaluate his or her ability to perform safely. However, since the time FRA last amended part 240, the Food and Drug Administration (FDA), issued the following cautionary information about the use of ChromaGen chromatic lenses: [7]

a. ChromaGen lenses do not help wearers to see ''new'' colors or to perceive or appreciate colors as people with normal color vision do, but merely add brightness/darkness or hue differences to colors that are otherwise difficult or impossible to distinguish;

b. The ability to pass diagnostic color vision tests with ChromaGen lenses does not imply the ability to perform other color vision-related tasks. Therefore, ChromaGen lenses should not be used with diagnostic color vision tests to meet occupational performance requirements; and

c. Persons using the darker shades of tint in their ChromaGen lenses may experience some or all of the following: Reduced 10W contrast acuity, reduced illumination at night, distortions in distance perception of moving objects or while driving, distortions of apparent velocity. Wearing darker lenses, especially at night, or under foggy, misty, or other adverse conditions, may make driving an automobile difficult.

Based on FDA's findings, and the fact that railroads generally operate to a degree under similar environmental lighting and weather conditions as operating an automobile, FRA recommends that railroads take a conservative approach.

Railroads should not permit locomotive engineers and conductors that have responsibility to recognize and distinguish between colors of railroad signals to safely perform as locomotive engineers and conductors until data from a valid, reliable, and comparable research study clearly establishes operating conditions when it is safe to use chromatic lenses for that purpose, and then restrict use to those operating conditions. Please note that both the FDA and FRA make a distinction between chromatic lenses and contact lenses manufactured to correct distant, intermediate, and near visual acuity that have a very light blue tint to aid the user

[6] Hovis, J.K., and Ramaswamy, S., The Effect of Test Distance on the CN Lantern Results. Visual Neuroscience, 23, 675–679 (2006).

[7] Premarket Notification Device Clearance for ChromaGen lenses (510(k) No. 994320), Ophthalmic Devices Panel Meeting Summary for November 8, 2000, Food and Drug Administration, retrieved from *http://www.fda.gov/advisorycommittees/committeesmeetingmaterials/medicaldevices/medicaldevicesadvisorycommittee/ophthalmicdevicespanel/ucm124831.htm* on Dec. 2, 2014. *See also* Summary of Safety and Effectiveness: ChromaGen v2.0 Haploscope System, for Color Vision Enhancement (510(k) No. 994320), Department of Health & Human Services Food and Drug Administration, Oct. 20, 2000, retrieved from *http://www.accessdata.fda.gov/cdrh_docs/pdf/k994320.pdf* on Dec. 2, 2014.

in locating, handling, and cleaning the contact lens. Railroads should not prohibit use of those blue-tinted contact lenses during testing and when performing as a locomotive engineer or conductor.

G. Documentation

The railroad medical examiners are required by FRA certification regulations to document the basis for his or her decision that a person can or cannot safely perform as a locomotive engineer or conductor. This includes reports of testing, and should the examiner use optometric or ophthalmologic referral, the report of testing and evaluation from the optometrist or ophthalmologist.

H. Part 240 and 242 Program Descriptions

FRA's locomotive engineer and conductor regulations require each railroad subject to those regulations to have a written visual testing program on file with FRA. Among other things, the certification program must include a railroad's procedure for evaluating the visual acuity of its locomotive engineers and conductors when those train crew members fail to meet the vision threshold criteria provided for in parts 240 and 242. *See* 49 CFR 240.101, 240.121, 242.101, and 242.117; 49 CFR part 240 Appendix F, and 49 CFR part 242 Appendix D. Such procedure is especially necessary to address situations where locomotive engineers and conductors have a history of safe performance that would normally suggest that they have the ability to safely perform their duties. A review of the programs on file with FRA, however, revealed that the railroads do not sufficiently describe their field testing procedures to allow FRA to determine whether those procedures are likely to produce valid, reliable, and comparable field tests. Thus, each railroad that utilizes field testing procedures should review the best practices provided in this interpretation and update its programs accordingly under part 240 and part 242.

FRA considers this type of program modification to be a ''material modification'' requiring railroads to submit their revised programs to FRA for review and approval. *See* 49 CFR 240.103(e) and 242.103(i). Before implementing a change to its field testing procedures, a railroad must submit a description of how it intends to modify the procedures in its program. For part 240 programs, the description of the modification must be submitted to FRA at least 30 days prior to implementation. *See* 49 CFR 240.103(e). For part 242 programs, the description of the modification must be submitted to FRA at least 60 days prior to implementation. *See* 49 CFR 242.103(i). The modified program is considered approved and may be implemented 30 days after being filed with FRA unless FRA notifies the railroad in writing that the program does not conform to the criteria set forth in parts 240 and 242. To facilitate the submission of modified programs to FRA, railroads may submit both parts 240 and 242 programs electronically using the procedures described in Appendix B to Part 242 for ''Submission by a Railroad.''

Attachment A. Best Industry Practices for Conducting Color Vision Field Testing

The following best practices are intended to guide each railroad in designing, implementing, and scoring color vision field testing for locomotive engineer and conductor certification. They are broadly drafted to allow each railroad to develop field testing procedures that will work for its own operational environment and to consider the unique medical circumstances of each examinee tested. Furthermore, these best practices will guide railroads to establish best field testing practices. Of course, FRA recognizes and appreciates that some railroads already follow many of these best practices, and will readily adopt additional best practices that are viewed as making the field test more valid, reliable, and comparable. FRA encourages each railroad to consider adopting all best practices.

(1) *Standardize Test Procedures.* The railroad's procedures for administering and scoring the test are standardized, and the railroad strictly adheres to the procedures established.

(2) *Qualified Supervisor Conducts the Test.* The person administering and scoring the field test (testing officer) is qualified to supervise certified locomotive engineers or conductors, as appropriate, and has knowledge of the railroad's field testing procedures.

(3) *The Testing Officer's Vision Meets the Regulatory Medical Thresholds.* For purposes of administering and scoring the field test, the testing officer meets the medical thresholds in 49 CFR 240.121(c) and 49 CFR 242.117(h).

(4) *Record the Test Results During Testing.* The railroad uses a standard form or method to record all relevant information. For example, the railroad may design a field testing form that will prompt the testing officer to record administrative and test data information such as:

a. The date and location of the test;

b. The participants' names and contact information;

c. The number of signals viewed;

d. Which signals were incorrectly identified; and

e. The aspects of each signal encountered.

(5) *Capture All Essential Data and Void Tests With Incomplete Data.* The railroad should design any standard form or method used so the testing officer must record all relevant information in a manner ensuring that all essential standard procedures for testing have been followed. If a form is required, and it is missing essential data, the railroad must void the test.

(6) *Testing Officer Affirms Test Data Accurately Recorded.* The railroad may gain an additional level of assurance by requiring the testing officer to sign an affirmation that the testing officer strictly adhered to the railroad's field testing procedures and that the data recorded was accurately documented.

(7) *Prior to Test, Inform the Examinee of the Test's Purpose and Procedures.* Each railroad should standardize the procedures for informing the examinee of the purpose of the test, what the examinee is required to do during the test, and how test data will be documented and scored. For example, before the start of the test, the testing officer reads a set of instructions out loud and answers any questions. An example of an alternative or additional approach would be to provide a written explanation and test instructions directly to the examinee before the test, either as a separate document or at the top of a railroad's testing form. The railroad may consider it a timesaver to provide this information to the examinee before the test so less time is spent explaining the testing protocol on the day of the test.

(8) *Considerations When Examinee Wears Corrective Lenses.* The examinee should be offered the opportunity to wear contact lenses or glasses prescribed by his or her optometrist or ophthalmologist to correct his or her distant visual acuity.

a. *Light Blue Tint May Be Acceptable.* Please note that both the FDA and FRA make a distinction between chromatic/ChromaGen lenses and contact lenses manufactured to correct distant, intermediate, and near visual acuity that have a light blue tint added solely to aid the user in locating, handling, and cleaning the contact lens. Thus, use of contact lenses with this type of tinting should be permitted.

b. *Corrective Lenses Worn During Test Must Be Worn On-Duty, If Certified.* The examinee should be warned that the use of any lenses or glasses during a passed

test will result in conditioning of the examinee's locomotive engineer or conductor certification on wearing those lenses or glasses.

c. *Notify Examinee, Preferably in Writing at Time of Test, What To Do If Corrective Lenses Are No Longer Needed In the Future.* If an examinee's certification is conditioned on wearing lenses or glasses, the railroad should notify the examinee in writing that if the examinee's eyes improve, whether on their own or through corrective surgery, the examinee should immediately contact the relevant railroad official who can verify the improved vision and remove the restriction from the certificate and certification records. The railroad should consider including this information on the copy of the test form provided to the examinee.

(9) *Either Prohibit Examinees from Wearing Chromatic/ChromaGen Lenses or Understand Their Limitations and Proceed Accordingly.* The FDA has issued cautionary information on the use of chromatic or ChromaGen lenses. Therefore, each railroad medical examiner should understand the limitations of these lenses before deciding whether to allow an examinee to wear them during a field test.

(10) *Consider Whether a Vision Condition Is Stable or Deteriorating.* Both examinees with stable vision deficiency conditions and those with deteriorating vision may pass field tests, but that does not mean a railroad, or its medical examiner, should treat these examinees in the same manner. FRA's regulations permit a railroad's medical examiner to consider an examinee's known medical condition, and find that the person either cannot be trusted to operate safely given the volatility of the condition or recommend that the examinee's certification be conditioned on more frequent medical or field testing vision testing than the minimum FRA mandate of every 3 years.

(11) *Design Tests With Validity, Reliability, and Comparability.*

a. *Validity to the Examinee's Expected Duties.* The railroad should design the test so that the examinee is tested on railroad signal indications the examinee will be expected to recognize and comply with as part of the examinee's typical locomotive engineer or conductor duties. The railroad should require the testing officer to allow the examinee an attempt to recognize signal aspects or indications within the same timeframe, at the appropriate sight distances, as the examinee would be expected to recognize the signal under actual operating or working conditions. Because the field test conditions should reasonably match actual operating or working conditions, the test should be performed outdoors. The examinee may be either on a moving train, positioned in a stationary locomotive, or standing on the ground at distances from a signal or other object that the person must see and recognize to perform safely as a locomotive engineer or conductor.

b. *Assess Content Validity.*

i. *Conduct Test On Actual Working Conditions.* The railroad should generally administer the test over territories where the examinee has previously demonstrated knowledge of the physical characteristics and will continue to work, if certified. If this is not feasible or practical, the tests should generally be administered over territories where the examinee will be expected to work upon being certified or recertified, to the extent possible. Under all conditions, the tests should be administered to replicate actual operating conditions that the examinee will encounter as a certified locomotive engineer or conductor.

ii. *FRA Does Not Require System-Wide Certification, Restrictions Permitted.* A railroad should not test the examinee on every possible railroad signal indication on the system if the examinee has previously been limited to yards, divisions, or other territories where the examinee would only encounter a subset of the types of signal indications found system-wide and the examinee has demonstrated a positive safety record. Moreover, the examinee's certification should be restricted to that limited work arrangement.

iii. *Consider Whether a Person Works in Dark Territory or is Not Required to Recognize Signals.* Not all railroad employees are assigned responsibility by a railroad to recognize and distinguish colored railroad signals. For those employees, providing a field test that requires recognition of colored railroad signals would not be a valid test. Rather, the field test in that instance should focus on whether the employee can safely perform his or her duties. For example, the field test may require the employee to identify blue signals or roadway worker flags.

iv. *If Expanding Examinee's Actual Working Conditions, Provide Rationale.* If a railroad intends to implement a system-wide type test for an examinee who has not previously worked system-wide, the railroad should provide its rationale for doing so. It is not acceptable for a railroad, or its medical examiner, to inform an examinee that the railroad must ignore a demonstrated positive safety record with a limited work arrangement because FRA's regulations apply a stricter standard, as that is not a true statement.

c. *Reliability.*

i. *Signal Sequence Should Not Be Predictable.* The railroad should consider the sequencing of railroad signal indications to remove the likelihood that an examinee could pass the test by predicting each signal with an educated guess. For instance, signals that predictably follow a particular sequence familiar to the examinee should be avoided. A qualified supervisor should know where these sequenced signal indications may occur and either avoid them for testing purposes or arrange for them to display an uncharacteristically different sequence of signal indications.

ii. *Remove Chance Guesses By Testing Each Signal Multiple Times.* The railroad should consider the number of signal indications viewed to remove the likelihood that an examinee could pass the test by chance guess. Statistics suggest that a minimum of 3 to 6 repetitions of the same signal indication may be necessary to avoid the chance that an examinee can pass with guesses. A railroad may certainly consider additional repetitions of a signal indication if it is designed to probe an examinee's ability to correctly identify signal aspects that a person with the examinee's known color vision deficiency is likely to confuse with another aspect.

iii. *Signal Aspects Must Be Actual Signals or Similar, And In Good Working Condition.* The blue flag, sign, or signal light used in testing must be of similar size and chromaticity [8] to the actual signal the person must recognize to safely perform locomotive engineer or conductor duties. For example, an unacceptable field testing practice is use of colored light bulbs that do not have similar size, chromaticity, and transmittance as colored lenses of railroad signals on the railroad systems on which the examinee is expected to perform as a locomotive engineer or conductor. Another unacceptable field testing practice is use of a railroad signal that has an incandescent light source to test an examinee on a safety-critical signal aspect that would typically be displayed by a signal with an LED light source. Similarly, it would

[8] *Chromaticity* means the colors (single or multiple) of light emitted by a railroad color-light signal or color-position light signal, specified as x-y or x and y chromaticity coordinates on the chromaticity diagram according to the 1931 Commission International d'Éclairage (CIE) Standard Observer and Coordinate System Railroad Signal Colors. The CIE is a professional organization recognized by the International Standards Organization as an international standardization body regarding illumination.

be unacceptable to conduct a test with a well-worn, faded blue flag.

iv. *Consider Daylight, Darkness, and Weather Conditions to the Extent Those Factors Might Skew the Test Results.* The railroad's procedures should allow a medical examiner to inform the testing officer that a particular examinee must be tested at night (*i.e.,* under darkness) or during the day with bright sunshine, or under some other condition, so that the test can appropriately focus on the examinee's known color vision deficiency found during the initial medical testing and will be an accurate indicator of whether the examinee can safely perform anticipated locomotive engineer or conductor duties. For most people, signal visibility will be the greatest at night and more challenging during the daytime in bright sun when the sky is clear. Field testing conducted at sunrise or sunset may pose a greater likelihood that severe glare could skew test results such that it would be difficult for individuals with normal color vision to identify a signal indication or aspect. FRA's regulations do not prohibit a railroad from requiring multiple field tests under different operating or working conditions, and certainly some examinees will warrant such testing based on their known vision deficiency. Likewise, if a test is conducted during a snowstorm, rainstorm, fog, or other weather conditions that would inhibit a person's vision, acceptable sight distances should be adjusted accordingly, and in some instances, may suggest that a test cannot be verified as reliable and should be voided.

d. *Comparability.*

i. *Implement Procedures To Address Bias Accusations.* To effectively address accusations that a particular test was unfairly designed, implemented, or scored, a railroad should allow the examinee to bring along a volunteer witness of the examinee's choosing, and all participants, including witnesses, should be afforded an opportunity to record their observations regarding whether testing procedures were followed and the conditions under which the test was conducted. The testing officer should have a standard method that will capture the names and contact information of any witnesses who observe the test, and the railroad should permit the examinee and any witnesses an opportunity to submit their observations in writing for direct review by the railroad's medical examiner. The railroad should provide the medical examiner with the authority to void any test in which the examinee or another witness makes a substantial showing that bias or prejudice may have led to a test failure and, in such a situation, request that a new test be conducted with a different testing officer.

ii. *Create Adequate Records and Provide to Examinee.* Because an examinee who fails a field test and is subsequently denied certification or recertification may request FRA to review that decision, each railroad should be prepared to provide the examinee with the results of any field tests. A railroad should consider developing a method or protocol by which the testing officer offers a copy of the completed test form to the examinee upon completion of the test. The railroad may want the testing officer to record on the form whether the examinee was offered a copy of the form, and whether the examinee accepted receipt. The form may also include a signature line for the examinee to acknowledge receipt of the completed test form.

Issued in Washington, DC, on November 17, 2015.

Robert C. Lauby,

Associate Administrator for Railroad Safety, Chief Safety Officer.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 110819516–5913–02]

RIN 0648–BB02

Atlantic Highly Migratory Species; Smoothhound Shark and Atlantic Shark Management Measures

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

ACTION: Final rule; fishery notification.

SUMMARY: This final rule implements Amendment 9 to the 2006 Consolidated Atlantic Highly Migratory Species (HMS) Fishery Management Plan (FMP) (Amendment 9) to bring smoothhound sharks under Federal management and establishes an effective date for previously-adopted shark management measures finalized in Amendment 3 to the 2006 Consolidated Atlantic HMS FMP (Amendment 3) and the 2011 Final Rule to Modify the Retention of Incidentally-Caught Highly Migratory Species in Atlantic Trawl Fisheries (August 10, 2011) (2011 HMS Trawl Rule). Specifically, this final rule establishes Atlantic and Gulf of Mexico regional smoothhound shark annual commercial quotas based on recent stock assessments; implements the shark gillnet requirements of the 2012 Shark and Smoothhound Biological Opinion (BiOp); and modifies current regulations related to the use of vessel monitoring systems (VMS) by Atlantic shark fishermen using gillnet gear. The term ''smoothhound sharks'' collectively refers to smooth dogfish (*Mustelus canis*), Florida smoothhound (*M. norrisi*), Gulf smoothhound (*M. sinusmexicanus*), small eye smoothhound (*M. higmani*), and any other *Mustelus* spp. that might be found in U.S. waters of the Atlantic, Gulf of Mexico, and Caribbean, collectively. This rule also implements the smooth dogfish specific provisions in the Shark Conservation Act of 2010 (SCA). The SCA requires that all sharks landed from Federal waters in the United States be landed with their fins naturally attached to the carcass, but includes a limited exception for smooth dogfish. For the Federal Atlantic shark fisheries, current HMS regulations require federally-permitted shark fishermen to land all sharks with fins naturally attached to the carcass. The SCA's fins-attached requirement is being addressed nationwide through a separate ongoing rulemaking. This final rule only addresses the provision contained in the SCA that allows at-sea fin removal of Atlantic smooth dogfish.

Additionally, NMFS will hold an operator-assisted, public conference call and webinar on December 15, 2015, to discuss the methodology used to calculate the Atlantic and Gulf of Mexico smoothhound shark quotas (see **ADDRESSES**).

DATES: Effective March 15, 2016. An operator-assisted, public conference call and webinar will be held on December 15, 2015, from 2:00 p.m. to 4:00 p.m., EST.

ADDRESSES: The conference call-in phone number is 1–800–857–9816; participant pass code is 9776014. Participants are strongly encouraged to log/dial in 15 minutes prior to the meeting. NMFS will show a brief presentation via webinar followed by public questions. To join the webinar go to: *https://noaa-meets.webex.com/noaa-meets/j.php?MTID=m812c15f48b46787ea7475fc010c7099e*, enter your name and email address, and click the ''JOIN'' button. If requested, the meeting number is 991 661 137 and the meeting password is NOAA. Participants who have not used WebEx before will be prompted to download and run a plug-

in program that will enable them to view the webinar.

Copies of Amendment 9, including the Final Environmental Assessment (EA) and other relevant documents, are available from the HMS Management Division Web site at *http://www.nmfs.noaa.gov/sfa/hms/*. Copies of the 2015 smoothhound shark stock assessment results are available on the Southeast Data Assessment and Review (SEDAR) Web site at *http://sedarweb.org/sedar-39.*

FOR FURTHER INFORMATION CONTACT: Steve Durkee by phone: 202–670–6637 or Karyl Brewster-Geisz by phone: 301–427–8503 or by fax: 301–713–1917.

SUPPLEMENTARY INFORMATION: Atlantic sharks are managed under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), and the authority to promulgate regulations under the Magnuson-Stevens Act has been delegated from the Secretary to the Assistant Administrator (AA) for Fisheries, NOAA. On October 2, 2006, NMFS published in the **Federal Register** (71 FR 58058) final regulations, effective November 1, 2006, which detailed management measures for Atlantic HMS fisheries, including for the smoothhound shark and Atlantic shark fisheries. The implementing regulations for the 2006 Consolidated HMS FMP and its amendments are at 50 CFR part 635. This final rule implements the conservation and management measures from Amendment 9 in the Atlantic shark and smoothhound shark fisheries and the measures in Amendment 3 and 2011 HMS Trawl Rule in the Atlantic smoothhound shark fishery.

Background

A brief summary of the background of this final action is provided below. A more detailed history of the development of these regulations and the alternatives considered are described in the Final Environmental Assessment (EA) for Amendment 9, which can be found online on the HMS Web site (see **ADDRESSES**).

NMFS published a proposed rule on August 7, 2014 (79 FR 46217), outlining the alternatives analyzed in the Draft EA, identifying preferred alternatives, and soliciting public comments on the measures, which would impact the smoothhound shark and Atlantic shark fisheries. Specifically, the proposed rule included the following measures: For smooth dogfish only, modifying prohibitions on at-sea fin removal to be consistent with the SCA; implementing Term and Condition 4 of the 2012 Shark BiOp; based on updated catch data, adjusting the smoothhound shark quota finalized in Amendment 3; and modifying the VMS requirements for shark gillnet vessels. The full description of the management and conservation measures considered is included in both the Final EA for Amendment 9 and the proposed rule and is not repeated here.

The comment period for the Draft EA and proposed rule for Amendment 9 ended on November 14, 2014. The comments received, and responses to those comments, are summarized below under the heading labeled Response to Comments.

Management measures in Amendment 9 will impact both the smoothhound shark and Atlantic shark fisheries. This rule finalizes most of the management measures, but modifies others, that were contained in the Draft EA and proposed rule for Amendment 9. This section provides a summary of the final management measures being implemented by Amendment 9 and notes changes from the proposed rule to this final rule. Measures that are different from the proposed rule, or measures that were proposed but not implemented, are described in detail under the heading titled Changes from the Proposed Rule.

This final rule implements the smooth dogfish-specific measures in the SCA to establish an allowance for the removal of smooth dogfish fins while at sea. To implement the measures, the proposed rule considered three categories of requirements—catch composition, state permitting, and geographic applicability of the exceptions—and a range of alternatives within each category (''sub-alternatives''). Only fishermen that meet the requirements under all three of these categories and that are, as specified in the Act, fishing within 50 nautical miles of shore and possess fins in an amount that does not exceed 12 percent of the carcass weight, would be authorized to remove smooth dogfish fins at sea.

For catch composition, NMFS preferred in the proposed rule a sub-alternative that would have required that smooth dogfish make up at least 75 percent of the retained catch on board and that no other sharks could be retained. For state permitting, the proposed rule included a sub-alternative that would have required an individual to hold a state commercial fishing permit that allows smooth dogfish retention, in addition to a Federal smoothhound permit. With regard to geographic applicability, the proposed rule included a sub-alternative that would have applied the SCA exception for smooth dogfish along the entire Atlantic coast but not to Florida's coast in the Gulf of Mexico. During the public comment period, NMFS received support for the two proposed sub-alternatives related to state fishing permits and geographic applicability of the SCA provisions. However, NMFS received many comments opposing the catch composition requirement of 75 percent and the ''no other sharks on board'' provision. Commenters expressed concern that these requirements do not meet the intent of the statutory exception because they do not reflect the mixed nature of catch in the smooth dogfish fishery and would render the exception largely meaningless. They also stated that the catch composition requirement would lead to excessive dead discards and would be burdensome.

As detailed under the Changes from the Proposed Rule heading, NMFS is implementing the two sub-alternatives related to state fishing permits and geographic applicability of the exception as originally proposed. NMFS is changing the catch composition requirement and will require smooth dogfish to make up at least 25 percent of the total retained catch in order to remove the fins of smooth dogfish while at sea. Additionally, fishermen may retain other sharks on board provided that the fins of other shark species remain naturally attached to the carcass through offloading. Only fishermen adhering to the measures in the three sub-alternatives, as well as fishing within 50 nautical miles of shore and possessing fins in an amount that does not exceed 12 percent of the carcass weight, will be authorized to remove smooth dogfish fins at sea.

This final rule also establishes separate Atlantic and Gulf of Mexico regional smoothhound shark total allowable catches (TACs) and commercial quotas based on the results of the 2015 Southeast Data Assessment and Review (SEDAR) 39 stock assessments for smoothhound sharks. The assessments were finalized and peer reviewed in March 2015. On June 29, 2015, NMFS issued a stock status determination notice (80 FR 36974) that stated that ''[d]ata from tagging and genetic research in SEDAR 39 support the existence of two distinct Atlantic and Gulf of Mexico stocks of smooth dogfish separated by peninsular Florida. Therefore, smooth dogfish was treated as two separate stocks, one in the Atlantic region and one in the Gulf of Mexico region.'' 80 FR 36974 (June 29, 2015). Each stock had a status of not overfished with no overfishing occurring. Based on public comments requesting that commercial quotas be based on stock assessments and not

landings, NMFS is implementing regional smoothhound shark TACs and commercial quotas based on SEDAR 39, instead of the proposed, single overall quota based on landings data. Specifically, while we proposed an overall commercial quota of 1,739.9 mt dw covering both the Atlantic and Gulf of Mexico regions (using commercial landings data in the absence of a stock assessment), this final rule establishes separate regional TACs and commercial quotas within those TACs as follows: An Atlantic regional smoothhound shark TAC of 1,430.6 mt dw with a commercial quota of 1,201.7 mt dw, and a Gulf of Mexico regional smoothhound shark TAC of 509.6 mt dw with a commercial quota of 336.4 mt dw. Implementing these science-based TACs and commercial quotas will ensure continued sustainable harvest of smoothhound sharks in the Atlantic and Gulf of Mexico regions and increase the likelihood of maintaining healthy smoothhound shark stocks in both regions. Additional details are provided below under the heading Changes from the Proposed Rule.

Term and Condition (TC) 4 of the 2012 Shark BiOp addressed soak time and net check requirements for gillnet gear. In order to comply with TC 4, this final rule modifies the soak time and net check requirements based on the type of gillnet gear used in the Atlantic shark and smoothhound shark fisheries. NMFS has determined that current regulations meet the specifications for other TCs in the 2012 BiOp. This final rule will establish a soak time limit of 24 hours for sink gillnet gear and a 0.5 to 2 hour net check requirement for drift gillnet gear in the Atlantic shark and smoothhound shark fisheries. This requirement would not significantly change smoothhound shark fishing practices, since most smoothhound shark gillnet fishermen primarily use sink gillnet gear and those fishermen already use a soak time of 24 hours or less.

This final rule also modifies current regulations related to the use of VMS by federal directed shark permit holders using gillnet gear. Before this rule, federal directed shark permit holders with gillnet gear on board were required to use VMS regardless of vessel location in order to simplify compliance and outreach for fishermen operating across multiple regions. This requirement was implemented as part of the 2003 Amendment 1 to the 1999 FMP for Atlantic Tunas, Swordfish, and Sharks to ensure shark gillnet vessels were complying with the Atlantic Large Whale Take Reduction Plan (ALWTRP) time/area closures and observer requirements (50 CFR 229.32). However, since implementation, it has become apparent that while some fishermen do fish in multiple regions, many do not fish in or even near the Southeast U.S. Monitoring Area. As such, this final rule will require federal directed shark permit holders with gillnet gear on board to use VMS only in the vicinity of the Southeast U.S. Monitoring Area, pursuant to ALWTRP requirements. Requirements to minimize large whale interactions would not change; rather, only the geographic area of the VMS requirement would change, consistent with the ALWTRP.

This final rule also establishes an effective date for previously-adopted smoothhound shark management measures in Amendment 3 and the 2011 HMS Trawl Rule. The final rule implementing conservation and management measures in Amendment 3 published on June 1, 2010 (75 FR 30484) but delayed the effective date of the smoothhound shark management measures until approximately 2012 pending approval for the data collection measures under the Paperwork Reduction Act (PRA) by the Office of Management and Budget (OMB), to provide time for implementation of a permit requirement, to provide time for NMFS to complete a Biological Opinion under Section 7 of the Endangered Species Act (ESA), and to provide time for affected fishermen to change business practices, particularly as it related to keeping shark fins attached to the carcass through offloading. OMB approved the PRA data collection in May of 2011 and NMFS met informally with smoothhound shark fishermen along the east coast in the fall of 2010. In November 2011, NMFS published a rule (76 FR 70064, November 10, 2011) that indefinitely delayed the effective date for all smoothhound shark management measures in both Amendment 3 and in another rule, the 2011 Final Rule to Modify the Retention of Incidentally-Caught Highly Migratory Species in Atlantic Trawl Fisheries (76 FR 49368, August 10, 2011 (2011 HMS Trawl Rule)), to provide time for NMFS to consider the smooth dogfish-specific provisions in the SCA and for NMFS to finalize a Biological Opinion on the federal actions in Amendment 3, among other things. Previously-adopted management measures from Amendment 3 that will become effective on January 1, 2016, include: A research set-aside quota; an accountability measure (AM), which closes the fishery when smoothhound shark landings reach, or are expected to reach, 80 percent of the quota; a requirement for a dealer permit to purchase smoothhound sharks; a requirement for dealers to report smoothhound shark purchases; a smoothhound permit requirement for commercial and recreational fishing and retention; a requirement for vessels fishing for smoothhound sharks to carry an observer, if selected; a requirement for vessels fishing for smoothhound sharks to comply with applicable Take Reduction Plans pursuant to the Marine Mammal Protection Act (MMPA); and a requirement for commercial vessels to sell catch only to Federally-permitted shark dealers. Management measures affecting smoothhound sharks in the HMS Trawl Rule will allow retention of smoothhound sharks caught incidentally with trawl gear, provided that the total smoothhound shark catch on board or offloaded does not exceed 25 percent of the total catch by weight.

Finally, this rule makes administrative changes to the observer regulations. Currently, the Atlantic shark fishery observer program is administered by the Southeast Fisheries Science Center (SEFSC). However, a portion of the commercial smoothhound shark fishery occurs in the Northeast region in an area typically covered by observer programs administered out of the Northeast Fisheries Science Center (NEFSC). Since the fishery spans the geographic area of both the NEFSC and SEFSC, smoothhound shark observer regulations need to accommodate the administrative processes of both programs. The two regional science center observer program processes are slightly different. The SEFSC process is currently outlined in the 50 CFR part 635 regulations but the NEFSC process is not. Thus, this final rule implements changes to the observer regulations in 50 CFR part 635 to incorporate the relevant portions of the NEFSC observer regulations found at 50 CFR part 648.

Response to Comments

During the proposed rule stage, NMFS received approximately 500 written comments from fishermen, States, environmental groups, academia and scientists, and other interested parties. NMFS also received feedback from the HMS Advisory Panel; constituents who attended the two public hearings in October 2014 in Toms River, New Jersey, and Manteo, North Carolina; and constituents who attended the conference calls/webinars held on September 24 and November 4, 2014. Additionally, NMFS consulted with the New England, Mid-Atlantic, South Atlantic, Gulf of Mexico, and Caribbean Regional Fishery Management Councils, along with the Atlantic States and Gulf

States Marine Fisheries Commissions. A summary of the comments received on the proposed rule during the public comment period is provided below with NMFS's responses. All written comments submitted during the comment period can be found at *http://www.regulations.gov* by searching for NOAA–NMFS–2014–0100.

Implementation of the Smooth-Dogfish Specific Provisions of the Shark Conservation Act

Comment 1: NMFS received comments in support of Alternative A1, which would not implement the smooth dogfish-specific measures in the Shark Conservation Act of 2010 and would require fins and tails of all smooth dogfish to remain naturally attached through offloading. Commenters felt that these exceptions to the U.S. ban on at-sea shark fin removal would jeopardize our nation's reputation as a shark conservation champion, and hurt U.S. arguments in support of Regional Fishery Management Organizations' adoption of fins attached requirements. Commenters also felt that the fins naturally attached method was widely recognized as the best practice for accurate data collection and enforcement of finning bans. Commenters felt that adopting a fins attached exception for smooth dogfish would undermine state bans on finning and would widen loopholes in certain state bans on the trade in shark fin products.

Response: The Shark Conservation Act of 2010, which includes the smooth dogfish-specific exception, became Federal law upon Presidential signature on January 4, 2011. Thus, NMFS must implement the law in a manner that reflects Congressional intent. The Congressional provision clearly creates an exception that allows removal of smooth dogfish shark fins at sea under certain circumstances and did not leave the Agency discretion to forego implementation of the exception.

Comment 2: NMFS received a comment stating that the 12 percent fin-to-carcass ratio included in the smooth dogfish-specific provision of the SCA was too high and should be lower.

Response: The 12 percent fin-to-carcass ratio is explicitly included in the smooth dogfish-specific provision of the SCA. Thus, NMFS must implement the provision as mandated. Nevertheless, some data support that a 12 percent fin-to-carcass ratio may be a close approximation of the true ratio for smooth dogfish. In the Atlantic States Marine Fisheries Commission (ASMFC) Shark Board briefing materials prepared for a May 21, 2013 meeting, the States of New Jersey and New Carolina provided analyses of smooth dogfish fin-to-carcass ratios using both landings data and direct measurements of processed sharks. Those analyses found a range of fin-to-carcass ratios from 7.5 percent to 13 percent, depending on the level of processing (*e.g.* whether the belly flaps were removed, whether the tail was retained).

Comment 3: NMFS received a large volume of comments expressing concern that the smooth dogfish-specific provision of the Shark Conservation Act allows finning of sharks. These commenters asked NMFS not to implement this provision and many of the comments provided information about the negative ecological impacts of sharks finning.

Response: The large volume of comments opposing finning of smooth dogfish appears to be based on a misunderstanding on this action. Finning, which is the removal of shark fins and disposal of the carcass at sea, has been prohibited in Atlantic U.S. shark fisheries since 1993, and will continue to be prohibited in all Atlantic shark fisheries. The exception in the Act allows for the removal of the fins at sea rather than requiring the sharks to be landed with their fins attached as the Act requires for other shark species. The fins and the carcasses still must be landed together.

Sub-Alternatives—Issue 1: Catch Composition

Comment 4: NMFS received several comments, including from the SAFMC, MAFMC, and the States of New Jersey, North Carolina and Maryland, opposing the proposed sub-alternative A2–1c that smooth dogfish must make up at least 75 percent of the retained catch (no other sharks can be retained). Commenters felt that the 75 percent catch composition would be difficult to enforce and burdensome for fishermen. Some felt that the 75 percent would lead to waste and discarding in cases where fishermen found that their catch percentages did not qualify them for the at-sea processing allowance. Others emphasized that the smoothhound fishery is a mixed fishery, and that fishermen needed more flexibility if the SCA exception were to have any utility. NMFS also received comments that the 75 percent catch composition was inconsistent with ASMFC requirements and that the new federal requirements might push fishermen into state waters where there are no catch composition requirements. Commenters felt that as a consequence, fishermen may avoid obtaining a federal smoothhound shark permit, leading to less data for federal mangers. NMFS received support from the MAFMC and the state of New Jersey for sub-alternative A2–1b that would require smooth dogfish make up at least 25 percent of the retained catch. NMFS also received some limited support for the 75 percent catch composition.

Response: In the Draft EA and proposed rule, NMFS interpreted the phrase ''fishing for smooth dogfish'' to mean fishing with the object of commercially harvesting smooth dogfish, but also emphasized that the SCA had specified that the exception applies when an individual is fishing ''for'' smooth dogfish as opposed to fishing ''for'' other species and incidentally catching smooth dogfish or simply stating that it applies ''when fishing.'' We then preferred a sub-alternative that smoothhound sharks must make up 75 percent of the retained catch on board a vessel to constitute a trip fishing ''for'' smooth dogfish and stated that this would preclude fishermen on trips for other species but who incidentally catch smooth dogfish from removing smooth dogfish fins at sea. The catch composition threshold of 75 percent is used in other fisheries that interact with HMS (*e.g.,* incidental swordfish catch in the squid trawl fishery) to distinguish between directed and incidental fisheries and NMFS felt this high level of retention was an appropriate way to identify those fishing ''for'' smooth dogfish.

Based on public comments, however, it has become apparent that the 75 percent level used in other fisheries is not appropriate in the smooth dogfish fishery and does not accurately reflect fishing practices in that fishery. To verify the feedback from commenters, NMFS reviewed data on the mixed nature of the smoothhound shark fishery and how well catch composition reflects the fishery and discovered that, as asserted by the commenters, the smooth dogfish fishery is far more mixed than NMFS assumed in the proposed rule. As a result, implementing a 75 percent catch composition requirement would make the exception largely meaningless. Thus, while NMFS' objective for the implementation of the smooth dogfish-specific provision of the SCA remains the same as described in the Draft EA, and NMFS still needs to give meaning to the phrase ''fishing for smooth dogfish'' as opposed to simply ''fishing,'' NMFS agrees with the majority of the commenters that a catch composition requirement of 25 percent is more appropriate. This is consistent with the smooth dogfish-specific provision in the SCA that limits the exception to those fishermen that are

fishing ''for'' smooth dogfish while acknowledging the need for enhanced flexibility in a mixed fishery. The reasons for the change include the four following factors, which were reflected in public comment on the proposed rule:

- Sink gillnet gear, the predominant gear used in the directed smooth dogfish fishery, often catches other species along with the targeted species. If a fisherman retains other legal species in an amount greater than 25 percent of the total retained catch, it does not necessarily mean that effort was not being directed on smooth dogfish, it could simply mean that other species were encountered in a greater amount than anticipated.
- Although a 75 percent catch composition is an appropriate indicator of target species in other HMS fisheries, such as the squid trawl fishery, it is not appropriate at this time in the smooth dogfish fishery. In the squid trawl fishery, swordfish caught in squid trawls can only be retained if at least 75 percent of the retained catch is squid, indicating that squid is the targeted fishery. In that fishery, the catch is predominantly squid but swordfish that are feeding on the squid are sometimes inadvertently caught. The smooth dogfish fishery is a more mixed fishery and the target species is often co-located with other species, resulting in less certainty of target species catch levels
- When fishermen decide to remove fins from smooth dogfish while at sea, the fins are not removed at the end of the trip. Rather, the fins are removed shortly after the smooth dogfish is brought on board in order to maintain the highest quality product. This processing method negates the benefits of a high catch composition requirement. For example: If a fishermen is directing effort on smooth dogfish and removing the fins as the smooth dogfish are brought on board, that fishermen does not know what the final catch composition will be. The first part of the trip could be 100 percent smooth dogfish, but if the catch transitions to predominantly other species, the fishermen may have found that he no longer meets the high catch composition requirement. In that case, the fisherman has two options: To either discard all the smooth dogfish carcasses and fins that have been processed or discard the non-smooth dogfish catch in an amount that will meet the catch composition requirement. Either way, a high catch composition could lead to unnecessary regulatory discards. Although this last example could also pertain to the preferred 25 percent catch composition, the lower threshold provides a greater amount of flexibility and reduces the instances of regulatory discards, consistent with National Standard 9.
- Smooth dogfish, and the fishery that targets them, closely follow specific water temperature gradients. Fisherman intending to land primarily smooth dogfish may find their gear in sub-optimal water temperatures leading to lower smooth dogfish catch despite the intention to directly target the species and resulting in a lower catch composition than expected.

Comment 5: NMFS received comments that NMFS was interpreting the smooth dogfish-specific provisions in the SCA incorrectly because the provision does not specify its application to the directed or incidental smooth dogfish fishery and that limiting fishermen to a directed fishery would only serve to inflict financial hardships on fishermen.

Response: The SCA does not explicitly state that it applies only to directed fisheries; however, the relevant SCA statutory text, (''an individual engaged in commercial fishing for smooth dogfish (*Mustelus canis*)'') included descriptive language such as ''engaged in'' and ''for'' that NMFS understood to be more limiting than if the statute had simply said ''while fishing.'' We thus interpreted ''fishing for smooth dogfish'' to limit the exception to those fishing primarily for smooth dogfish, as reflected by the 75 percent retention requirement. Had Congress intended to allow all trips to remove smooth dogfish fins at sea, this qualifying language and emphasis on fishing ''for'' smooth dogfish would not have been included. As explained in the previous response, the final rule's lower percentage requirement for smooth dogfish catch composition (25 percent v. 75 percent) should address some of the concerns about the practicality of the proposed rule's catch composition requirements in light of the very mixed nature of the fishery, while still ensuring that the exception is limited to those fishing ''for'' smooth dogfish.

Comment 6: NMFS received comments, including from the SAFMC, MAFMC, NCDMR, and the States of New Jersey and Maryland opposing the ''no other sharks on board'' provision. The commenters stated that this provision would be burdensome for fishermen and would lead to unnecessary waste and discards of other valuable shark species since it is a mixed, variable fishery. Others noted that NMFS is interpreting the smooth dogfish-specific provisions of the SCA incorrectly because ''no other sharks on board'' is never mentioned in the statute and that it is inconsistent with ASMFC requirements. Additionally, NMFS received comments stating that a large number of common thresher sharks are often caught with smooth dogfish and if these species had to be discarded, this would be wasteful and could lead to economic impacts to shark fishermen.

Response: After considering public comment, NMFS has determined that it is more appropriate and consistent with the SCA to implement Sub-Alternative A2–1e, which allows other sharks to be retained when removing smooth dogfish fins at seas, provided those sharks are maintained in a condition where the fins and tail remain naturally attached to the carcass through landing. This measure is included in the new sub-alternative based on public comment and additional analyses, and in recognition that a prohibition on having other sharks on board would likely increase regulatory discards, contrary to National Standard 9. The smooth dogfish fishery is more mixed than previously thought, and other sharks, particularly spiny dogfish and common thresher sharks, make up a portion of the catch and contribute considerable revenue to fishermen participating in the smooth dogfish fishery. Under the new preferred sub-alternative, fishermen would not have to choose whether to land smooth dogfish with the fins removed or another species of shark. This is a change from the proposed rule, which would have prohibited retention of other sharks when removing the fins from smooth dogfish at sea. As proposed, a fisherman who wanted to remove fins of smooth dogfish at sea would have had to discard all non-smooth dogfish sharks even if they were dead and were otherwise legal to retain based on species, size, and permits. Alternatively, as proposed, a fisherman could decide to retain non-smooth dogfish sharks and discard any smooth dogfish carcasses and fins that had already been processed. In either situation, as proposed, dead discards would likely increase, given the mixed catches in the smooth dogfish fishery.

Allowing other sharks onboard is consistent with the objective of Amendment 9 to narrowly focus the at-sea fin removal allowance for the smooth dogfish fishery and would not undermine the enforcement of the limited smooth dogfish exception or impact the conservation of non-smooth dogfish sharks because smooth dogfish carcasses can be readily differentiated from other non-smoothhound shark carcasses by the presence of a pre-dorsal ridge. As a practical matter, smooth dogfish and other smoothhound species

are indistinguishable in the field. But geographically, smooth dogfish largely are the only smoothhound species found in the Atlantic, which is the only place where smooth dogfish fins can be removed, thus largely alleviating that identification concern. Under the new preferred sub-alternative, other sharks would be allowed on board while removing smooth dogfish fins at sea as long as the fins of non-smooth dogfish sharks remain naturally attached through offloading as currently required. NMFS will monitor all shark catches and discards and dead discards to ensure the conservation of all shark species and will take the additional action, as necessary, to address any conservation or management issues that may arise.

Sub-Alternatives—Issue 2: State Fishing Permit

Comment 7: NMFS received several comments, including from the MAFMC and the States of New Jersey and Maryland, supporting the preferred Sub-Alternative A2–2b to require any state commercial fishing permit appropriate for the retention of smoothhound sharks when removing smooth dogfish fins at sea. Some of these comments noted the non-preferred sub-alternative, which would require a smoothhound-specific state commercial fishing permit, could require new regulations and may necessitate cost recovery of permit administration.

Response: NMFS agrees that requiring a smoothhound-specific state fishing permit could be burdensome to states and fishermen. In the Draft EA and proposed rule, NMFS asked for comment on this issue, particularly from the states that would need to develop and administer a smoothhound-specific permit. The states that commented on this issue were unanimously opposed to a smoothhound-specific permit and favored the preferred Sub-Alternative A2–2b. For these reasons, NMFS will implement Sub-Alternative A2–2b as proposed.

Sub-Alternatives—Issue 3: Geographic Applicability

Comment 8: NMFS received comments, including from the MAFMC and the State of Florida, in support of the preferred Sub-Alternative A2–3b to apply the exception for smooth dogfish along the Atlantic Coast and not to Florida's coast in the Gulf of Mexico. Conversely, NMFS also received a comment stating that the exception should be applicable in the Gulf of Mexico so that the historical boundaries between the Gulf and South Atlantic Councils are honored and the State of Florida can manage the fishery in a balanced way.

Response: As a practical matter, smooth dogfish and other smoothhound species are indistinguishable in the field. The best available scientific information indicates that smooth dogfish are the predominant smoothhound shark species along the Atlantic coast (only a handful of Florida smoothhound have ever been recorded in the Atlantic and those have been near southern Florida). In the Gulf of Mexico, however, there are at least three different smoothhound species, with no practical way to readily distinguish among them. By limiting the exception to the Atlantic region, as specified at § 635.27(b)(1), this sub-alternative will ensure that the exception only applies where the population is almost entirely smooth dogfish, reducing identification problems and inadvertent finning violations. Furthermore, the State of Florida found the preferred sub-alternative limiting the exception to the Atlantic to be consistent with the Florida Coastal Management Program.

Commercial Quota Adjustment for the Smoothhound Shark Fishery

Comment 9: Multiple commenters, including the SAFMC, the States of Maryland, New Jersey, Georgia, and the Commonwealth of Virginia, suggested that none of the landings-based methodologies should be used to establish a smoothhound shark quota. Instead, NMFS should base the quota on the SEDAR 39 smoothhound shark stock assessment that was underway at that time, and which was proposed as an alternative, although the results had not yet been finalized at the time of proposed rule publication. NMFS also received comments opposing the preferred alternative B3, establishing a smoothhound quota equal to the maximum annual landings from 2004–2013 plus two standard deviations because some commenters thought this quota was too high and seemed contrary to a risk averse approach.

Response: NMFS agrees that it is preferable to establish scientifically-based quotas using results from the SEDAR 39 stock assessments. Since publication of the proposed rule, the SEDAR 39 stock assessments have been completed. Based on the availability of the stock assessment results and public comments, NMFS no longer prefers the alternative to establish a landings-based quota and now is basing the quotas on the results of the stock assessments. Thus, NMFS is establishing a smoothhound shark TAC of 1,430.6 mt dw and a commercial quota of 1,201.7 mt dw in the Atlantic region, and a TAC of 509.6 mt dw and commercial quota of 336.4 mt dw in the Gulf of Mexico region, based on results of SEDAR 39. Section 2 of the Final EA provides a summary of the calculations used to determine these quotas.

Comment 10: NMFS received a comment asking NMFS not to wait until the stock assessment was completed and to implement Alternative B1, the smoothhound quota of 715.5 mt dw established in Amendment 3 to the 2006 Consolidated HMS FMP.

Response: NMFS recognizes the benefits of establishing a quota to limit mortality in the commercial fisheries. However, based on the timing of both this action and the SEDAR 39 stock assessments, NMFS determined that establishing scientifically-based quotas using results of the stock assessments outweigh benefits of implementing a landings-based quota. Since the stock assessments are now available, NMFS is establishing quotas based on those stock assessments.

Biological Opinion Implementation

Comment 11: NMFS received support for the preferred alternative C4 to establish a 24-hour soak time limit for sink gillnets and a 0.5 to 2 hour net check requirement for drift gillnet gear. The MAFMC and State of New Jersey also expressed support for the preferred alternative but asked that the definitions of sink and drift gillnets be clarified so that a sink gillnet cannot be mistaken for a net that is drifting in the water column. The State of Maryland expressed support for alternative C3 (24-hour soak time for smoothhound permit holders) stating that net checks are not enforceable. NMFS also received comments suggesting that gillnet fishermen should be required to do both net checks and limit soak time to 24 hours. Other commenters asked NMFS to consider a reduced soak time because they felt that 24 hours was too long and would not reduce the risk of large whale interactions.

Response: NMFS agrees that a 24-hour soak time limit for sink gillnets and a 0.5 to 2 hour net check requirement for drift gillnet gear are appropriate ways to implement the Term and Condition 4 of the 2012 Shark BiOp. NMFS also agrees that the definitions of sink and drift gillnet need to be clear so as not to confuse fishery participants and enforcement officials. As detailed in the Final EA, most smoothhound shark gillnet fishermen will be required to limit soak times to 24 hours since they primarily use sink gillnet gear. This requirement will not significantly change smoothhound shark fishing

practices. With regard to other Atlantic shark fishermen, fishermen who use sink gillnet gear will be required to limit soak times to 24 hours and those that use drift gillnets will be required to perform net checks at least every 2 hours. Currently, all Atlantic shark fishermen that use gillnet gear to fish for or who are in possession of any large coastal, small coastal, or pelagic shark, regardless of gillnet type, are required to perform net checks at least every 2 hours (see § 635.21(e)(3)(v)). During the net checks, fishermen are required to look for and remove any sea turtles, marine mammals, or smalltooth sawfish. In the 2012 Shark BiOp, the requirement to use either net checks or the 24-hour set limitation was determined to ensure that any incidentally taken ESA-listed species are detected and released in a timely manner, reducing the likelihood of mortality. As such, NMFS has determined that this alternative will likely have short and long-term minor beneficial ecological impacts on protected resources because it will implement one of the Terms and Conditions of the 2012 Shark BiOp to minimize impacts on protected resources. Because this alternative complies with the 2012 Shark BiOp, has beneficial ecological impacts to protected species, and allows all smoothhound shark gillnet fishermen to continue current fishing practices, NMFS will implement soak time limits for sink gillnets and net checks for drift gillnets, as proposed, in the final rule.

Comment 12: NMFS received a comment stating that NMFS has not received authorization of the incidental take of endangered large whales that may result due to the operation of the fishery. The comment stated that without incidental take of endangered whales authorized under both the MMPA and ESA, federal management violates those laws. The commenter stated that NMFS must acquire take authorization under the MMPA section 101(a)(5)(E) for the expected whale takes associated with the smoothhound fishery and that NMFS must delay Amendment 9 until completion of a negligible impact analysis for North Atlantic right whale, humpback whale and fin whale. NMFS also received comments stating that (1) since the completion of the BiOp, critical habitat has been designated for loggerhead sea turtles, which triggers the requirement to reinitiate consultation in the shark fishery, and (2) the Draft EA fails to discuss effects of the fishery on loggerhead critical habitat.

Response: As required by section 7(a)(2) of the ESA, the HMS Management Division of NMFS Office of Sustainable Fisheries consulted with the NMFS Protected Resources Division (PRD) over proposed Atlantic shark fishery management measures in December 2009. That consultation was completed in 2012, and the Shark BiOp was issued in December 2012. The Biological Opinion concluded that the actions as proposed—including the operation of the smoothhound fishery—were not likely to jeopardize the continued existence of Atlantic sturgeon, smalltooth sawfish or any species of ESA-listed large whales or sea turtles.

Section 9 and regulations implementing section 4(d) of the ESA prohibit the ''take'' or incidental take of listed species without an exemption. Under the terms of Section 7(b)(4) and Section 7(o)(2), otherwise prohibited take that is incidental to and not intended as part of the agency action may be permitted if it complies with reasonable and prudent measures (RPMs) and terms and conditions of an incidental take statement (ITS). Two RPMs were included in the 2012 Shark BiOp to minimize the effects of the action on sea turtles, smalltooth sawfish, and Atlantic sturgeon by the smoothhound and Atlantic shark fisheries and to monitor the level of incidental take: (1) Minimize the Potential Effects to Sea Turtles, Smalltooth Sawfish, Atlantic Sturgeon and Marine Mammals, and (2) Monitor the Frequency and Magnitude of Incidental Take. One remaining term and condition will be implemented in this final rule and will require gillnet fishermen to conduct net checks and limit gillnet soak times mitigating or reducing interactions with protected species.

Since finalizing the 2012 BiOp, NMFS issued a final determination to list four separate DPSs of the scalloped hammerhead shark (*Sphyrna lewini*) under the ESA (79 FR 38214, July 3, 2014). The DPSs are Central and Southwest Atlantic, Indo-West Pacific, Eastern Atlantic, and Eastern Pacific. The Eastern Atlantic and Eastern Pacific DPSs are listed as endangered, and the Central and Southwest Atlantic and the Indo-West Pacific DPSs are listed as threatened. NMFS determined that each of the DPSs was significant and distinct based on genetic, behavioral, and physical factors, and in some cases, differences in the control of exploitation of the species across international boundaries. On August 27, 2014, NMFS published a final rule to list the following 20 coral species as threatened: Five in the Caribbean, including Florida and the Gulf of Mexico (*Dendrogyra cylindrus, Orbicella annularis, Orbicella faveolata, Orbicella franksi, and Mycetophyllia ferox*); and 15 in the Indo-Pacific (*Acropora globiceps, Acropora jacquelineae, Acropora lokani, Acropora pharaonis, Acropora retusa, Acropora rudis, Acropora speciosa, Acropora tenella, Anacropora spinosa, Euphyllia paradivisa, Isopora crateriformis, Montipora australiensis, Pavona diffluens, Porites napopora,* and *Seriatopora aculeata*). Two Caribbean species currently listed as threatened (*Acropora cervicornis* and *Acropora palmata*) still warranted listing as threatened. The Central and Southwest Atlantic DPS of scalloped hammerhead shark and the seven Caribbean species of coral occur within the boundary of Atlantic HMS commercial and recreational fisheries.

On October 30, 2014, based on the new listings, NMFS requested re-initiation of ESA section 7 consultation on the continued operation and use of HMS gear types (bandit gear, bottom longline, buoy gear, handline, and rod and reel) and associated fisheries management actions in the 2006 Consolidated Atlantic HMS FMP and its amendments. NMFS has preliminarily determined that the ongoing operation of the fisheries is consistent with existing biological opinions and is not likely to jeopardize the continued existence of the Central and Southwest DPS of scalloped hammerhead sharks or the threatened coral species or result in an irreversible or irretrievable commitment of resources which would foreclose formulation or implementation of any reasonable and prudent alternative measures for these species.

Regarding marine mammals, the final 2014 MMPA List of Fisheries classified the southeastern Atlantic shark gillnet fishery as Category II (occasional serious injuries and mortalities). The southeastern Mid-Atlantic and Gulf of Mexico shark BLL shark fishery is classified as Category III (remote likelihood or no known serious injuries or mortalities). Commercial passenger fishing vessel (charter/headboat) fisheries are subject to Section 118 and are listed as a Category III fishery. This action would not significantly increase fishing effort rates, levels, or locations or fishing mortality. The preferred alternatives would not increase effort because the smoothhound quotas are based on the most recent smoothhound shark stock assessments (SEDAR 39). In addition, final management measures are not expected to alter interactions with protected species.

Atlantic Shark Gillnet Vessel Monitoring System Requirements

Comment 13: NMFS received support for the preferred alternative of requiring directed shark permit holders with gillnet gear on board to use VMS only in the Southeast U.S. Monitoring Area, including from the States of North Carolina, New Jersey, and Maryland, and the MAFMC. NMFS also received comments preferring the status quo stating that VMS should be required regardless of where the vessel is fishing.

Response: Currently, under Federal HMS regulations, Atlantic shark gillnet fishermen are required to use VMS at certain times of the year regardless of where they are fishing. However, per 50 CFR 229.32(h)(2)(i), the implementing regulations for the Atlantic Large Whale Take Reduction Plan (ALWTRP), Atlantic shark gillnet fishermen are only required to have VMS if they are fishing in the Southeast U.S. Monitoring Area. Because NMFS has determined that VMS is not necessary for Atlantic shark gillnet fishermen in the other ALWTRP restricted areas through the implementation of the ALWTRP regulations, NMFS believes it is best to maintain consistency with these regulations. Maintaining consistency between the Atlantic HMS and ALWTRP regulations will reduce confusion, help fishermen comply with these regulations more easily, and will avoid unnecessary economic burdens on shark fishery participants.

Previously Adopted Smoothhound Shark Measures in Amendment 3 and the HMS Trawl Rule

Comment 14: NMFS received a comment stating that smoothhound sharks should be managed by the Regional Fishery Management Councils in cooperation with ASMFC.

Response: As detailed in Amendment 3 to the 2006 Consolidated Atlantic HMS FMP, smoothhound sharks are ''oceanic sharks'' as defined by the Magnuson-Stevens Act and are subject to management by the Secretary of Commerce under that Act. Please refer to Amendment 3 to the 2006 Consolidated Atlantic HMS FMP for a detailed explanation of why smoothhound sharks are appropriately subject to Federal management.

Comment 15: NMFS received a comment stating that the Federal smoothhound permit could trigger an increase in directed smooth dogfish effort. A comment was also received suggesting that the fishery, once permitted, should not be open access and that a control date should be set to discourage new entrants.

Response: Based on the nature of the fishery, which is labor-intensive and high-volume, additional management burdens such as permit requirements are unlikely to result in an increase in effort. In fact, a slight reduction is more likely. Since effort increases are not expected, NMFS does not believe that introducing a limited access permit in this fishery is necessary at this time. Nevertheless, this action will implement scientifically-based quotas and landings will be closely monitored to ensure that total mortality does not exceed scientifically-determined limits. If, in fact, directed smooth dogfish effort increases, protections will be in place to ensure that fishing pressure does not exceed sustainable levels while NMFS considers if additional measures are necessary.

Comment 16: NMFS received a comment from the State of Maryland stating that they are concerned about the measure to close the fishery when 80 percent of the smoothhound quota has been caught. They feel that this measure may limit access to some states later in the year. The State of Maryland recommends working with the other Atlantic states to close each state's smoothhound fishery once 80 percent of the state's allocation has been harvested.

Response: In all quota-managed Atlantic shark fisheries, NMFS closes the applicable fishery when landings reach, or are expected to reach, 80 percent of the quota. This measure mitigates for possible late reporting, which could result in quota overharvests. Based on the success of this measure in the other shark fisheries, NMFS prefers to implement the 80-percent accountability measure (AM) in the smoothhound shark fisheries as finalized in Amendment 3 to the 2006 Consolidated HMS FMP rather than risk exceeding the quotas in the smoothhound fisheries.

Through Addendum II to the Coastal Sharks Interstate FMP, the ASMFC instituted state shares of the Federal smoothhound shark quota. Although this system was finalized in May 2013 before the Federal smoothhound shark quota was effective, Addendum II proactively divided the quota among several of the Atlantic states in an amount that would total 100 percent of the Federal quota. This agreement among the Atlantic states to limit each state's harvest does not impact nor influence the Federal quota. Although NMFS recognizes that closing the fishery when landings reach, or are expected to reach, 80 percent of the quota could prevent some states from harvesting their full state share of the quota per the ASMFC plan, the measure is an important and effective way to ensure that the sustainability of the smoothhound shark fishery is not jeopardized by overharvests.

Comment 17: NMFS received a comment stating that NMFS should not implement the smoothhound retention allowance from the 2011 HMS Trawl Rule because the increased retention will lead to increased fishing mortality and this mortality will not be adequately quantified and counted against the quota. There are no reporting requirements with open access permits and fisheries tend to underreport incidental catches.

Response: Since January 1, 2013, all commercial landings of Atlantic HMS, regardless of gear type or permit, are required to be reported on a weekly basis. Through these weekly reports, NMFS monitors commercial landings of Atlantic HMS, which will include smoothhound sharks upon implementation of this action. Trawl gear and open access permits do not present unique reporting concerns. Allowing smoothhound sharks to be landed by fishermen who use trawl gear or possess an open access permit does not raise unique concerns about the sustainability of the fishery.

General Comments

Comment 18: NMFS received comments that Amendment 9 is too narrowly focused on smoothhound sharks and should instead consider all species managed under the 2006 Consolidated HMS FMP. The commenter asserts that a multispecies management approach is preferable. Furthermore, the commenter noted that NMFS' decision to include all HMS in a single, consolidated FMP effectively categorizes all HMS fisheries as a single ''fishery.'' Thus, all National Standards (NS) under the Magnuson-Stevens Act must be considered in the context of all HMS, not just smoothhound sharks and Atlantic sharks. Specifically, the commenter suggested that NS 3 (''To the extent practicable, an individual stock of fish shall be managed as a unit throughout its range, and interrelated stocks of fish shall be managed as a unit or in close coordination'') requires NMFS to optimize access and management of all HMS, not just smoothhound sharks and Atlantic sharks. Additionally, the commenter felt that NS 1, which mandates achieving optimum yield from each fishery, should be applied across all HMS since all HMS should be categorized as one single fishery.

Response: While a multispecies management approach is advantageous in some instances, NMFS disagrees that

Amendment 9 should broadly consider all HMS (including tunas, billfish, and swordfish) as a single fishery. In 2006, NMFS merged all Atlantic HMS management into a single, consolidated FMP. In the 2006 Consolidated Atlantic HMS FMP, NMFS noted that the interrelated nature of HMS fisheries and the need to consider management actions together necessitated merging the two existing HMS FMPs into one FMP. In addition, NMFS identified some adverse ramifications stemming from separation of the plans, including unnecessary administrative redundancy and complexity, loss of efficiency, and public confusion over the management process. It is important to note that NMFS consolidated management of all HMS under one FMP because of the interrelated nature of some of the fisheries and to streamline administration, not because all HMS constitute a single fishery. As appropriate, NMFS analyzes the impacts of management actions for each HMS fishery and optimizes management for all affected HMS fisheries. The Environmental Assessment appropriately considers any effects on the environment, including effects on other fish stocks or fisheries that may result from the actions in Amendment 9. The analyses show that the actions considered in Amendment 9 are unlikely to affect non-smoothhound shark fisheries or Atlantic shark fisheries. The management objectives are narrowly focused on smoothhound sharks, smooth dogfish, and/or Atlantic sharks caught in gillnet gear, the predominant gear type used in the directed smoothhound shark fishery. None of the fisheries considered in this action are likely to encounter other non-smoothhound shark or Atlantic shark in large numbers. Billfish, swordfish, tunas, and pelagic sharks are unlikely to co-occur with the smoothhound sharks nor can swordfish or tunas be retained if caught in gillnet gear. The one exception is the measure to establish an effective date for the 2011 HMS Trawl Rule. Trawl gear does have the potential to interact with a variety of HMS, including smoothhound sharks, Atlantic sharks, and swordfish. The 2011 HMS Trawl rule, recognizing the potential interaction between trawl gear and some HMS, considered an allowance for the limited retention of incidentally caught swordfish and smoothhound sharks. As such, that action considered impacts and explicitly optimized access to affected HMS. With respect to consistency with NS 1 and 3, each HMS management action considers all National Standards in the context of the affected HMS. For detailed information about Amendment 9's consistency with National Standards, please see Section 10 of the Final EA.

Changes From the Proposed Rule (79 FR 46217, August 7, 2014)

NMFS made several changes from the proposed rule, as described below.

1. *Catch Composition and ''No Other Sharks'' Requirements for Removing Smooth Dogfish Fins at Sea* (§ 635.30(c)(5)(iii)). The SCA has provisions related to the removal of smooth dogfish fins while at sea that apply when an individual is fishing ''for'' smooth dogfish. Thus, the proposed rule considered sub-alternatives to apply the exception only to those fishing with the object of commercially harvesting smooth dogfish by focusing on catch composition. This final rule is not implementing the preferred catch composition sub-alternative (75 percent of retained catch must be smooth dogfish), but another sub-alternative (25 percent smooth dogfish) that had been discussed in the proposed rule and analyzed in the draft EA.

NMFS received numerous public comments that the 75 percent catch composition requirement did not adequately reflect the mixed nature of the smooth dogfish fishery and would lead to excessive dead discards. Based on this public comment, NMFS reconsidered the 75 percent smooth dogfish requirement, and determined that it does not properly reflect fishing ''for'' smooth dogfish. According to public comment, fishermen that fish for smooth dogfish often encounter and retain other species of fish. NMFS verified this by evaluating data from vessel trip reports (VTR). On trips that landed smooth dogfish caught in sink gillnet gear between 2003 and 2014, smooth dogfish only made up 36 percent of the total retained catch while other species such as croaker, bluefish, monkfish, and spiny dogfish made up the remainder. *See* Final EA at Section 3.4.1 for further detail. If NMFS retained the 75 percent requirement, then this could result in dead discards as well as lost revenues from those species. The 25 percent requirement adopted in the final rule better reflects fishing ''for'' smooth dogfish, and is within the range of alternatives considered and analyzed in the proposed rule.

Related to the catch composition change and concern about discards, this final rule also makes a change from the proposed rule by allowing retention of other shark species provided that their fins remain naturally attached to the carcass through offloading. This measure is included based on public comment and additional analyses and recognizing that a prohibition on having other sharks on board would likely increase regulatory discards. Specifically, additional analyses indicate that the smooth dogfish fishery is more mixed than previously thought, and that other sharks, particularly spiny dogfish and common thresher sharks, make up a portion of the catch and revenue for fishermen also fishing for smooth dogfish. Given that fishermen process smooth dogfish as they are brought on board, including removing the fins where allowable, the proposed rule approach would have forced fishermen to choose whether to land smooth dogfish with the fins removed (and discard the other species) or land the other species of shark with the fins attached and discard the smooth dogfish with their fins removed at sea. As proposed, a fisherman who wanted to remove smooth dogfish fins at sea would not have been able to retain non-smooth dogfish sharks even if those sharks were dead and otherwise legally retainable based on species, size, and permits. In either situation, as proposed, dead discards would likely have increased given the mixed catches in the smooth dogfish fishery. Thus, other sharks will be allowed on board when smooth dogfish fins have been removed at sea as long as the fins of the non-smooth dogfish sharks remain naturally attached through offloading, as is currently required.

Allowing other sharks on board should not raise enforcement concerns or impact the conservation of non-smooth dogfish sharks because smooth dogfish carcasses can be readily differentiated from other shark carcasses by the presence of a pre-dorsal ridge. While other ''ridgeback sharks'' have an interdorsal ridge, smooth dogfish are the only shark species in the Atlantic that have a pre-dorsal ridge. We will work with the Office of Law Enforcement to ensure that they are aware of this identifying feature and will update outreach information for shark identification including relevant workshops as appropriate to make permitted shark fishermen and dealers aware of the distinction. NMFS will also continue to monitor all shark catches and discards and take additional action, if necessary to address non-compliance.

The changes in this final rule are consistent with the conservation and management objectives of the Magnuson-Stevens Act and Amendment 9 and the SCA. These changes will not impact the conservation of smooth dogfish or other sharks because landings of these species, regardless of catch

composition percentage, will be capped at or under the commercial quota through AMs and/or closures. These changes thus will not have an effect on the status of these stocks, nor are other adverse environmental impacts anticipated. They will also provide for a flexible, profitable, and sustainable smooth dogfish fishery.

2. *Atlantic and Gulf of Mexico Regional Commercial Smoothhound Shark Quotas* (§ 635.27(b)(1)(xi)). NMFS proposed a smoothhound shark quota equal to the maximum annual landings from 2004–2013 plus two standard deviations (1,739.9 mt dw) using commercial landings data in the absence of a stock assessment and methodology outlined in Amendment 3. At that time, NMFS anticipated that the SEDAR 39 stock assessment for smoothhound sharks would be completed in 2014. Consequently, the proposed rule discussed, and the draft EA analyzed, a quota alternative that would ''implement a TAC and smoothhound shark quota(s) consistent with the results of the 2014 smoothhound shark stock assessment if the results become available before publication of the final rule for this action.'' (*See* Alternative B4 in the Draft EA for Amendment 9). The proposed rule also stated that ''[t]he 2014 smoothhound shark stock assessment could separate one or more of the stocks into regional stocks between the Atlantic and Gulf of Mexico,'' and that for the purposes of the environmental analyses, ''NMFS assumes one overarching quota but these alternatives and analyses could apply to multiple regions as well.''

During the public comment period on the proposed rule and draft EA, commenters expressed concern about implementing a smoothhound shark commercial quota based on historical landings, and requested that NMFS wait for SEDAR 39 to be completed. Based on these comments, in this final rule, NMFS is implementing region-specific commercial quotas based on SEDAR 39. Specifically, this final rule establishes an overall TAC of 1,940.2 mt implemented as follows: An Atlantic regional smoothhound shark TAC of 1,430.6 mt dw with a commercial quota of 1,201.7 mt dw, and a Gulf of Mexico regional smoothhound shark TAC of 509.6 mt dw with a commercial quota of 336.4 mt dw. Although the TAC identified in the final rule is inclusive of sources of mortality other than a commercial quota (which is thus necessarily less than the TAC), the overall TAC in the final rule is only 201 mt more than the 1,739.9 mt dw commercial quota from the proposed rule. Thus, establishing a TAC of this level does not raise concerns about requiring additional environmental analyses or additional regulatory action, which may have been the case if the stock assessment had identified a significantly greater allowable TAC (and resultant commercial quota) than those anticipated and analyzed in the proposed rule. The proposed rule presented and analyzed an alternative that anticipated the stock assessment would determine that ''the commercial smoothhound shark quota should be set at approximately equal to or greater than 1,739.9 mt dw.'' As acknowledged in the EA, even with a higher quota, effort is likely to remain the same relative to current effort. Thus the ecological, economic and social impacts of quota establishing a quota greater than 1,739.9 mt would be within the range analyzed in the Draft EA. In the final rule, the combined regional commercial quotas (1,538.1 mt) are twelve percent less than the original proposed overall quota (1,739.9 mt) but higher than recent annual commercial landings. Both the commercial quotas and the overall TAC in this final rule are within the range of actions considered in the proposed rule and analyzed in the draft EA.

With regard to the regional quota approach, in the Draft EA, NMFS acknowledged that the stock could be split between two regions based on the SEDAR 39 stock assessments and that the analyses performed for one over-arching quota could apply to multiple regions. Based on information supplied during the Data Workshop for SEDAR 39, including tagging data, the stock assessment scientists decided to split smoothhound sharks into two regional stocks, with smooth dogfish in the Atlantic and smooth dogfish, Florida smoothhound, and Gulf smoothhound in the Gulf of Mexico. This regional split, however, does not affect the impact analyses detailed in the Draft EA under Alternative B4, scenario 4. As noted in Section 3.4 of the Draft EA and as confirmed in the SEDAR 39 stock assessments, the smoothhound shark fishery primarily occurs in the Mid-Atlantic region and is composed entirely of smooth dogfish catch. In the Gulf of Mexico region, only a very small, negligible, number of commercial landings occur and there is no commercial fishery. Thus, the Draft EA Alternative B4 quota analyses were informed entirely by data from the Atlantic region including catch location, price data, landings data, and fishery operations. If NMFS applied the single over-arching quota analyses to regional smoothhound shark quotas at the Draft stage, there would have been no information available for the Gulf of Mexico and, with no commercial fishery in that region, a finding of neutral impact. In the Atlantic region where the fishery is located, all impacts detailed in the Draft EA would apply because all data, including catch location, price data, landings data, and fishery operations, came from the Atlantic. Furthermore, the Atlantic smoothhound shark stock assessment would not have resulted in any new impacts because the assessment found current harvest levels and effort are sustainable with no changes required. In summary, the impact analyses detailed in the Draft EA under Alternative B4, scenario 4 are equally applicable to two regional quotas as to one over-arching quota. The changes in this final rule are consistent with the conservation and management objectives of the Magnuson-Stevens Act and Amendment 9 and based on the best scientific information available. Implementing TACs based on the stock assessment results would ensure continued sustainable harvest of smoothhound sharks in the Atlantic and Gulf of Mexico regions and increase the likelihood of maintaining healthy smoothhound shark stocks in both regions.

3. *Administrative changes* (§§ 635.2, 635.7(g)). NMFS is making minor clarifications to the drift and sink gillnet definitions at § 635.2 to indicate that drift gillnets typically are ''floating'' in the water column and that sink gillnets are fished on or near the ''ocean'' bottom and can have weights ''and/or'' anchors. Additionally, NMFS is changing the administrative processes by which vessels are selected for at-sea observer coverage at § 635.7(g). The changes were made, in part, based on consultation with the Northeast and Southeast Observer Programs so that smoothhound shark observer selection is consistent with both programs. The administrative changes to this section should not have any practical effect; rather, they will ensure that the selection processes currently in place may continue.

4. *Administrative Additions* (§ 635.19(d)). NMFS is adding language to § 635.19(d) to indicate that trawl gear is an authorized gear for the capture and retention of smoothhound sharks subject to the restrictions specified in § 635.24(a)(7). Regulatory text to authorize retention of smoothhound sharks caught in trawl gear was added to other sections of § 635, including § 635.24(a)(7), and was discussed in the proposed rule but was inadvertently omitted from this part of the regulatory text itself. No substantive changes will occur as a result.

Commercial Fishing Season Notification

Pursuant to the measures being implemented in this final rule, the 2016 base quotas for smoothhound sharks in the Atlantic and Gulf of Mexico regions would be 1,201.7 mt dw and 336.4 mt dw, respectively. The fishing season for the smoothhound shark fishery will open on January 1, 2016.

Classification

The AA has determined that this final rule is consistent with the 2006 Consolidated Atlantic HMS FMP and its amendments, the Magnuson-Stevens Act, and other applicable law.

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

A Final Regulatory Flexibility Analysis (FRFA) was prepared for this rule. The FRFA incorporates the Initial Regulatory Flexibility Analysis (IRFA), and a summary of the analyses completed to support the action. The full FRFA and analysis of economic and ecological impacts are available from NMFS (see **ADDRESSES**). A summary of the FRFA follows.

Section 604(a)(1) of the Regulatory Flexibility Act (RFA) requires a succinct statement of the need for and objectives of the rule. Chapter 1 of the Final EA and the final rule fully describe the need for and objectives of this final rule. The purpose of this final rulemaking, consistent with the Magnuson-Stevens Act, the ESA, and the MMPA, and the 2006 Consolidated HMS FMP and its amendments, is to provide for the sustainable management of smoothhound sharks and Atlantic shark species. The management objectives are to achieve the following: Implement the smooth dogfish-specific provisions of the SCA; implement smoothhound shark quotas based on the results of SEDAR 39; implement Term and Condition 4 of the 2012 Shark BiOp related to gillnet impacts on ESA-listed species; and revise Atlantic shark gillnet VMS regulations in compliance with the ALWTRP, per the MMPA.

Section 604(a)(2) of the RFA requires a summary of the significant issues raised by the public comments in response to the IRFA and a summary of the assessment of the Agency of such issues, and a statement of any changes made in the rule as a result of such comments. NMFS received many comments on the proposed rule and the Draft EA during the public comment period. A summary of these comments and the Agency's responses, including changes as a result of public comment, are included above. NMFS did not receive comments specifically on the IRFA.

Section 604(a)(4) of the RFA requires agencies to provide an estimate of the number of small entities to which the rule would apply. The small business size standard for Finfish Fishing is $ 20.5 million, for Shellfish Fishing is $5.5 million, and for Other Marine Fishing is $7.5 million. *See* 79 FR 33647 (June 24, 2014). Under any of these standards, all Atlantic HMS permit holders subject to this rulemaking would be considered small entities.

NMFS does not have exact numbers on affected commercial fishermen. The smoothhound shark commercial permit has not yet been established, so NMFS does not know how many smoothhound shark fishermen will be impacted. An annual average of 169 vessels reported retaining smooth dogfish through VTR from 2003–2014. This is NMFS' best estimate of affected smoothhound shark fishermen.

Additionally, while the retention of sharks in Federal waters requires one of two limited access commercial shark permits, these permits do not specific gear type, including gillnets. For this reason, NMFS does not know the exact number of affected shark gillnet fishermen. As of May 21, 2015, there are 208 directed shark and 253 incidental shark permit holders. Logbook records indicate that there are usually about 18 Atlantic shark directed permit holders that use gillnet gear in any year. However, the universe of directed permit holders using gillnet gear can change from year to year and could include anyone who holds an Atlantic shark directed permit.

As of May 21, 2015, there are 97 Atlantic shark dealers. These dealers could be affected by these measures to varying degrees. Not all of these dealers purchase smoothhound sharks and those that do are concentrated in the Mid-Atlantic region. NMFS will know more about the number of affected dealers when smoothhound reporting requirements become effective. Similarly, not all of these dealers purchase Atlantic sharks caught with gillnet gear. The number is likely low and is concentrated in Florida and the Gulf of Mexico.

Section 604(a)(5) of the RFA requires Agencies to describe any new reporting, record-keeping and other compliance requirements. The Federal commercial smoothhound shark permit requirement analyzed in Amendment 3 will become effective upon the effective date of this rule. NMFS submitted a PRA change request to The Office of Management and Budget (OMB) to add this permit to the existing HMS permit PRA package (OMB control number 0648–0327). OMB subsequently approved the change request to add the Federal commercial smoothhound shark permit to the HMS permit PRA package in May 2011. In November 2015, NMFS submitted a revision to transfer the previously approved commercial smoothhound shark permit from the HMS permit PRA package (OMB Control Number 0648–0327) to the Southeast Regional Office (SERO) permit PRA package (OMB Control Number 0648–0205). That request is still pending approval. Once OMB approves the request, NMFS will issue a notice in the **Federal Register** announcing the approval of the information collection requirements and the availability of applications for the commercial smoothhound shark permit. This final rule contains a collection-of-information requirement subject to the Paperwork Reduction Act (PRA) and which has been approved by OMB under OMB Control number 0648–0372. Public reporting burden will be reduced under the modified VMS requirements under this final rule. The burden estimate burden will be reduced by this rule, but the changes will be requested as part of the 2016 extension, at which time the estimate of the burden change will be more accurate.

The RFA requires a description of the steps the Agency has taken to minimize any significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and the reason that each one of the other significant alternatives to the rule considered by the Agency that affect small entities was rejected. These impacts are discussed below and in the FRFA for Amendment 9. Additionally, the RFA (5 U.S.C. 603 (c)(1)–(4)) lists four general categories of ''significant'' alternatives that could assist an agency in the development of significant alternatives. These categories of alternatives are: Establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; use of performance rather than design standards; and, exemptions from coverage of the rule for small entities.

In order to meet the objectives of this rule, consistent with Magnuson-Stevens Act and ESA, we cannot exempt small entities or change the reporting requirements only for small entities because all the entities affected are

considered small entities. Thus, there are no alternatives discussed that fall under the first and fourth categories described above. NMFS does not know of any performance or design standards that would satisfy the aforementioned objectives of this rulemaking while, concurrently, complying with the Magnuson-Stevens Act. Thus, there are no alternatives considered under the third category. As described below, NMFS analyzed several different alternatives in this rulemaking and provided the rationale for identifying the preferred alternative to achieve the desired objective.

The alternatives considered and analyzed are described below. The FRFA assumes that each vessel will have similar catch and gross revenues to show the relative impact of the final action on vessels.

Alternatives To Implement the Smooth Dogfish-Specific Provisions of the Shark Conservation Act of 2010

With regard to the implementation of the SCA, NMFS considered two alternatives. Alternative A1, which would not implement the smooth dogfish-specific provisions of the SCA and would instead implement the fins-attached requirement finalized in Amendment 3, and Alternative A2, which would implement the smooth dogfish-specific provisions of the SCA and has sub-alternatives that address the specific elements of the of the smooth dogfish-specific provisions.

Alternative A1 would not implement the smooth dogfish-specific provisions of the SCA and would require all smooth dogfish to be landed with fins naturally attached. This alternative would change current fishing practices since smooth dogfish caught in the directed and incidental fisheries are fully processed while at sea. As a result, this Alternative A1 would likely lead to reduced landings and a lower ex-vessel price because the product would not be fully processed. This could lead to adverse socioeconomic impacts.

Under Alternative A2, the preferred alternative, an allowance for the removal of smooth dogfish fins at sea would increase efficiency in the smooth dogfish fishery and provide a more highly processed product for fishermen to sell to dealers. Quantifying the financial benefits is difficult because baseline effort and increases in efficiency cannot be calculated, but the benefit would fall somewhere between the two extremes of $0 and $699,364, the ex-vessel value of the entire fishery (Section 3.6.2). Assuming that amount is spread evenly across all 169 vessels per year that retain smooth dogfish (Section 6.1), the benefit to individual vessels would be $4,138. However, vessels and trips retain smooth dogfish in widely varying amounts, thus, this per vessel estimate may not provide an accurate picture of individual revenues.

Supporting entities, such as bait and tackle suppliers, ice suppliers, dealers, and other similar businesses, could experience increased revenue if the efficiency of fin removal at sea results in a higher quality product. However, while supporting businesses would benefit from the increased profitability of the fishery, they do not solely rely on the smooth dogfish fishery. In the long-term, it is likely that changes in the smooth dogfish fishery would not have large impacts on these businesses.

Catch Composition Sub-Alternatives

Under Sub-Alternative A2–1a, smooth dogfish could make up any portion of the retained catch on board provided that no other sharks are retained. This sub-alternative would authorize smooth dogfish fishermen to retain any non-shark species of fish while still availing themselves of the at-sea fin removal allowance. Smooth dogfish are often caught incidentally during other fishing operations, thus, this sub-alternative would allow fishermen to maximize the profitability of each trip and allow individual operators the flexibility to make decisions, before the trip and while on the water, as to the retained catch composition that would maximize ex-vessel revenues. Under this alternative, fishermen could remove smooth dogfish fins at sea during any type of trip including those trips that are directing effort on other non-shark species. This alternative would maintain the current practice in the fishery and vessels could continue to have ex-vessel revenues of $699,364 per year across the entire fishery (Section 3.6.2).

Under Sub-Alternative A2–1b, fishermen could avail themselves of the at-sea fin removal allowance only if smooth dogfish comprise 25 percent of the retained catch on board. This sub-alternative would authorize smooth dogfish fishermen to retain some non-shark species of fish while still availing themselves of the at-sea fin removal allowance. This sub-alternative would allow some fishermen to maintain the profitability of each trip and allow individual operators some flexibility to make decisions, before the trip and while on the water, as to the retained catch composition that would increase ex-vessel revenues. This increase in flexibility would be to a lesser extent than Sub-Alternative A2–1a which would not have a catch composition requirement, but greater than the other sub-alternatives that limit the fins-attached exception to higher catch composition percentages. This sub-alternative would decrease total ex-vessel revenues relative to the current level of $699,364 per year (Section 3.6.2).

Under Sub-Alternative A2–1c fishermen could avail themselves of the at-sea fin removal allowance only if smooth dogfish comprise 75 percent of the retained catch on board. This sub-alternative would allow fishermen limited flexibility to maintain the profitability of each trip and would allow fishermen to make decisions, before the trip and while on the water, as to the retained catch composition that would increase ex-vessel revenues. While limited, the flexibility in this alternative would be greater than in sub-alternative A2–1d, which would require smooth dogfish catch composition of 100 percent. Because some fishermen catch smooth dogfish along with other species, this sub-alternative could decrease the number of mixed species trips where fishermen could take advantage of the at-sea fin removal allowance. This sub-alternative would likely decrease total ex-vessel revenues relative to the current level of $699,364 per year.

Sub-Alternative A2–1d would require smooth dogfish to comprise 100 percent of the retained catch on board the vessel in order for fishermen to avail themselves of the at-sea fin removal allowance for smooth dogfish. This sub-alternative would eliminate the ability of mixed trips to take advantage of the at-sea fin removal, and would reduce flexibility in deciding which species to retain on each fishing trip. However, approximately 31 vessels (annual average 2003–2014) on directed smooth dogfish trips often only retain smooth dogfish due to the processing practices in place. Thus, these fishermen would not be impacted by a 100 percent smooth dogfish requirement and would benefit from the ability to remove the smooth dogfish fins at sea. This sub-alternative would likely decrease total ex-vessel revenues relative to the current level of $699,364 per year.

Sub-Alternative A2–1e, the preferred sub-alternative, would, similar to Sub-Alternative A2–1b, allow fishermen to avail themselves of the at-sea fin removal allowance only if smooth dogfish comprise 25 percent of the retained catch on board. However, under Sub-Alternative A2–1e, other sharks could be retained as well, provided they are maintained with the fins naturally attached to the carcass. This sub-alternative would allow some

fishermen to maintain the profitability of each trip and allow individual operators some flexibility to make decisions, before the trip and while on the water, as to the retained catch composition that would increase ex-vessel revenues. This increase in flexibility would be to a lesser extent than Sub-Alternative A2–1a, which would not have a catch composition requirement, but greater than the other sub-alternatives that limit the fins-attached exception to higher catch composition percentages. This sub-alternative would decrease total ex-vessel revenues relative to the current level of $699,364 per year (Section 3.6.2).

State Fishing Permit Requirement Sub-Alternatives

Sub-Alternative A2–2a would require federal smoothhound permitted fishermen to obtain a smooth dogfish-specific state commercial fishing license in order to be able to remove smooth dogfish fins at sea. The requirement to obtain a smooth dogfish-specific state commercial fishing license may be more difficult for fishermen who are in states that do not have smooth dogfish-specific permits in place. This sub-alternative would result in the increased burden on fishermen to obtain another permit, and depending upon the state, could result in an additional permit charge. Since most permits are valid for one year, fishermen would likely need to renew the permit each year for as long as they wish to retain smooth dogfish and remove the fins while at sea. Because not all states have smooth dogfish-specific permits, NMFS does not prefer this alternative.

Sub-Alternative A2–2b, the preferred alternative, would require fishermen to hold any state commercial fishing permit that allows retention of smooth dogfish. It is likely, however, that most smooth dogfish fishermen already hold this type of state permit and would be unaffected by this requirement. This sub-alternative would likely be the most straightforward for regulatory compliance because the permit requirement would be the simpler than sub-alternative A2–2a. Thus, NMFS prefers this sub-alternative.

Geographic Applicability of Exception Sub-Alternatives

NMFS considered two alternatives for Geographic Application of the SCA exception. Under Sub-Alternative A2–3a, the exception would apply along the Atlantic Coast and the Florida west coast in the Gulf of Mexico. As explained earlier, as a practical matter, smooth dogfish and other smoothhound species are indistinguishable, although smoothhound are distinguishable from other ridgeback sharks by the presence of a pre-dorsal ridge. The best available scientific information indicates that smooth dogfish are likely the only smoothhound shark species along the Atlantic coast. In the Gulf of Mexico, however, there are at least three different smoothhound species, with no practical way to distinguish among them. This sub-alternative would apply the smooth dogfish exception 50 nautical miles from the baseline of all the States that fall under the SCA definition of ''State.'' This sub-alternative could result in other smoothhound sharks indirectly falling under the exception, because they cannot be distinguished from smooth dogfish. NMFS does not expect any impacts because there is no commercial fishery for smooth dogfish in the Gulf of Mexico at this time. However, NMFS does not prefer this sub-alternative because, if a fishery does develop, species misidentification could result in enforcement action.

Under Sub-Alternative 3b, the preferred sub-alternative, the exception would only apply along the Atlantic coast and not the Florida west coast in the Gulf of Mexico. By not extending the exception into the Gulf of Mexico, this sub-alternative would ensure that the SCA's exception to the fins-attached requirements for smooth dogfish would only apply along the Atlantic Coast where the population is almost entirely smooth dogfish, reducing identification problems and inadvertent finning violations. NMFS does not expect any impacts because, at this time, there is no commercial fishery for smooth dogfish in the Gulf of Mexico. NMFS prefers this sub-alternative because it simplifies enforcement and compliance without adverse impacts. This sub-alternative would not affect total ex-vessel revenues relative to the current level of $699,364 per year.

Smoothhound Shark Commercial Quotas

With regard to the smoothhound quota alternatives, NMFS considered four alternatives. Alternative B1, which would implement the smoothhound shark quota finalized in Amendment 3; Alternative B2, which would establish a rolling quota based on the most recent five years of landings data; Alternative B3, which would calculate the smoothhound quota using the same method as in Amendment 3 but would use updated smoothhound landings information; and Alternative B4, which would establish smoothhound shark quotas that reflects the results of the SEDAR 39 smoothhound shark stock assessments.

Alternative B1 would implement the quota finalized in Amendment 3 (715.5 mt dw), which was based on highest annual landings from (1998 to 2007) and adding two standard deviations. Current reported smoothhound shark landings are higher than the quota level in Alternative B1. As such, implementing this quota would prevent fishermen from fishing at current levels, resulting in lost revenues. In 2010 when landings peaked, total smoothhound shark landings totaled 2,688,249 lb dw (ACCSP data) resulting in ex-vessel revenues across the entire smoothhound sink gillnet fishery of $2,458,135 (2,688,249 lb of meat, 322,590 lb of fins). Implementation of the Amendment 3 quota (715.5 mt dw) would result in ex-vessel revenues of only $1,442,367 (1,577,391 lb of meat, 189,287 lb of fins), which is $1,015,768 less than current ex-vessel revenues. Both of these estimates assume $1.62/lb for fins, $0.72/lb for meat, and a 12 percent fin-to-carcass ratio (prices based on 2014 dealer data and fin-to-carcass ratio based on the SCA). Seventy-five percent of all landings in the smoothhound shark fishery come from sink gillnets and there are approximately 77 vessels that use sink gillnet gear to fish for smoothhound sharks in any given year. Assuming an average of 77 sink gillnet vessels fishing for smoothhound sharks, the quota in this alternative would result in annual ex-vessel revenues of $18,732 per vessel which is less than 2010 ex-vessel revenues of $31,923 per vessel. This is an average across all directed and incidental sink gillnet vessels and this individual annual vessel ex-vessel revenue may fluctuate based on the degree to which fishermen direct on smoothhound sharks.

The quota in Alternative B1 does not accurately characterize current reported landings of smoothhound sharks. Vessels that fish for smoothhound sharks likely fished opportunistically on multiple species of coastal migratory fish and elasmobranches, and it is unlikely that any sector within the fishing industry in the Northeast (fisherman, dealer, or processor) relies wholly upon smoothhound sharks. Longer-term impacts are expected to be neutral given the small size of the fishery and the generalist nature of the sink gillnet fishery.

Alternative B2 would establish a rolling smoothhound shark quota set above the maximum annual landings for the preceding five years; this quota would be recalculated annually to account for the most recent landing

trends within the smoothhound complex (2016 quota would be 1,729 mt dw based on 2010–2014 data). The 2016 quota under this alternative is likely to result in annual revenues of $3,485,466 (3,811,753 lb of meat, 457,410 lb of fins) assuming an ex-vessel price of $1.62 lb for fins and $0.72 lb for meat. Seventy-five percent of all landings in the smoothhound shark fishery come from sink gillnets and there are approximately 77 vessels that use sink gillnet gear to fish for smoothhound sharks. Assuming an average of 77 sink gillnet vessels fishing for smoothhound sharks, the quota in this alternative would result in individual vessel annual revenues of $45,266 which is more than 2010 ex-vessel revenues of $31,923 per vessel. This is an average across all sink gillnet vessels, regardless of catch levels, and this individual annual vessel revenue may fluctuate based on the degree to which fishermen direct on smoothhound sharks.

Setting the quota above current landings levels should allow the fishery to continue, rather than be closed, allowing for NMFS to collect more information that can be used in future stock assessments. Alternative B2 is consistent with the intent of Amendment 3, which was to minimize changes to the fishery while information on catch and participants was collected. Because landings in the smoothhound shark fishery are likely underreported, it is unclear at this time whether the increase in reported landings is due to existing smoothhound fishermen reporting in anticipation of future management or increased effort (*e.g.*, new entrants into the fishery). While a rolling quota would cover all current reporting and likely cover all underreporting of landings, the fishery could grow exponentially if reported landings continue to increase over consecutive years, possibly resulting in stock declines and in turn a potential loss of revenue to the fishing industry. The rolling quota could also lead to lower quotas in consecutive years if landings decrease over time. Thus, the changing nature of the rolling quota could lead to uncertainty in the fishery and could cause direct and indirect minor adverse socioeconomic impacts in the long term.

Alternative B3 would create a smoothhound quota equal to the maximum annual landings from 2005–2014 plus two standard deviations and would equal 1,733.9 mt dw. This alternative would establish a smoothhound quota two standard deviations above the maximum annual landings reported over the last ten years which is the method used to calculate the smoothhound shark quota that was finalized in Amendment 3. This quota would result in potential annual revenues in the entire fishery of $3,495,345 (3,822,556 lb of meat, 458,707 lb of fins) assuming an ex-vessel price of $1.62 lb for fins and $0.72 for meat. Seventy-five percent of all landings in the smoothhound shark fishery come from sink gillnets and there are approximately 77 vessels that use sink gillnet gear to fish for smoothhound sharks. Assuming an average of 77 sink gillnet vessels fishing for smoothhound sharks, the quota proposed in this alternative would result in individual vessel annual revenues of $45,394. This is an average across all sink gillnet vessels, regardless of catch levels, and this individual annual vessel revenue may fluctuate based on the degree to which fishermen direct on smoothhound sharks.

At the time of publication for the Draft EA, the SEDAR 39 smoothhound stock assessments were underway, but not yet complete. In anticipation that the final stock assessments could be finalized before this final rule, NMFS considered a range of scenarios under Alternative B4 to implement potential results and scenarios, recognizing that results beyond the scope of those analyzed could require additional analysis or regulatory action. The SEDAR 39 stock assessment is now final; thus, the scenarios considered in the Draft EA are no longer appropriate to consider. Rather, NMFS has analyzed the actual results of the stock assessments, which would establish an Atlantic smoothhound commercial quota of 1,201.7 mt dw and a Gulf of Mexico smoothhound shark quota of 336.4 mt dw. These quotas would result in annual revenues of $2,422,251.54 (2,649,006 lb of meat, 317,881 lb fins), assuming an ex-vessel price of $1.62 lb for fins and $0.72 lb for meat. Seventy-five percent of all landings in the smoothhound shark fishery come from sink gillnets and there are approximately 77 vessels that use sink gillnet gear to fish for smoothhound sharks. Assuming an average of 77 sink gillnet vessels fishing for smoothhound sharks, the quota in this alternative would result in individual vessel annual revenues of $31,458. This is an average across all sink gillnet vessels, regardless of catch levels, and this individual annual vessel revenue may fluctuate based on the degree to which fishermen direct on smoothhound sharks. The quotas under Alternative B4 are both consistent with the intent of Amendment 3, which was to minimize changes to the fishery while information on catch and participants was collected, while also implementing science-based quotas to ensure continued sustainable harvest of smoothhound sharks in the Atlantic and Gulf of Mexico regions. NMFS anticipates short-term, direct minor beneficial socioeconomic impacts under this alternative given the combined commercial quotas for the Atlantic and Gulf of Mexico regions under this alternative would result in increased revenues compared to the commercial quota under Alternative B1, though lower than those anticipated under Alternatives B2 or B3. These commercial quotas would allow the fishery to continue at the rate and level observed in recent years into the future without having to be shut down prematurely. Given that the fishery would expect to operate as it currently does, NMFS anticipates in the short term, indirect, minor, positive socioeconomic impacts for shark dealers and processor. Since this alternative establishes scientifically-based quotas and would result in beneficial socioeconomic impacts, NMFS prefers this alternative.

Biological Opinion Implementation

In order to implement TC 4 of the 2012 Shark BiOp in the smoothhound shark fishery, NMFS considered 4 alternatives. The No Action alternative, which would not implement TC 4 of the 2012 Shark BiOp; alternative C2, which would require smoothhound shark fishermen to conduct net checks at least every 2 hours; alternative C3, which would require smoothhound shark fishermen to limit their gillnet soak time to 24 hours and those smoothhound shark fishermen that also have a Atlantic shark limited access permit to check their nets at least every 2 hours; and finally, Alternative C4, which would require smoothhound and Atlantic shark fishermen using sink gillnet to soak their nets no longer than 24 hours and those fishermen using drift gillnets to check their nets at least every 2 hours.

Alternative C1 would not implement the BiOp term and condition that would require all smoothhound shark permit holders to either check their gillnet gear at least every 2.0 hours or limit their soak time to no more than 24 hours. This alternative would likely result in short and long-term neutral direct socioeconomic impacts. Under Alternative C1, smoothhound shark fishermen would continue to fish as they do now and so this alternative would not have economic impacts that differ from the status quo. Similarly, this alternative would likely result in neutral short and long-term indirect

socioeconomic impacts since supporting businesses including dealers and bait, tackle, and ice suppliers would not be impacted.

Alternative C2 would require smoothhound shark fishermen using gillnet gear to conduct net checks at least every 2.0 hours to check for and remove any protected species, and would likely result in short and long-term direct moderate adverse socioeconomic impacts. Some smoothhound shark gillnet fishermen fish multiple nets at one time or deploy their net(s), leave the vicinity, and return later. Alternative C2 would require these fishermen to check each gillnet at least once every 2 hours, making fishing with multiple nets or leaving nets unattended difficult. This would likely lead to a reduction in effort and landing levels, resulting in lower ex-vessel revenues. Quantifying the loss of income is difficult without information characterizing the fishery including the number of nets fished. However, limiting the amount of fishing effort in this manner is likely to reduce total landings of smoothhound sharks or, in order to keep landing levels high, extend the length of trips. Landings of incidentally caught fish species could be reduced as well, although under preferred Sub-Alternative A2–1c, smoothhound shark fishermen that wish to remove smooth dogfish fins at sea could not retain other species. This alternative would not have a large impact on supporting businesses such as dealers or bait, tackle, and ice suppliers since these businesses do not solely rely on the smoothhound shark fishery. The smoothhound shark fishery is small relative to other fisheries. Thus, Alternative C2 would likely result in short and long-term indirect neutral socioeconomic impacts. Alternative C2 would impact the approximately 77 vessels that annually catch smoothhound sharks with gillnet gear (annual average from 2003–2014, Table 3.1).

Alternative C3 would establish a gillnet soak time limit of 24 hours for smoothhound shark permit holders. Under this alternative, fishermen holding both an Atlantic shark limited access permit and a smoothhound shark permit must abide by the 24 hour soak time restriction and conduct net checks at least every 2 hours. This alternative would likely result in short- and long-term direct minor adverse socioeconomic impacts to those smoothhound permitted fishermen that also have an Atlantic shark limited access permit and therefore would be required to check their nets at least every 2 hours. Currently, smoothhound shark gillnet fishermen sometimes fish multiple nets or leave nets unattended for short periods of time. Rarely are these nets soaked for more than 24 hours, thus, this alternative would not impact smoothhound shark gillnet fishermen that do not have an Atlantic shark limited access permit. Adverse socioeconomic impacts resulting from this alternative would likely occur to the subset of smoothhound shark fishermen that also hold an Atlantic shark limited access permit. These smoothhound shark fishermen would be at a disadvantage to other smoothhound shark fishermen that do not have an Atlantic shark limited access permit because they would be required to check their gillnets at least every 2 hours which is a large change in the way the smoothhound shark fishery currently operates. Dropping the Atlantic shark permit to avoid the net check requirement is unlikely to be feasible because Atlantic shark permits allow limited access (NMFS is no longer issuing new permits) and cannot be easily obtained. Additionally, pelagic longline fishermen are required to have an incidental or directed shark permit when targeting swordfish or tunas, even if they are not fishing for sharks, due to the likelihood of incidental shark catch. In practical terms, this could result in smoothhound shark gillnet fishermen abiding by the 2 hour net check requirement even if they do not fish for Atlantic sharks and only hold a Atlantic shark limited access permit to fish for swordfish or tunas (note that gillnets cannot be used to target swordfish or tunas, but some vessels may switch gears between trips). For this subset of fishermen, basing gillnet requirements on permit types could introduce fishing inefficiencies when compared to other smoothhound fishermen, likely resulting in adverse socioeconomic impacts to these fishermen. It is unlikely that this alternative would have a large impact on supporting businesses such as dealers or bait, tackle, and ice suppliers since these businesses do not solely rely on the smoothhound shark fishery. The smoothhound shark fishery is small relative to other fisheries. It is difficult to determine the number of fishermen that would be adversely affected because NMFS does not yet know which vessels will obtain a smoothhound shark fishing permit. However, it is likely that this number will be approximately equal to 169 which is the average annual number of vessel that retain smoothhound sharks (Section 3.4).

Alternative C4, the preferred alternative, would establish a soak time limit of 24 hours for fishermen using sink gillnet gear and a 2 hour net check requirement for fishermen using drift gillnet gear in the Atlantic shark and smoothhound shark fisheries. Drift gillnets would be defined as those that are unattached to the ocean bottom with a float line at the surface and sink gillnet gear would be defined as those with a weight line that sinks to the ocean bottom, has a submerged float line, and is designed to be fished on or near the bottom. Alternative C4 would likely result in neutral short and long-term direct socioeconomic impacts. Smoothhound shark fishermen, who typically use sink gillnets, would be required to limit soak times to 24 hours and as discussed above, this requirement is unlikely to significantly alter smoothhound shark fishing practices. Drift gillnet fishermen, who are more likely to target Atlantic sharks rather than smoothhound sharks, would be required to check their nets at least every 2 hours, as is currently required. Thus, this alternative is unlikely to have any socioeconomic impacts to Atlantic shark and smoothhound shark fishermen because it would not change current fishing practices. Similarly, this alternative would likely result in neutral short and long-term indirect socioeconomic impacts because supporting businesses including dealers and bait, tackle, and ice suppliers should not be impacted. Alternative C4 would impact the approximately 77 vessels that annually catch smoothhound sharks with gillnet gear (annual average from 2003–2014, Table 3.1). Because Alternative C4 would have minimal economic impact but is still consistent with the 2012 Shark BiOp, NMFS prefers this alternative.

Atlantic Shark Gillnet Vessel Monitoring System Requirements

NMFS also considered two alternatives to streamline the current VMS requirements for Atlantic shark fishermen with gillnet gear on board. The No Action alternative would maintain the current requirement to have VMS on board when fishing for Atlantic sharks with gillnet regardless of where the vessel is fishing and alternative D2 would require VMS on board only for Atlantic shark fishermen using gillnet gear in an area specified by the ALWTRP requirements at 50 CFR 229.32.

Alternative D1 would maintain the current requirement of requiring Atlantic shark permit holders fishing with gillnet gear to have VMS on board, regardless of where the vessel is fishing.

These VMS requirements were put in place as an enforcement tool for complying with the ALWTRP requirements set forth in 50 CFR 229.32. Atlantic shark gillnet fishermen are only required to have VMS if they are fishing in the Southeast U.S. Monitoring Area. See 50 CFR 229.32(h)(2)(i). Purchasing and installing a VMS unit costs approximately $3,500, and monthly data transmission charges cost, on average, approximately $44.00. Because these monthly costs are currently incurred whenever a shark gillnet fishermen is fishing, these costs can affect the fishermen's annual revenues. Although the affected fishermen already have VMS installed, they continue to pay for transmission and maintenance costs, and could need to buy a new unit if theirs fails. It is possible that a NMFS VMS reimbursement program could defray part of the purchase cost, but is not certain. Thus, it is likely that this alternative could have short and long-term direct minor adverse socioeconomic impacts to fishermen due to the cost of purchasing and maintaining a VMS unit. While the retention of sharks in federal waters requires one of two limited access commercial shark permits, these permits do not specify gear type, including gillnets. For this reason, NMFS does not know the exact number of affected shark gillnet fishermen. As of October 11, 2014, there are 206 directed shark and 258 incidental shark permit holders. Logbook records indicate that there are usually about 18 Atlantic shark directed permit holders that use gillnet gear in any year. However, the universe of directed permit holders using gillnet gear can change from year to year and could include anyone who holds an Atlantic shark directed permit.

Alternative D2, the preferred alternative, would change the gillnet VMS requirements and would require federal directed shark permit holders with gillnet gear on board to use VMS only in the vicinity of the Southeast U.S. Monitoring Area, pursuant to ALWTRP requirements, and would have short and long-term direct minor beneficial socioeconomic impacts. Atlantic shark gillnet fishermen fishing in the vicinity of the Southeast U.S. Monitoring Area would still incur the installation costs of the VMS, but data transmission would be limited to those times when the vessel is in this area. Furthermore, shark gillnet fishermen outside of this area that do not fish in the vicinity of the Southeast U.S. Monitoring Area would not need to install a VMS unit or, if they already have one, maintain the VMS unit or replace a malfunctioning one. Thus, the socioeconomic impacts from this alternative, while still adverse, are of a lesser degree than those under Alternative D1, the No Action alternative. This alternative would likely result in neutral short and long-term indirect socioeconomic impacts because supporting businesses, including dealers and bait, tackle, and ice suppliers, would not be impacted. While the retention of sharks in federal waters requires one of two limited access commercial shark permits, these permits do not specify gear type, including gillnets. For this reason, NMFS does not know the exact number of shark gillnet fishermen that would be affected by this alternative. As of October 11, 2014, there are 206 directed shark and 258 incidental shark permit holders. Logbook records indicate that there are usually about 18 Atlantic shark directed permit holders that use gillnet gear in any year. However, the universe of directed permit holders using gillnet gear can change from year to year and could include anyone who holds an Atlantic shark directed permit. Because this alternative is more in line with the requirements of the ALWTRP, and because it would reduce socioeconomic impacts while still maintaining beneficial ecological impacts for protected whale species, NMFS prefers this alternative.

This final rule contains a collection-of-information requirement subject to the Paperwork Reduction Act (PRA) and which has been approved by OMB under control number 0648–0372. Public reporting burden will be reduced under the modified VMS requirements under this final rule. The burden estimate burden will be reduced by this rule, but the changes will be requested as part of the 2016 extension, at which time the estimate of the burden change will be more accurate.

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, a letter to permit holders that also serves as small entity compliance guide (the guide) was prepared. Copies of this final rule are available from the HMS Management Division (see **ADDRESSES**) and the guide (*i.e.,* permit holder letter) will be sent to all holders of permits for the Atlantic shark and smoothhound shark commercial fisheries. The guide and this final rule will be available upon request.

List of Subjects in 50 CFR Part 635

Fisheries, Fishing, Fishing vessels, Foreign relations, Imports, Penalties, Reporting and recordkeeping requirements, Treaties.

Dated: November 12, 2015.

Samuel D. Rauch III,

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

For reasons set out in the preamble, 50 CFR part 635 is amended as follows:

PART 635—ATLANTIC HIGHLY MIGRATORY SPECIES

■ 1. The authority citation for part 635 continues to read as follows:

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

■ 2. In § 635.2, add definitions for ''Atlantic States,'' ''Drift gillnet,'' ''Sink gillnet,'' and ''Smoothhound shark(s)'' in alphabetical order to read as follows:

§ 635.2 Definitions.

* * * * *

Atlantic States, consistent with section 803 of Public law 103–206 (16 U.S.C. 5102), refers to Maine, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Pennsylvania, Delaware, Maryland, Virginia, North Carolina, South Carolina, Georgia, Florida, the District of Columbia, and the Potomac River Fisheries Commission, for purposes of applying the Shark Conservation Act exception at 50 CFR 635.30(c)(5).

* * * * *

Drift gillnet means a gillnet that is floating unattached to the ocean bottom and not anchored, secured, or weighted to the ocean bottom.

* * * * *

Sink gillnet means a gillnet that is designed to be or is fished on or near the ocean bottom in the lower third of the water column by means of a weight line or enough weights and/or anchors that the bottom of the gillnet sinks to, on, or near the ocean bottom.

* * * * *

Smoothhound shark(s) means one of the species, or part thereof, listed in section E of Table 1 in Appendix A to this part.

* * * * *

■ 3. In § 635.4, add paragraph (e)(4) and revise paragraph (m)(2) to read as follows:

§ 635.4 Permits and fees.

* * * * *

(e) * * *

(4) Owners of vessels that fish for, take, retain, or possess the Atlantic oceanic sharks listed in section E of Table 1 of Appendix A to this part with an intention to sell them must obtain a Federal commercial smoothhound permit. In addition to other permits issued pursuant to this section or other authorities, a Federal commercial smoothhound permit may be issued to a vessel alone or to a vessel that also holds either a Federal Atlantic commercial shark directed or incidental limited access permit.

* * * * *

(m) * * *

(2) *Shark and swordfish permits.* A vessel owner must obtain the applicable limited access permit(s) issued pursuant to the requirements in paragraphs (e) and (f) of this section and/or a Federal commercial smoothhound permit issued under paragraph (e) of this section; or an HMS Commercial Caribbean Small Boat permit issued under paragraph (o) of this section, if: The vessel is used to fish for or take sharks commercially from the management unit; sharks from the management unit are retained or possessed on the vessel with an intention to sell; or sharks from the management unit are sold from the vessel. A vessel owner must obtain the applicable limited access permit(s) issued pursuant to the requirements in paragraphs (e) and (f) of this section, a Swordfish General Commercial permit issued under paragraph (f) of this section, an Incidental HMS Squid Trawl permit issued under paragraph (n) of this section, an HMS Commercial Caribbean Small Boat permit issued under paragraph (o) of this section, or an HMS Charter/Headboat permit issued under paragraph (b) of this section, which authorizes a Charter/Headboat to fish commercially for swordfish on a non for-hire trip subject to the retention limits at § 635.24(b)(4) if: The vessel is used to fish for or take swordfish commercially from the management unit; swordfish from the management unit are retained or possessed on the vessel with an intention to sell; or swordfish from the management unit are sold from the vessel. The commercial retention and sale of swordfish from vessels issued an HMS Charter/Headboat permit is permissible only when the vessel is on a non for-hire trip. Only persons holding non-expired shark and swordfish limited access permit(s) in the preceding year are eligible to renew those limited access permit(s). Transferors may not renew limited access permits that have been transferred according to the procedures in paragraph (l) of this section.

* * * * *

■ 4. Revise § 635.7 to read as follows:

§ 635.7 At-sea observer coverage.

(a) *Applicability.* NMFS may select for at-sea observer coverage any vessel that has an Atlantic HMS, tunas, shark, or swordfish permit issued under § 635.4 or § 635.32. When selected, vessels are required to take observers on a mandatory basis. Vessels permitted in the HMS Charter/Headboat and Angling categories may be requested to take observers on a voluntary basis.

(b) *Selection of vessels.* NMFS will notify a vessel owner, in writing, by email, by phone, or in person when his or her vessel is selected for observer coverage. Vessels will be selected to provide information on catch, bycatch and other fishery data according to the need for representative samples.

(c) *Notification of trips.* If selected to carry an observer, it is the responsibility of the vessel owner to arrange for and facilitate observer placement. The owner or operator of a vessel that is selected under paragraph (b) of this section must notify NMFS, at an address or by phone at a number designated by NMFS, before commencing any fishing trip that may result in the incidental catch or harvest of Atlantic HMS. Notification procedures and information requirements will be specified in a selection letter sent by NMFS.

(d) *Assignment of observers.* Once a selected vessel notifies NMFS or its designee, NMFS will assign an observer for that trip based on current information needs relative to the expected catch and bycatch likely to be associated with the indicated gear deployment, trip duration and fishing area. If an observer is not assigned for a fishing trip, NMFS, or their designated observer service provider, will issue a waiver for that trip to the owner or operator of the selected vessel, so long as the waiver is consistent with other applicable laws. If an observer is assigned for a trip, the operator of the selected vessel must arrange to embark the observer and shall not fish for or retain any Atlantic HMS unless the NMFS-assigned observer is aboard.

(e) *Requirements.* The owner or operator of a vessel on which a NMFS-approved observer is embarked, regardless of whether required to carry the observer, must comply with safety regulations in § 600.725 and § 600.746 of this chapter and—

(1) Provide accommodations and food that are equivalent to those provided to the crew.

(2) Allow the observer access to and use of the vessel's communications equipment and personnel upon request for the transmission and receipt of messages related to the observer's duties.

(3) Allow the observer access to and use of the vessel's navigation equipment and personnel upon request to determine the vessel's position.

(4) Allow the observer free and unobstructed access to the vessel's bridge, working decks, holding bins, weight scales, holds, and any other space used to hold, process, weigh, or store fish.

(5) Allow the observer to inspect and copy the vessel's log, communications logs, and any records associated with the catch and distribution of fish for that trip.

(6) Notify the observer in a timely fashion of when fishing operations are to begin and end.

(f) Vessel responsibilities. An owner or operator of a vessel required to carry one or more observer(s) must provide reasonable assistance to enable observer(s) to carry out their duties, including, but not limited to:

(1) Measuring decks, codends, and holding bins.

(2) Providing the observer(s) with a safe work area.

(3) Collecting bycatch when requested by the observer(s).

(4) Collecting and carrying baskets of fish when requested by the observer(s).

(5) Allowing the observer(s) to collect biological data and samples.

(6) Providing adequate space for storage of biological samples.

■ 5. In § 635.19, revise paragraph (d) to read as follows:

§ 635.19 Authorized gears.

* * * * *

(d) *Sharks.* No person may possess a shark in the EEZ taken from its management unit without a permit issued under § 635.4. No person issued a Federal Atlantic commercial shark permit under § 635.4 may possess a shark taken by any gear other than rod and reel, handline, bandit gear, longline, or gillnet, except that smoothhound sharks may be retained incidentally while fishing with trawl gear subject to the restrictions specified in § 635.24(a)(7). No person issued an HMS Commercial Caribbean Small Boat permit may possess a shark taken from the U.S. Caribbean, as defined at § 622.2 of this chapter, by any gear other than with rod and reel, handline or bandit gear. No person issued an HMS Angling permit or an HMS Charter/Headboat permit under § 635.4 may possess a shark if the shark was taken from its

management unit by any gear other than rod and reel or handline, except that persons on a vessel issued both an HMS Charter/Headboat permit and a Federal Atlantic commercial shark permit may possess sharks taken with rod and reel, handline, bandit gear, longline, or gillnet if the vessel is not engaged in a for-hire fishing trip.

* * * * *

■ 6. In § 635.20, add paragraph (e)(5) to read as follows:

§ 635.20 Size limits.

* * * * *

(e) * * *

(5) There is no size limit for smoothhound sharks taken under the recreational retention limits specified at § 635.22(c)(6).

* * * * *

■ 7. In § 635.21, revise the section heading, and paragraphs (g)(2) and (3) to read as follows:

§ 635.21 Gear operation and deployment restrictions.

* * * * *

(g) * * *

(2) While fishing with a drift gillnet, a vessel issued or required to be issued a Federal Atlantic commercial shark limited access permit and/or a Federal commercial smoothhound permit must conduct net checks at least every 2 hours to look for and remove any sea turtles, marine mammals, Atlantic sturgeon, or smalltooth sawfish, and the drift gillnet must remain attached to at least one vessel at one end, except during net checks. Smalltooth sawfish must not be removed from the water while being removed from the net.

(3) While fishing with a sink gillnet, vessels issued or required to be issued a Federal Atlantic commercial shark limited access permit and/or a Federal commercial smoothhound permit must limit the soak time of the sink gillnet gear to no more than 24 hours, measured from the time the sink gillnet first enters the water to the time it is completely removed from the water. Smalltooth sawfish must not be removed from the water while being removed from the net.

* * * * *

■ 8. In § 635.22, add paragraph (c)(6) to read as follows:

§ 635.22 Recreational retention limits.

* * * * *

(c) * * *

(6) The smoothhound sharks listed in Section E of Table 1 of Appendix A to this part may be retained and are subject only to the size limits described in § 635.20(e)(5).

* * * * *

■ 9. In § 635.24, add paragraph (a)(7) to read as follows:

§ 635.24 Commercial retention limits for sharks, swordfish, and BAYS tunas.

* * * * *

(a) * * *

(7) A person who owns or operates a vessel that has been issued a Federal commercial smoothhound permit may retain, possess, and land smoothhound sharks if the smoothhound fishery is open in accordance with §§ 635.27 and 635.28. Persons aboard a vessel in a trawl fishery that has been issued a Federal commercial smoothhound permit and are in compliance with all other applicable regulations, may retain, possess, land, or sell incidentally-caught smoothhound sharks, but only up to an amount that does not exceed 25 percent, by weight, of the total catch on board and/or offloaded from the vessel. A vessel is in a trawl fishery when it has no commercial fishing gear other than trawls on board and when smoothhound sharks constitute no more than 25 percent by weight of the total catch on board or offloaded from the vessel.

* * * * *

■ 10. In § 635.27, add paragraphs (b)(1)(i)(E), (b)(1)(ii)(F), and (b)(4)(iv) to read as follows:

§ 635.27 Quotas.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(E) *Atlantic smoothhound sharks.* The base annual commercial quota for Atlantic smoothhound sharks is 1,201.7 mt dw.

(ii) * * *

(F) *Gulf of Mexico smoothhound sharks.* The base annual commercial quota for Gulf of Mexico smoothhound sharks is 336.4 mt dw.

* * * * *

(4) * * *

(iv) The base annual quota for persons who collect smoothhound sharks under a display permit or EFP is 6 mt ww (4.3 mt dw).

* * * * *

■ 11. In § 635.30, revise paragraphs (c)(1) through (3), and add paragraph (c)(5) to read as follows:

§ 635.30 Possession at sea and landing.

* * * * *

(c) *Shark.* (1) In addition to the regulations issued at part 600, subpart N, of this chapter, a person who owns or operates a vessel issued a Federal Atlantic commercial shark permit under § 635.4 must maintain all the shark fins including the tail naturally attached to the shark carcass until the shark has been offloaded from the vessel, except for under the conditions specified in paragraph (c)(5) of this section. While sharks are on board and when sharks are being offloaded, persons issued a Federal Atlantic commercial shark permit under § 635.4 are subject to the regulations at part 600, subpart N, of this chapter.

(2) A person who owns or operates a vessel that has a valid Federal Atlantic commercial shark permit may remove the head and viscera of the shark while on board the vessel. At any time when on the vessel, sharks must not have the backbone removed and must not be halved, quartered, filleted, or otherwise reduced. All fins, including the tail, must remain naturally attached to the shark through offloading, except under the conditions specified in paragraph (c)(5) of this section. While on the vessel, fins may be sliced so that the fin can be folded along the carcass for storage purposes as long as the fin remains naturally attached to the carcass via at least a small portion of uncut skin. The fins and tail may only be removed from the carcass once the shark has been landed and offloaded, except under the conditions specified in paragraph (c)(5) of this section.

(3) A person who owns or operates a vessel that has been issued a Federal Atlantic commercial shark permit and who lands sharks in an Atlantic coastal port, including ports in the Gulf of Mexico and Caribbean Sea, must have all fins and carcasses weighed and recorded on the weighout slips specified in § 635.5(a)(2) and in accordance with part 600, subpart N, of this chapter. Persons may not possess any shark fins not naturally attached to a shark carcass on board a fishing vessel at any time, except under the conditions specified in paragraph (c)(5) of this section. Once landed and offloaded, sharks that have been halved, quartered, filleted, cut up, or reduced in any manner may not be brought back on board a vessel that has been or should have been issued a Federal Atlantic commercial shark permit.

* * * * *

(5) A person who owns or operates a vessel that has been issued a Federal commercial smoothhound permit may remove the fins and tail of a smooth dogfish shark prior to offloading if the conditions in paragraphs (c)(5)(i) through (iv) of this section have been met. If the conditions in paragraphs (c)(5)(i) through (iv) of this section have

not been met, all fins, including the tail, must remain naturally attached to the smooth dogfish through offloading from the vessel:

(i) The smooth dogfish was caught within waters of the United States located shoreward of a line drawn in such a manner that each point on it is 50 nautical miles from the baseline of an Atlantic State from which the territorial sea is measured, from Maine south through Florida to the Atlantic and Gulf of Mexico shark regional boundary defined in § 635.27(b)(1).

(ii) The vessel has been issued both a Federal commercial smoothhound permit and a valid State commercial fishing permit that allows for fishing for smooth dogfish.

(iii) Smooth dogfish make up at least 25 percent of the catch on board at the time of landing.

(iv) Total weight of the smooth dogfish fins landed or found on board a vessel cannot exceed 12 percent of the total dressed weight of smooth dogfish carcasses on board or landed from the fishing vessel.

* * * * *

■ 12. In § 635.69, revise paragraph (a)(3) to read as follows:

§ 635.69 Vessel monitoring systems.

(a) * * *

(3) Pursuant to Atlantic large whale take reduction plan requirements at 50 CFR 229.32(h), whenever a vessel issued a directed shark LAP has a gillnet(s) on board.

* * * * *

■ 13. In § 635.71, revise paragraphs (d)(6) and (7), and add paragraph (d)(18) to read as follows:

§ 635.71 Prohibitions.

* * * * *

(d) * * *

(6) Fail to maintain a shark in its proper form, as specified in § 635.30(c). Fail to maintain naturally attached shark fins through offloading as specified in § 635.30(c), except for under the conditions specified in § 635.30(c)(5).

(7) Sell or purchase smooth dogfish fins that are disproportionate to the weight of smooth dogfish carcasses, as specified in § 635.30(c)(5).

* * * * *

(18) Retain or possess on board a vessel in the trawl fishery smoothhound sharks in an amount that exceeds 25 percent, by weight, of the total fish on board or offloaded from the vessel, as specified at § 635.24(a)(7).

* * * * *

■ 14. In Appendix A to Part 635, add Section E to Table 1 to read as follows:

Appendix A to Part 635—Species Tables

Table 1 of Appendix A to Part 635—Oceanic Sharks

* * * * *

E. Smoothhound Sharks

Smooth dogfish, *Mustelus canis*
Florida smoothhound, *Mustelus norrisi*
Gulf smoothhound, *Mustelus sinusmexicanus Mustelus species*

[FR Doc. 2015–29516 Filed 11–23–15; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 80, No. 226
Tuesday, November 24, 2015

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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–4070; Directorate Identifier 2015–NE–31–AD]

RIN 2120–AA64

Airworthiness Directives; Turbomeca S.A. Turboshaft Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Turbomeca S.A. Arriel 1E2 turboshaft engines. This proposed AD was prompted by reports of uncommanded in-flight shutdowns (IFSDs). This proposed AD would require removing the tachometer box on affected engines. We are proposing this AD to prevent failure of the tachometer box, which could lead to failure of the engine, IFSD, and loss of control of the helicopter.

DATES: We must receive comments on this proposed AD by January 25, 2016.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

For service information identified in this proposed AD, contact Turbomeca S.A., 40220 Tarnos, France; phone: 33 (0)5 59 74 40 00; fax: 33 (0)5 59 74 45 15. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–4070; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Philip Haberlen, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7770; fax: 781–238–7199; email: *philip.haberlen@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–4070; Directorate Identifier 2015–NE–31–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM based on those comments.

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2015–0175, dated August 24, 2015 (referred to hereinafter as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

There have been reports of Arriel 1E2 engines having experienced an uncommanded in-flight shut-down (IFSD) due to an untimely activation of the tachometer box shut-off system which was activated by the power turbine monitoring function of the tachometer box.

This condition, if not corrected, could potentially lead to further cases of IFSD, possibly resulting in a forced landing.

You may obtain further information by examining the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–4070.

Related Service Information

Turbomeca S.A. has issued Mandatory Service Bulletin No. 292 77 0844, Version B, dated July 6, 2015. The service information describes procedures for removing pre-TU 369 tachometer boxes. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of France, and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. This NPRM would require removing the pre-TU 369 tachometer box from the engine.

Costs of Compliance

We estimate that this proposed AD affects 200 engines installed on helicopters of U.S. registry. We also estimate that it would take about 3 hours per engine to comply with this proposed AD. The average labor rate is $85 per hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $51,000.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue

rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

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

Regulatory Findings

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

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

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

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

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Turbomeca S.A.: Docket No. FAA–2015–4070; Directorate Identifier 2015–NE–31–AD.

(a) Comments Due Date

We must receive comments by January 25, 2016.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to Turbomeca S.A. Arriel 1E2 turboshaft engines with tachometer boxes with the following part number (P/N) and serial number (S/N) combinations:

(i) P/N 9580116170—all S/Ns

(ii) P/N 9580116260—all S/Ns

(iii) P/N 9580116900—all S/Ns

(iv) P/N 9580117110—all S/Ns

(v) P/N 9580117550—all S/Ns 1499 and below with or without suffix letters and all S/Ns 1500 and above that do not contain the suffix letters EL.

(2) This AD applies only to Turbomeca S.A. Arriel 1E2 turboshaft engines with tachometer boxes identified in paragraph (c)(1) of this AD that also have installed electrical connectors labeled as P10106, P10098, and P10108 or P11F, P13F, and P15F.

(d) Reason

This AD was prompted by reports of uncommanded in-flight shutdowns (IFSDs). We are issuing this AD to prevent failure of the tachometer box, which could lead to failure of the engine, IFSD, and loss of control of the helicopter.

(e) Actions and Compliance

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

(1) Within 1,600 flight hours after the effective date of this AD, remove the affected tachometer box from the engine.

(2) Reserved.

(f) Credit for Previous Action

You may take credit for the action required by paragraph (e) of this AD if you performed the action before the effective date of this AD in accordance with Turbomeca S.A. MSB 292 77 0844, Version A, dated March 4, 2015 or earlier version.

(g) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(h) Related Information

(1) For more information about this AD, contact Philip Haberlen, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7770; fax: 781–238–7199; email: *philip.haberlen@faa.gov.*

(2) Refer to MCAI European Aviation Safety Agency AD 2015–0175, dated August 24, 2015, which includes Mandatory Service Bulletin No. 292 77 0844, Version B, dated July 6, 2015, for related information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2015–4070.

(3) You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on November 12, 2015.

Colleen M. D'Alessandro,

Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2015–29748 Filed 11–23–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–3753; Directorate Identifier 2015–NE–26–AD]

RIN 2120–AA64

Airworthiness Directives; Turbomeca S.A. Turboshaft Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Turbomeca S.A. Arriel 2B, 2B1, 2C, 2C1, 2C2, 2D, 2E, 2S1, and 2S2 turboshaft engines. This proposed AD was prompted by a report of an uncommanded in-flight shutdown of an Arriel 2 engine caused by rupture of the 41-tooth gear, which forms part of the bevel gear in the engine accessory gearbox (AGB). This proposed AD would require inspection, and, depending on the results, removal of the engine AGB. We are proposing this AD to prevent failure of the engine AGB, which could lead to in-flight shutdown, damage to the engine, and damage to the aircraft.

DATES: We must receive comments on this proposed AD by January 25, 2016.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200

New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

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

• *Fax:* 202–493–2251.

For service information identified in this proposed AD, contact Turbomeca S.A., 40220 Tarnos, France; phone: 33 0 5 59 74 40 00; fax: 33 0 5 59 74 45 15. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3753; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Philip Haberlen, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7770; fax: 781–238–7199; email: *philip.haberlen@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–3753; Directorate Identifier 2015–NE–26–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2015–0162, dated August 6, 2015 (referred to hereinafter as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> An uncommanded in-flight shut-down (IFSD) of an ARRIEL 2 engine was reported, caused by rupture of the 41-tooth gear, which forms part of the bevel gear of the accessory gearbox (module M01). The subsequent investigation revealed that wear on the housing of the front bearing of this gear was a major contributor to this rupture. In addition, the investigation showed that this wear mechanism had resulted in positive Spectrometric Oil Analysis (SOA) indications before the event.
>
> This condition, if not detected and corrected, could potentially lead to further cases of IFSD, possibly resulting in an emergency landing.

You may obtain further information by examining the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3753.

Related Service Information Under 1 CFR Part 51

Turbomeca S.A. has issued Mandatory Service Bulletin No. 292 72 2861, Version A, dated April 24, 2015. The service information describes procedures for inspecting the engine AGB. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this document.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of France, and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. This proposed AD would require inspection, and, depending on the results, removal of the engine AGB.

Costs of Compliance

We estimate that this proposed AD affects 250 engines installed on aircraft of U.S. registry. We also estimate that it would take about 0.5 hours per engine to comply with the initial inspection requirement in this proposed AD and about 2 hours per engine to remove the engine AGB. The spectrometric oil analysis kit costs about $79. The average labor rate is $85 per hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $72,875.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Turbomeca S.A.: Docket No. FAA–2015–3753; Directorate Identifier 2015–NE–26–AD.

(a) Comments Due Date

We must receive comments by January 25, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Turbomeca S.A. Arriel 2B, 2B1, 2C, 2C1, 2C2, 2D, 2E, 2S1, and 2S2 turboshaft engines with an engine accessory gearbox (AGB), part number 0292120650, with a machined front casing.

(d) Reason

This AD was prompted by a report of an uncommanded in-flight shutdown of an Arriel 2 engine caused by rupture of the 41-tooth gear, which forms part of the bevel gear in the engine AGB. We are issuing this AD to prevent failure of the engine AGB, which could lead to in-flight shutdown, damage to the engine, and damage to the aircraft.

(e) Actions and Compliance

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

(1) Initial Spectrometric Oil Analysis (SOA)

(i) Perform an initial SOA within the compliance times given in paragraph (e)(1)(i)(A) or (e)(1)(i)(B) of this AD:

(A) If the engine AGB has less than 800 engine hours (EHs) since new or since last overhaul, do an initial SOA before exceeding 850 EHs since new or since last overhaul.

(B) If the engine AGB has 800 EHs or more since new or since last overhaul, or if the EHs are unknown, do an initial SOA within 50 EHs after the effective date of this AD.

(C) Use paragraphs 2.4.2.1 and 2.4.2.2 of Turbomeca S.A. Mandatory Service Bulletin (MSB) No. 292 72 2861, Version A, dated April 24, 2015, to perform the SOA required by paragraph (e) of this AD.

(ii) Reserved.

(2) Repetitive SOA

(i) If the aluminum concentration determined from the most recent SOA is less than 0.8 parts per million (PPM), repeat the SOA required by paragraph (e) of this AD within 100 EHs time since last analysis (TSLA).

(ii) If the aluminum concentration determined from the most recent SOA is between 0.8 PPM and 1.4 PPM, inclusive, repeat the SOA required by paragraph (e) of this AD within 50 EHs TSLA. Do not perform draining before doing the next SOA.

(iii) If the aluminum concentration determined from the most recent SOA is greater than 1.4 PPM, remove the engine AGB from service within 50 EHs TSLA.

(f) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(g) Related Information

(1) For more information about this AD, contact Philip Haberlen, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7770; fax: 781–238–7199; email: *philip.haberlen@faa.gov.*

(2) Refer to MCAI European Aviation Safety Agency AD 2015–0162, dated August 6, 2015, for more information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2015–3753.

(3) Turbomeca S.A. MSB No. 292 72 2861, Version A, dated April 24, 2015, can be obtained from Turbomeca S.A., using the contact information in paragraph (g)(4) of this proposed AD.

(4) For service information identified in this proposed AD, contact Turbomeca S.A., 40220 Tarnos, France; phone: 33 0 5 59 74 40 00; fax: 33 0 5 59 74 45 15.

(5) You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on November 12, 2015.

Colleen M. D'Alessandro,

Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2015–29747 Filed 11–23–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2015–3108; Airspace Docket No. 12–AAL–15]

Proposed Establishment of Class E Airspace, South Naknek, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace extending upward from 700 feet above the surface at South Naknek NR 2 Airport, South Naknek, AK, to accommodate new Area Navigation (RNAV) Global Positioning System (GPS) standard instrument approach procedures developed for the airport. The FAA is proposing this action to enhance the safety and management of Instrument Flight Rules (IFR) operations at the airport.

DATES: Comments must be received on or before January 8, 2016.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–9826. You must identify FAA Docket No. FAA–2015–3108; Airspace Docket No. 12–AAL–15, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527), is on the ground floor of the building at the above address.

FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy and ATC Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 29591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Richard Roberts, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4517.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in

Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish Class E airspace at South Naknek NR 2 Airport, South Naknek, AK.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2015–3108/Airspace Docket No. 12–AAL–15.'' The postcard will be date/time stamped and returned to the commenter.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Availability and Summary of Documents Proposed for Incorporation by Reference

This document would amend FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by establishing Class E airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the South Naknek NR 2 Airport, South Naknek, AK. Development of new RNAV (GPS) standard instrument approach procedures have made this action necessary for continued safety and management of IFR operations at the airport.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

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

* * * * *

AAL AK E5 South Naknek, AK [New]

South Naknek NR 2 Airport, Alaska
(Lat. 58°42′08″ N., long. 157°00′09″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of South Naknek NR 2 Airport.

Issued in Seattle, Washington, on November 10, 2015.

Christopher Ramirez,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2015–29789 Filed 11–23–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2015–3771; Airspace Docket No. 15–ANM–28]

Proposed Establishment of Class E Airspace, South Bend, WA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at Willapa Harbor Heliport, South Bend, WA, to accommodate new standard instrument approach and departure procedures developed at the heliport. Controlled airspace is necessary for the safety and management of Instrument Flight Rules (IFR) operations at the heliport.

DATES: Comments must be received on or before January 8, 2016.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–9826. You must identify FAA Docket No. FAA–2015–3771; Airspace Docket No. 15–ANM–28, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527), is on the ground floor of the building at the above address.

FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy and ATC Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 29591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Steve Haga, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4563.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2015–3771; Airspace Docket No. 15–ANM–28.'' The postcard will be date/time stamped and returned to the commenter.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Availability and Summary of Documents Proposed for Incorporation by Reference

This document would amend FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by establishing Class E airspace extending upward from 700 feet above the surface at Willapa Harbor Heliport, South Bend, WA. Establishment of a GPS approach and departure procedure has made this action necessary for the safety and management of IFR operations at the heliport. Class E airspace would be established within a 1.8-mile radius of the Willapa Harbor Heliport, with a segment extending from the 1.8-mile radius to 5.5 miles northwest of the heliport.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

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

current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

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

* * * * *

ANM WA E5 Willapa Harbor Heliport, South Bend, WA [New]

Willapa Harbor Heliport, WA
(Lat. 46°39′47″ N., long. 123°48′44″ W.)

That airspace extending upward from 700 feet above the surface within a 1.8-mile radius of Willapa Harbor Heliport, and that airspace bounded by a line beginning at a point where the Willapa Harbor 278° bearing intersects the Willapa Harbor 1.8-mile radius, thence northwest to lat. 46°42′26″ N., long. 123°55′39″ W.; to lat. 46°45′28″ N., long. 123°52′46″ W.; to lat. 46°43′55″ N., long. 123°48′46″ W.; to lat. 46°41′18″ N., long. 123°46′14″ W.; to a point where the Willapa Harbor 98° bearing intersects the Willapa Harbor 1.8-mile radius, thence clockwise along the 1.8-mile radius to the point of beginning.

Issued in Seattle, Washington, on November 10, 2015.

Christopher Ramirez,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2015–29788 Filed 11–23–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2015–F–4282]

BASF Corp.; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that BASF Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of sodium formate as a feed acidifier in poultry feed.

DATES: The food additive petition was filed on October 15, 2015.

FOR FURTHER INFORMATION CONTACT: Chelsea Trull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6729, *chelsea.trull@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2293) has been filed by BASF Corp., 100 Park Ave., Florham Park, NJ 07932. The petition proposes to amend the food additive regulations in 21 CFR part 573 *Food Additives Permitted in Feed and Drinking Water of Animals* to provide for the safe use of sodium formate as a feed acidifier in poultry feed.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(r) because it is of a type that does not individually or cumulatively have a significant effect on the human environment. In addition, the petitioner has stated that to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: November 18, 2015.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2015–29832 Filed 11–23–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 549

[BOP–1169–P]

RIN 1120–AB69

Infectious Disease Management: Voluntary and Involuntary Testing

AGENCY: Bureau of Prisons, Justice.

ACTION: Proposed rule.

SUMMARY: In this document, the Bureau of Prisons proposes two minor revisions to its regulations on the management of infectious diseases. One change would remove the requirement for HIV pre-test counseling for inmates, because the counseling requirement has become an obstacle to necessary testing. Inmates testing positive for HIV will continue to receive HIV post-test counseling. The second change would alter language regarding tuberculosis (TB) testing to clarify that it is testing for the TB infection, but not ''skin testing.'' This would account for advances in medical technology that allow for newer testing methods.

DATES: Written comments must be submitted on or before January 25, 2016.

ADDRESSES: Rules Unit, Office of General Counsel, Bureau of Prisons, 320 First Street NW., Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT: Rules Unit, Office of General Counsel, Bureau of Prisons, phone (202) 353–8214.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at *www.regulations.gov.* Such information

includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

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 posted online, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also locate all the personal identifying information you do not want posted online 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 posted online, 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. If a comment contains so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on *www.regulations.gov.*

Personal identifying information identified and located as set forth above will be placed in the agency's public docket file, but not posted online. Confidential business information identified and located as set forth above will not be placed in the public docket file. If you wish to inspect the agency's public docket file in person by appointment, please see the ''For Further Information Contact'' paragraph.

SUPPLEMENTARY INFORMATION: The Bureau proposes two minor revisions to its regulations on the infectious disease management program (28 CFR, part 549, subpart A). One change would remove the requirement for HIV pre-test counseling for inmates, because the counseling requirement has become an obstacle to necessary testing. Inmates testing positive for HIV will continue to receive HIV post-test counseling. The second change would alter language regarding tuberculosis (TB) testing to clarify that it is testing for the TB infection, but not ''skin testing.'' This would account for advances in medical technology that allow for newer testing methods.

Clarifications to inmate information procedures. 28 CFR 549.12(a)(1) currently states that the ''Bureau tests inmates who have sentences of six months or more if health services staff determine, taking into consideration the risk as defined by the Centers for Disease Control Guidelines, that the inmate is at risk for HIV infection.'' We propose to make minor clarifying changes to this language to make it clear that such inmates will be informed orally or in writing that HIV testing will be performed unless they decline testing. This would be a minor change to be consistent with CDC Guidelines, which state that ''HIV screening is recommended for patients in all health-care settings after the patient is notified that testing will be performed unless the patient declines (opt-out screening)''. In light of the CDC Guidelines, we propose to change the regulation language to clarify that HIV screening is recommended for all inmates because risk factors are present in the correctional health-care setting. The language as it currently exists in the regulation does not make it clear that inmates will be so notified, although this has already been the Bureau's longstanding procedure during Admission and Orientation of inmates.

Eliminating the requirement for HIV pre-test counseling and HIV post-test counseling for HIV-negative inmates. In 28 CFR 549.12 (Testing), subparagraph (a)(5) currently states that ''Inmates being tested for HIV will receive pre- and post-test counseling, regardless of the test results.'' We propose altering this subparagraph to read as follows: ''Inmates testing positive for HIV will receive post-test counseling.'' This change would eliminate the requirement that the Bureau provide pre-test counseling for inmates and post-test counseling for HIV-negative inmates. We propose these changes to bring our requirements in conformance with those recommended by the Center for Disease Control (CDC) in their report entitled ''Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings'' (2006, MMWR 55(RR14); 1–17); *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm.*

The CDC set forth guidelines in 1994 for counseling and testing persons with high-risk behaviors which specified prevention (pre-test) counseling to develop specific prevention goals and strategies for each person (client-centered counseling). However, in 2003, CDC introduced an initiative entitled ''Advancing HIV Prevention: New Strategies for a Changing Epidemic''. One key point of this initiative was to make HIV testing a routine part of medical care on the same voluntary basis as other diagnostic and screening tests. In its technical guidance, CDC acknowledged that although prevention (pre-test) counseling is desirable for all persons at risk for HIV, such counseling might not be appropriate or feasible in all settings. Because time constraints caused some providers to perceive requirements for prevention counseling and written informed consent as a barrier to uniform testing, the initiative advocated streamlined approaches. The CDC found that although targeted testing programs, like the Bureau's infection disease management program, were implemented in acute-care settings and nearly two thirds of patients in these settings accept testing; risk assessment and prevention (pre-test) counseling are time-consuming, so only a limited proportion of eligible patients can be tested.

There are significant benefits of HIV testing for inmates because treatment for HIV can be initiated promptly preventing serious complications and death. The CDC has found that requirements for pre-test prevention counseling pose a barrier to testing and therefore CDC recommends that an ''opt-out'' testing protocol be utilized, in which persons are informed that they will be tested unless they choose not to be tested. Specifically CDC recommends that:

- HIV screening is recommended for patients in all health-care settings after the patient is notified that testing will be performed unless the patient declines (opt-out screening).
- Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing.
- Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings.

''Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings'' (2006, MMWR 55(RR14); 1–17); *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm.*

In addition to the above, the Bureau also notes that eliminating the pre-test counseling requirement would save Bureau staff approximately 20 minutes per counseling session. Since the Bureau strives to test all inmates, the time savings this would permit are substantial. We therefore propose to delete the requirement for pre-test counseling in order to conform with CDC guidelines and to remove this barrier to testing as many inmates as possible.

We also propose to remove the requirement for post-HIV-test counseling for inmates who have tested negative for HIV. Those testing positive will continue to receive post-test

counseling. Those testing negative, however, have no need for further counseling, but may ask questions of Health Services staff as needed. Eliminating the post-test counseling requirement for inmates testing HIV negative would also save 20 minutes per counseling session per inmate. Again, the time saving is quite substantial, considering that more than 98% of HIV tests performed are negative results.

Changing terminology to clarify that TB testing is no longer ''skin testing.'' In 28 CFR 549.12(b)(4), we currently state that ''[i]f an inmate refuses *skin testing,* and there is no contraindication to *tuberculin skin testing,* then, institution medical staff will test the inmate involuntarily.'' (Emphasis added.) We now proposed to alter this sentence to read as follows: ''If an inmate refuses testing for TB infection, and there is no contraindication to testing, then institutional medical staff will test the inmate involuntarily.'' The only alteration we make in this language is to clarify that Tuberculosis testing is no longer ''skin testing.''

The Bureau currently primarily uses the tuberculin skin test for testing for latent TB infection. However, a new type of test for TB infection has become available, a blood test called the Interferon Gamma Release Assay (IGRA). In the next 5 to 10 years it is anticipated that blood tests for TB infection will replace the tuberculin skin test. These tests appear to be at least as accurate as the skin test and have the benefit of requiring only one interaction with an inmate to draw blood (rather than place the skin test and reading it 2 to 3 days later). Using this type of test would eliminate the need for a second health care visit to conduct the test, as no ''reading'' would be required, which would result in great time savings to Bureau staff.

Once more, we make this change to bring the Bureau into conformance with CDC guidelines. In 2010, the CDC issued ''Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* infection—United States, 2010'' (MMWR 59(RR–5) 1–13; *http://www.cdc.gov/mmwr/pdf/rr/rr5905.pdf.* In this report, the CDC states that ''[b]efore 2001, the tuberculin skin test (TST) was the only practical and commercially available immunologic test for TB infection approved in the United States.''

However, several risks are associated with the use of TSTs: Difficulty with the very specific administration needed, unreliable patient return to the health-care provider for the test reading, and inaccuracies and biases existing in reading the TSTs, such as false-positives. IGRAs, however, assess the presence of specific tuberculosis proteins, and therefore offer improved test specificity compared with TSTs.

For this reason, the CDC has recommended increasing use of IGRAs. Although skin testing may still be used, it will not be used exclusively, so we propose to update our regulatory language to allow for the possibility of other kinds of testing for TB infection.

Other changes for clarity:

We also propose to make minor changes to § 549.12(a)(2), Exposure incidents, to clarify that the current language stating that the Bureau will test ''when there is a well-founded reason to believe that the inmate may have transmitted the HIV infection'' means the following: The Bureau tests an inmate, regardless of the length of sentence or pretrial status, when there is a well-founded reason to believe that the inmate *has been the source of a percutaneous or mucous membrane blood exposure, via an altercation or accident or other means to Bureau employees, other non-inmates who are lawfully present in a Bureau institution, or other inmates,* regardless of whether the exposure was intentional or unintentional. Exposure incident testing does not require the inmate's consent. This language more accurately reflects the intention of the regulation.

Executive Order 12866

This proposed regulation has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review'', section 1(b), Principles of Regulation. The Director, Bureau of Prisons has determined that this proposed regulation is a ''significant regulatory action'' under Executive Order 12866, section 3(f), and accordingly this proposed regulation has been reviewed by the Office of Management and Budget.

Executive Order 13132

This proposed regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, under Executive Order 13132, we determine that this proposed regulation does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Flexibility Act

The Director of the Bureau of Prisons, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), reviewed this proposed regulation and certifies that it will not have a significant economic impact upon a substantial number of small entities for the following reasons: This proposed regulation pertains to the correctional management of inmates committed to the custody of the Attorney General or the Director of the Bureau of Prisons. Its economic impact is limited to the Bureau's appropriated funds.

Unfunded Mandates Reform Act of 1995

This proposed regulation will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This proposed rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 804. This proposed regulation will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 28 CFR Part 571

Prisoners.

Charles E. Samuels, Jr.,

Director, Bureau of Prisons.

Under rulemaking authority vested in the Attorney General in 5 U.S.C. 301; 28 U.S.C. 509, 510 and delegated to the Director, Bureau of Prisons in 28 CFR 0.96, we proposed to amend 28 CFR part 549 as follows.

SUBCHAPTER C—INSTITUTIONAL MANAGEMENT

PART 549—MEDICAL SERVICES

■ 1. The authority citation for 28 CFR part 549 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. 876b; 18 U.S.C. 3621, 3622, 3524, 4001, 4005, 4042, 4045, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), Chapter 313, 5006–5024 (Repealed October 12, 1984 as to offenses committed after that date), 5039; 28 U.S.C. 509, 510.

■ 2. Amend § 549.12 by revising paragraphs (a) and (b)(4) to read as follows:

§ 549.12 Testing.

(a) *Human Immunodeficiency Virus (HIV)*—(1) *Testing.* All inmates who have sentences of six months or more will be informed upon admission either orally or in writing that HIV testing will be performed unless they refuse testing. If the inmate refuses testing and the inmate has risk factors for HIV infection as defined by the Centers for Disease Control and Prevention, staff will provide pre-test counseling, and if the inmate continues to refuse testing, staff may initiate an incident report for refusing to obey an order. Any inmate may request HIV testing during the pre-release process.

(2) *Exposure incidents.* The Bureau tests an inmate, regardless of the length of sentence or pretrial status, when there is a well-founded reason to believe that the inmate has been the source of a percutaneous or mucous membrane blood exposure, via an altercation or accident or other means to Bureau employees, other non-inmates who are lawfully present in a Bureau institution, or other inmates, regardless of whether the exposure was intentional or unintentional. Exposure incident testing does not require the inmate's consent.

(3) *Surveillance testing.* The Bureau conducts HIV testing for surveillance purposes as needed. If the inmate refuses testing, staff will offer pre-test counseling, and if the inmate continues to refuse testing, staff may initiate an incident report for refusing to obey an order.

(4) *Inmate request.* An inmate may request to be tested. The Bureau limits such testing to no more than one per 12-month period unless the Bureau determines that additional testing is warranted.

(5) *Counseling.* Inmates testing positive for HIV will receive post-test counseling.

(b) * * *

* * * * *

(4) An inmate who refuses TB screening may be subject to an incident report for refusing to obey an order. If an inmate refuses testing for TB infection, and there is no contraindication to testing, then, institution medical staff will test the inmate involuntarily.

[FR Doc. 2015–29790 Filed 11–23–15; 8:45 am]

BILLING CODE 4410–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2013–0760]

RIN 1625–AA11

Regulated Navigation Area; Reporting Requirements for Barges Loaded With Certain Dangerous Cargoes, Inland Rivers, Eighth Coast Guard District; Stay (Suspension) Expiring

AGENCY: Coast Guard, DHS.

ACTION: Notice of intent.

SUMMARY: The stay of reporting requirements under the Regulated Navigation Area (RNA) applicable to barges loaded with certain dangerous cargoes on the inland rivers in the Eighth District area of responsibility (AOR) is scheduled to expire on December 31, 2015. The Coast Guard intends to allow the stay to expire in part. Once the stay partially expires, RNA reporting requirements in a limited form will resume under the existing regulation. The Coast Guard is developing an amendment to the existing regulation.

DATES: November 24, 2015.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email Shelley Miller, Coast Guard; telephone 504–671–2330, email *Shelley.R.Miller@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Background and Regulatory History

The reporting requirements under 33 CFR 165.830, ''Regulated Navigation Area; Reporting Requirements for Barges Loaded with Certain Dangerous Cargoes, Inland Rivers, Eighth Coast Guard District,'' were initially suspended in January 2011 due to the expiration of the contract for the reporting system at the Inland River Vessel Movement Center (IRVMC). This suspension was published in the **Federal Register** on January 10, 2011 and was due to expire on January 15, 2013 (76 FR 1360). On January 2, 2013, the Coast Guard extended this suspension through September 30, 2013 (78 FR 25) and on October 1, 2013, the Coast Guard extended the suspension again through December 31, 2015 (78 FR 60216). The suspension of reporting requirements is scheduled to expire on December 31, 2015.

Additionally, the Coast Guard published a final rule in January 2015 (80 FR 5282), titled Vessel Requirements for Notices of Arrival and Departure, and Automatic Identification System. This rule contains an exemption, at 33 CFR 160.204(a)(3), for any vessel required to report its movements, its cargo, or the cargo in barges it is towing under 33 CFR 165.830 after December 31, 2015.

II. Discussion

The Coast Guard intends to allow the suspension of certain reporting requirements under 33 CFR 165.830 to expire as scheduled. The Coast Guard does not intend to reinstate reporting, 24 hours per day, 365 days per year, at 90 plus reporting points under the RNA as currently published. Rather, we anticipate reporting will be required in response to specific concerns, under a limited form of the RNA currently in the CFR.

Specifically, the Coast Guard is considering whether existing § 165.830(d)(1)(ix), (d)(2)(iv), (f)(9), (g)(4), and (h) of the existing RNA may take effect on January 1, 2016, with revisions to the references to IRVMC. Although we have not yet developed revisions to the existing regulation, we are publishing this document to inform members of the public who are aware of, and may have questions about, the upcoming expiration of the suspension.

This document is issued under authority of 5 U.S.C. 552(a).

Dated: November 9, 2015.

D.R. Callahan,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 2015–29714 Filed 11–23–15; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0545; FRL–9937–27–Region 9]

Disapproval of California Air Plan Revisions, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to disapprove revisions to the South Coast Air Quality Management District (SCAQMD) portion of the California State Implementation Plan (SIP) concerning Vehicle Scrapping, Employee Trip Reduction, and procedures for the hearing board concerning variances and subpoenas.

We are proposing action on local rules that regulate these activities under the Clean Air Act (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by December 24, 2015.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2015–0545, by one of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the on-line instructions.

2. *Email: steckel.andrew@epa.gov.*

3. *Mail or deliver:* Andrew Steckel (Air–4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *www.regulations.gov* or email. *www.regulations.gov* is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: Generally, documents in the docket for this action are available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps), and some may not be publicly available in either location (*e.g.,* CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Idalia Pérez, EPA Region IX, (415) 972–3248, *perez.idalia@epa.gov.*

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

Table of Contents

I. The State's Submittal

A. What rules did the State submit?

Table 1 lists the rules proposed for disapproval with the date that they were adopted or amended and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED RULES

Local agency	Rule No.	Rule title	Adopted or amended	Submitted
SCAQMD	1610	Old-Vehicle Scrapping	05/09/97	06/03/97
SCAQMD	2202	On-Road Motor Vehicle Mitigation Options	10/09/98	06/03/99
SCAQMD	503.1	Ex Parte Petitions for Variances	02/05/88	02/07/89
SCAQMD	504	Rules from which Variances Are Not Allowed	01/05/90	05/13/91
SCAQMD	511.1	Subpoenas	02/05/88	02/07/89

On December 3, 1997, the submittal for SCAQMD Rule 1610 was deemed by operation of law to meet the completeness criteria in 40 CFR part 51, appendix V, which must be met before formal EPA review. On December 3, 1999, the submittal for SCAQMD Rule 2202 was deemed by operation of law to meet the completeness criteria. On May 5, 1989, the EPA determined that the submittal for SCAQMD Rules 503.1 and 511.1 met the completeness criteria. On July 10, 1991, the EPA determined that the submittal for SCAQMD Rule 504 met the completeness.

B. Are there other versions of these rules?

There are no previous versions of Rule 1610 in the SIP, although the SCAQMD adopted earlier versions of this rule on 02/11/94, 10/13/95, 02/08/96 and 04/11/97, and CARB submitted them to us on 07/13/94, 10/18/96, 10/18/96 and 06/03/97 respectively. There are no previous versions of Rule 2202 in the SIP, although the SCAQMD adopted earlier versions of this rule on 12/08/95, 03/08/96 and 11/08/96, and CARB submitted them to us on 11/26/96, 11/26/96 and 12/19/97 respectively. There are no previous versions of Rules 503.1 and 511.1. There are no previous versions of Rule 504 in the SIP, although the SCAQMD adopted an earlier version of this rule on 02/05/88. While we can only act on the most recently submitted version, we have reviewed materials provided with previous submittals.

C. What is the purpose of the submitted rules?

Nitrogen oxides (NO_X) and volatile organic compounds (VOCs) help produce ground-level ozone, smog and particulate matter (PM), which harm human health and the environment. Section 110(a) of the CAA requires States to submit regulations that control VOC and NO_X emissions. Rule 1610 is a voluntary rule with the goal of reducing motor vehicle exhaust emissions of VOC, NO_X, carbon monoxide (CO), and PM by issuing mobile source emission reduction credits (MSERCs) in exchange for the scrapping of old, high emitting vehicles. Rule 2202 requires employers with 250 or more full or part-time employees at a worksite to reduce mobile source emissions of VOC, NO_X and CO generated from employee commutes. The EPA's technical support documents (TSDs) have more information about rules 1610 and 2202.

Rules 503.1 describes procedures for how sources can apply for ex parte variances. Rule 504 specifies rules for which the SCAQMD hearing board will not grant variances. Rule 511.1

describes procedures for the hearing board regarding subpoenas.

II. EPA's Evaluation and Action

A. How is the EPA evaluating these rules?

SIP rules must be enforceable (see CAA section 110(a)(2)), must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)), and must not modify certain SIP control requirements in nonattainment areas without ensuring equivalent or greater emissions reductions (see CAA section 193). In addition, pursuant to CAA section 110(i), neither EPA nor a state may revise a SIP by issuing an ''order, suspension, plan revision, or other action modifying any requirement of an applicable implementation plan'' without a plan promulgation or revision.

Generally, SIP rules must require Reasonably Available Control Technology (RACT) for each category of sources covered by a Control Techniques Guidelines (CTG) document as well as each major source of VOCs and NO_X in ozone nonattainment areas classified as moderate or above (see CAA section 182(b)(2) and 182(f)). The SCAQMD regulates an ozone nonattainment area classified as extreme for the 1997 and 2008 8-hour ozone standards (40 CFR 51.305). In addition, SIP rules must implement Reasonably Available Control Measures (RACM) in moderate $PM_{2.5}$ nonattainment areas (see CAA sections 172(c)(1) and 189(a)(1)(C)). The SCAQMD regulates a $PM_{2.5}$ nonattainment area classified as moderate for the annual and 24-hour standards (40 CFR 51.312). A RACM evaluation is generally performed in context of a broader plan.

Guidance and policy documents that we use to evaluate enforceability, revision/relaxation and rule stringency requirements for the applicable criteria pollutants include the following:

1. ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' 57 FR 13498 (April 16, 1992); 57 FR 18070 (April 28, 1992).
2. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' EPA, May 25, 1988 (the Bluebook, revised January 11, 1990).
3. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' EPA Region 9, August 21, 2001 (the Little Bluebook).
4. ''Review of State Implementation Plans and Revisions for Enforceability and Legal Sufficiency,'' EPA from J. Craig Potter, Thomas L. Adams Jr., Francis S. Blake, September 23, 1987.
5. ''Guidance an Enforceability Requirements for Limiting Potential to Emit through SIP and § 112 Rules and General Permits'' EPA from Kathie A. Stein, January 25, 1995.

B. Do the rules meet the evaluation criteria?

EPA supports SCAQMD efforts to implement nontraditional and innovative strategies for reducing air pollutant emissions, including commuter programs to reduce the frequency that employees drive alone to work, and programs to incentivize early adoption and turnover to cleaner, less-polluting mobile sources.[1] Nonetheless, we have identified several provisions in these rules that do not meet the evaluation criteria. These deficiencies are summarized below and discussed further in the TSDs. Because these deficiencies are significant enough to prevent our approval of these rules, we have not attempted to identify all other potential approvability issues, and are not providing a detailed analysis of all the evaluation criteria listed above. While we cannot propose to approve SCAQMD Rules 1610 and 2202 at this time, we commend SCAQMD's leadership in developing and implementing creative programs like these for many years and we commit to continued collaboration to address SCAQMD's air quality challenges.

EPA and California have long recognized that a state-issued variance, though binding as a matter of state law, does not prevent EPA from enforcing the underlying SIP provisions unless and until EPA approves that variance as a SIP revision. The variance provisions in Rules 503.1 and 504 are deficient for various reasons, including their failure to address the fact that a state- or district-issued variance has no effect on enforcing the underlying federal requirement unless the variance is submitted to and approved by EPA as a SIP revision. Therefore, the inclusion of these rules in the SIP is inconsistent with the Act and may be confusing to regulated industry and the general public.

States and Districts can adopt various provisions describing local agency investigative or enforcement authority, including the authority to issue subpoenas such as in Rule 511.1, to demonstrate adequate enforcement authority under section 110(a)(2) of the Act. These rules should not be approved into the applicable SIP, however, to avoid potential conflict with EPA's independent authorities provided in CAA section 113, section 114 and elsewhere.

[1] See, *e.g.,* U.S. EPA, Transportation and Climate Division, Office of Transportation and Air Quality, ''Commuter Programs: Quantifying and Using Their Emission Benefits in SIPs and Conformity'' (February 2014) and Memorandum from Richard D. Wilson, Acting Assistant Administrator for Air and Radiation, to EPA Regional Administrators, re: ''Guidance on Incorporating Voluntary Mobile Source Emission Reduction Programs in State Implementation Plans (SIPs)'' (October 1997).

C. What are the identified rule deficiencies?

The deficiencies listed below are some of the provisions that of the submitted rules that do not satisfy the requirements of section 110 and part D of Title I of the Act and prevent full approval of the SIP submittals.

We propose to disapprove the SIP revision for Rule 1610 based at least in part on the following deficiencies:

1. The Section (e)(2) requirement that engines of scrapped vehicles be destroyed is insufficiently federally enforceable for various reasons.
2. The Section (f)(2)(A) requirement that the vehicle be registered for two years within SCAQMD is not fully enforceable by allowing the Executive Officer to approve different documentation.
3. The Section (g) requirement of a visual and functional inspection of the vehicle has no recordkeeping requirements.
4. There is no recordkeeping requirement to demonstrate compliance with the Section (g)(1) requirement that vehicles be driven under their own power to the scrapping site.
5. There is no requirement to maintain records for the life of the MSERCs.

We propose to disapprove the SIP revision for Rule 2202 based at least in part on the following deficiencies:

1. Per Section (f)(1), the rule relies on Regulation XVI, which is not currently in the SIP.
2. Per Section (f)(3), the rule relies on AQIP (Rule 2501), which is not currently in the SIP.
3. Per Section (f)(4), the rule relies on emission reduction strategies approved on a case-by-case basis by the Executive Officer.
4. Per Section (g)(4), the rule relies on vehicle miles travelled reduction programs approved on a case-by-case basis by the Executive Officer.

We propose to disapprove the SIP revision for Rules 503.1 and 504 because they conflict with CAA sections 110(a) and (i) and fail to address that a state- or district-issued variance has no effect on enforcing the underlying federal requirement unless the variance is submitted to and approved by EPA as a SIP revision.

We propose to disapprove the SIP revision for Rule 511.1 to avoid potential conflict with EPA's independent authorities provided in CAA section 113, section 114 and elsewhere.

D. Proposed Action and Public Comment

As authorized in section 110(k)(3) of the Act, we are proposing full disapproval of the submitted SCAQMD Rules 1610, 2202, 503.1, 504, and 511.1. There are no sanctions or Federal Implementation Plan (FIP) implications should EPA finalize this disapproval. Sanctions would not be imposed under CAA section 179(b) because the submittal of Rules 1610 and 2202 is discretionary (*i.e.,* not required to be included in the SIP). A FIP would not be imposed under CAA section 110(c)(1) because the disapproval does not reveal a deficiency in the SIP that such a FIP must correct. Specifically: (1) Rule 1610 is voluntary and only serves to provide for an alternative method of compliance for stationary and other emission sources subject to other District regulations that allow the use of credits as a compliance option; and (2) Rule 2202 is not a required CAA submittal because the CAA gives state and local agencies discretion, but does not require, employers ''to implement programs to reduce work-related vehicle trips and miles travelled by employees'' (see CAA section 182(d)(1)(B)). Additionally, at this time, we have not credited emission reductions from Rules 1610 or 2202 in an approved SIP and we are not aware of a SCAQMD plan submitted to EPA that relies on emission reductions from these rules to fulfill a CAA requirement. Accordingly, the failure of the SCAQMD to adopt revisions to Rules 1610 and 2202 would not adversely affect the SIP's compliance with the CAA's requirements, such as the requirements for section 182 ozone RACT, reasonable further progress, and attainment demonstrations. Rules 503.1, 504 and 511.1 regulate hearing board procedures and do not control emission sources or otherwise generate emission reductions nor are they required elements of the SIP. Thus, EPA does not need to impose sanctions or promulgate a FIP upon their disapproval. Note that the submitted rules have been adopted by the SCAQMD, and a final disapproval by the EPA would not prevent the local agency from enforcing them or the revised versions of these rules subsequently adopted by SCAQMD as a matter of State law.

We will accept comments from the public on the proposed disapproval for the next 30 days.

III. Statutory and Executive Order Reviews

A. Executive Order 12866, Regulatory Planning and Review

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

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,* because this proposed SIP disapproval under section 110 and subchapter I, part D of the Clean Air Act will not in-and-of itself create any new information collection burdens but simply disapproves certain State requirements for inclusion into the SIP. Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this proposed rule on small entities, I certify that this action will not have a significant impact on a substantial number of small entities. This proposed rule does not impose any requirements or create impacts on small entities. This proposed SIP disapproval under section 110 and subchapter I, part D of the Clean Air Act will not in-and-of itself create any new requirements but simply disapproves certain State requirements for inclusion into the SIP. Accordingly, it affords no opportunity for EPA to fashion for small entities less burdensome compliance or reporting requirements or timetables or exemptions from all or part of the rule. Therefore, this action will not have a significant economic impact on a substantial number of small entities.

We continue to be interested in the potential impacts of this proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This action contains no federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538, for State, local, or tribal governments or the private sector. EPA has determined that the proposed disapproval action does not include a federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This action proposes to disapprove pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

E. Executive Order 13132, Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, because it merely disapproves certain State requirements for inclusion into the SIP and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, Executive Order 13132 does not apply to this action.

F. Executive Order 13175, Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP rules EPA is proposing to disapprove would not apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets E.O. 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the E.O. has the potential to influence the regulation. This action is not subject to E.O. 13045 because it is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997). This proposed SIP disapproval under section 110 and subchapter I, part D of the Clean Air Act will not in-and-of itself create any new regulations but simply disapproves certain State requirements for inclusion into the SIP.

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

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

The EPA believes that this action is not subject to requirements of Section 12(d) of NTTAA because application of those requirements would be inconsistent with the Clean Air Act.

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

Executive Order (E.O.) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA lacks the discretionary authority to address environmental justice in this rulemaking.

List of Subjects in 40 CFR Part 52

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

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

Dated: October 30, 2015.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2015–29802 Filed 11–23–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2015–0593; A–1–FRL–9939–23–Region 1]

Air Plan Approval; ME; Repeal of the Maine's General Conformity Provision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Maine. This revision removes State Regulation Chapter 141 Conformity of General Federal Actions from the SIP.

DATES: Written comments must be received on or before December 24, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2015–0593 by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: arnold.anne@epa.gov.*
3. *Fax:* (617) 918–0047
4. *Mail:* ''EPA–R01–OAR–2015–0593'', Anne Arnold, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912.
5. *Hand Delivery or Courier.* Deliver your comments to: Anne Arnold, Manager, Air Quality Planning Unit, Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

Please see the direct final rule which is located in the Rules Section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Ariel Garcia, Air Quality Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912, telephone number (617) 918–1660, fax number (617) 918–0660, email *garcia.ariel@epa.gov* .

SUPPLEMENTARY INFORMATION: In the Final Rules Section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt

as final those provisions of the rule that are not the subject of an adverse comment.

For additional information, see the direct final rule which is located in the Rules Section of this **Federal Register**.

Dated: November 5, 2015.

H. Curtis Spalding,

Regional Administrator, EPA New England.

[FR Doc. 2015–29824 Filed 11–23–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 69

[WC Docket No. 05–25 and RM–10593; DA 15–1239]

Wireline Competition Bureau Extends Comment and Reply Comment Deadlines in Business Data Services (Also Referred to as Special Access Services) Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of comment and reply deadlines.

SUMMARY: In this document, the Wireline Competition Bureau grants in part a request seeking an extension to the comment and reply comment deadlines in the business data services (also referred to as special access services) rulemaking proceeding, *Special Access FNPRM.*

DATES: Comments may be filed on or before January 6, 2016, and reply comment comments may be filed by February 5, 2016.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Joseph Price, Pricing Policy Division, Wireline Competition Bureau, 202–418–1540 or *Joseph.Price@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, WC Docket 05–25, RM–10593, DA 15–1239, released November 2, 2015. This document does not contain information collection(s) subject to the Paperwork Act of 1995 (PRA), Public Law 104–93. In addition, therefore, it does not contain any new or modified ''information collection burdens[s] for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002. The full text of this document may be downloaded at the following Internet address: *http://transition.fcc.gov/Daily_Releases/Daily_Business/2015/db1102/DA-15-239A1.pdf.* To request alternative formats for persons with disabilities (*e.g.* accessible format documents, sign language, interpreters, CARTS, etc.), send an email to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 or (202) 418–0432 (TTY).

Background

In Section IV.B of the FNPRM accompanying the Data Collection Order, adopted on December 11, 2012, the Commission sought comment on possible changes to its rules for the business data services provided by incumbent local exchange carriers in price cap areas. The Commission set the comment deadlines on this portion of the *Special Access FNPRM,* 78 FR 2600 (Jan. 11, 2013), several months beyond the document's release date to allow interested parties opportunity to review the data and information collected before filing comments. The Bureau has extended these deadlines, upon request and in consideration of oppositions filed in response to the request for extensions of time, to allow interested parties adequate time to access and review the data and information collected. Accordingly, the deadline for filing comments is extended to January 6, 2016, and the deadline for reply comments is extended to February 5, 2016.

Federal Communications Commission.

Pamela Arluk,

Chief, Pricing Policy Division.

[FR Doc. 2015–29906 Filed 11–23–15; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 80, No. 226
Tuesday, November 24, 2015

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

Francis Marion-Sumter Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Francis Marion-Sumter Resource Advisory Committee (RAC) will meet in Columbia, South Carolina. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. Additional RAC information, including the meeting agenda and the meeting summary/minutes can be found at the following Web site: *http://www.fs.usda.gov/main/scnfs/workingtogether/advisorycommittees.*

DATES: The meeting will be held December 10, 2015, at 10:00 a.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 Harbision State Forest, Environmental Education Center, 5600 Broad River Road, Columbia, South Carolina.

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 Francis Marion and Sumter National Forest Headquarters. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Mary Morrison, RAC Coordinator, by phone at 803–561–4000 or via email *at mwmorrison@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:

1. Review project proposals; and
2. Recommend Title II projects.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by November 5, 2015, 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 to make oral comments must be sent to Mary Morrison, RAC Coordinator, 4931 Broad River Road, Columbia, South Carolina 29212; by email to *mwmorrison@fs.fed.us* or via facsimile to 803–561–4004.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: November 17, 2015.

John Richard Lint,

Forest Supervisor, Francis Marion and Sumter National Forest.

[FR Doc. 2015–29877 Filed 11–23–15; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Shasta-Trinity National Forest; California; Trinity Post Fire Hazard Reduction and Salvage

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The proposed action would treat approximately 8,100 acres to reduce hazardous conditions within a buffer along open roads that burned in the 2015 wildfires. Standing dead and downed trees would be utilized to the extent practicable.

DATES: Comments concerning the scope of the analysis must be received by December 24, 2015. The draft environmental impact statement is expected April 2016 and the final environmental impact statement is expected August 2016.

ADDRESSES: Send written comments to Trinity Post Fire Hazard Reduction and Salvage Project, Attn: Brenda Olson, Shasta-Trinity National Forest, 3644 Avtech Parkway, Redding, CA 96002. Comments may also be sent via email to *comments-pacificsouthwest-shasta-trinity@fs.fed.us,* or via facsimile to 530–226–2475.

FOR FURTHER INFORMATION CONTACT: Brenda Olson by phone at 530–226–2422, or by email at *brendaolson@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 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The Shasta-Trinity National Forest and Six Rivers National Forest have experienced wildfire on approximately 220,000 acres as a result of lighting in 2015. The majority of acres affected are the result of a July 30, 2015 lightning event. Much of the fire areas burned through National Forest System lands, but a number of private landowners were also affected. Approximately 161,000 acres of the Shasta-Trinity National Forest were burned. Wildfires affected most land allocations including designated Wilderness, Adaptive Management Areas, and Late-Successional Reserve, as well as Inventoried Roadless Areas. Fires burned in a mosaic of intensities; acres burned have been categorized into high, moderate and low severity based on Rapid Assessment of Vegetation Condition After Wildfire (RAVG) data. Five fire complexes and one separate

fire burned on the Shasta-Trinity National Forest:

- The Fork Complex near the communities of Hayfork, Post Mountain, and Wildwood (34,500 acres; 8,900 acres of high and moderate severity);
- The South Complex north and east of the community of Hyampom (29,400 acres; 5,900 acres high and moderate severity);
- The Mad River Complex near the communities of Mad River, Ruth, and Forest Glen (39,200 acres; 6,600 acres high and moderate severity);
- The Route Complex near the communities of Mad River and Hyampom (35,700 acres; 6,300 acres high and moderate severity);
- The River Complex near the Hoopa Reservation, the communities of Burnt Ranch and Denny, and within the Trinity Alps Wilderness Area (78,600 acres; 17,100 acres high and moderate severity); and
- The Saddle Fire northwest of the town of Hyampom (1,500 acres; 600 acres high and moderate severity).

A portion of the areas that burned at moderate and high severity had conifer forest cover prior to the fires (other acres were brush, grasslands or oak woodlands). The acres of conifer and mixed conifer forest that burned at high severity generally have no remaining live trees, and the areas that burned at moderate severity also have a high likelihood of deforestation or large pockets of mortality due to fire-injury. Many trees showing signs of live branches or tops immediately following the fire will be lost due to cambium death or secondary mortality from insects compounded by years of drought.

The areas affected by the 2015 wildfires on the Shasta-Trinity National Forest include vegetation along 387 miles of road (353 miles of National Forest System roads, 32 miles administered by state and county). Of these 387 miles, 248 miles are open to the public, including 233 miles through National Forest System lands. The vegetation along these roads experienced wildfire at varying degrees of intensity. Forested lands experiencing moderate and high intensity fire has resulted in a substantial number of dead and dying trees. Structural integrity of fire-killed trees has been compromised and it is expected many of them will fall during a wind or storm event.

Current conditions within the burned area differ from the desired condition as identified in the Shasta-Trinity National Forest Land and Resource Management Plan (Forest Plan; 1995). Trees that were killed by the fire become less stable and increase the risk to all forest users. Once this material is on the ground and combined with the dead brush, fire behavior is likely to be more intense and more difficult to control. Because of the expected future fire behavior and the elevated risk of fire killed trees falling on firefighters, wildfire suppression strategies would be limited. Desired future conditions would be safe firefighter and public access; conditions that lead to a slower rate of wildfire spread and reduced intensity, with associated increased effectiveness of initial attack by firefighters; and roadside conditions that could be used as a line of defense for control of wildfires.

Within areas experiencing large scale disturbance on the Shasta-Trinity National Forest in 2015 due to wildfire, the purpose of this project is to move towards the desired conditions in the following ways:

1. Reduce hazards (*i.e.* fire-killed trees and excessive fuels) that threaten public and firefighter safety along open National Forest System, County, and State roads;
2. Sustain and establish forest cover; and,
3. Within the treated areas, capture the economic value of felled trees and support the economies of local communities by providing forest products.

Based on the Forest Plan and post fire assessment, we have identified a need to:

- Provide for public safety and protection of structures by managing fuel loading, distribution and arrangement within Wildland Urban Interface for low flame lengths and rate of spread (Forest Plan 4–18);
- Remove danger/hazard trees (Forest Plan 4–26);
- Reduce surplus activity fuels that remain after meeting wildlife, riparian, soil and other environmental needs (Forest Plan, pg. 4–17);
- Create conditions that will support the restoration of fire to its natural role in the ecosystem (Forest Plan 4–4).
- Establish forest stands at densities appropriate to contribute to forest harvest in the future and to maintain wildlife habitat (Forest Plan, pg. 4–154).
- Quickly recover the monetary value of wood through salvage and sale, where feasible and appropriate, to provide economic stimulus to local communities (Forest Plan 4–5).

Proposed Action

Dead vegetation will be treated on National Forest System lands along 233 miles of roads open to the public (*i.e.* National Forest System Roads (NFS), county roads, and state highways) that burned during the 2015 wildfire season. Treatments are proposed along 233 miles of public roads which cross National Forest System lands, including:

- 153 miles of NFS Maintenance Level 2 (accessible with high clearance vehicles) roads;
- 34 miles of NFS Maintenance Level 3 (accessible with passenger cars) roads;
- 19 miles of NFS Maintenance Level 4 (paved) roads; and
- 27 miles of state and county roads.

Treatments along these roads could include:

- Remove or treat dead vegetation (using one of the ''treatment types'' listed below) within a 300 foot total width buffer. Width of the buffer on either side of the road would change but would always total 300 feet; *i.e.* if conditions lend to a wider treatment on the uphill side, the uphill side may be treated up to 275 feet from the road and the downhill side would be treated for 25 feet from the road. The area of treatment is approximately 8,100 acres. The minimum treatment area along either side of the road will be 25 feet. Treatment types for both initial entry and maintenance could include:
  - Hand felling of dead trees and brush. Dead vegetation will be identified at the time of treatment.
  - Mastication, which pulverizes or chops standing trees and logs into small particles. This treatment can include mowing, mulching, or chipping.
  - Lopping woody debris (slash) and scattering around the treated area, which redistributes woody material.
  - Hand piling slash, which reduces surface fuels.
  - Machine piling slash, which reduces surface fuels.
  - Pile burning, which reduces surface fuels.
  - Jackpot burning, which is a burning method used to reduce heavy intermittent fuel concentrations, where fuels are not continuous enough to carry a broadcast fire.
  - Broadcast burning, which is a burning method used where heavy continuous fuel concentrations exist.
  - Chipping, which pulverizes or chops trees, brush, and logs into small particles.
- Maintain treated areas through understory burning, where feasible.
- Utilize wood products whenever possible. This can include salvage logs, commercial or personal firewood, biomass removal, etc.
  - Large timber sales are expected to be feasible on up to 128 miles of the roads proposed for treatment.
- Provide for future forest cover through planting, utilizing a species

composition consistent with historic conditions, with spacing between seedlings of 18 to 30 feet.

- Create a control line on the outside edge of treatment areas where necessary to maintain fuel reductions with prescribed fire.
- Where appropriate, stumps of freshly cut conifers will be treated with an EPA-registered borate compound to prevent spread of Heterobasidion root disease.
- Trees or snags that are imminent hazards to the road and/or operations would felled; trees that are felled outside the treatment buffer would be left onsite.
- No treatments are proposed within Wilderness.
- Additional Resource Protection Measures will be developed to address resource concerns for wildlife, watersheds, soils and other issues that are identified.

Fuels reduction treatment goals are to:

- Reduce downed logs to 10–20 tons per acre. Downed logs includes woody material >3-inches in diameter including fuels created by salvage and suppression actions.
- Reduce dead brush by 50–100%.

Responsible Official

David R. Myers, Forest Supervisor, Shasta-Trinity National Forest.

Nature of Decision To Be Made

The Forest Supervisor will decide whether to implement the proposed action, take an alternative action that meets the purpose and need or take no action.

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. This project is within Wildland Urban Interface and as such is consistent with the Healthy Forest Restoration Act of 2003 (HFRA), which contains provisions to expedite hazardous fuels reduction and forest restoration projects on federal lands. Project authorized under HFRA are defined under Section 102(a) of the act and are designed to actively involve the public (Section 104(e) and (f) of the act). In an effort to provide for collaborative design of this project or alternatives, you are invited to participate in open public meetings at the following locations and times: Hyampom Community Center on November 30, 2015 at 5:00 p.m.; Weaverville Board of Supervisor's Chambers on December 1, 2015 at 5:00 p.m.; Trinity County Fairgrounds dining hall in Hayfork on December 2, 2015 at 5:00 p.m.; Ruth Lake Community Services District Hall in Mad River on December 3, 2015; and, Burnt Ranch School on December 4, 2015 at 5:00 p.m. Additional project information is available on the project Web site: *http://www.fs.usda.gov/project/?project=48060.*

It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the environmental impact statement. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and alternative means of meeting the purpose and need.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered; however, anonymous comments will not provide the respondent with standing to participate in subsequent administrative review or judicial review. An Emergency Situation Determination will be requested for this project consistent with regulations at 36 CFR 218.21. An Emergency Situation Determination would eliminate the 30-day Objection period prior to a decision.

Dated: November 17, 2015.

David R. Myers,

Forest Supervisor.

[FR Doc. 2015–29878 Filed 11–23–15; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Docket No.: 151106999–5999–01]

Call for Applications for the International Buyer Program Calendar Year 2017

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice and Call for Applications.

SUMMARY: In this notice, the U.S. Department of Commerce (DOC) International Trade Administration (ITA) announces that it will begin accepting applications for the International Buyer Program (IBP) for calendar year 2017 (January 1, 2017, through December 31, 2017). The announcement also sets out the objectives, procedures and application review criteria for the IBP. The purpose of the IBP is to bring international buyers together with U.S. firms in industries with high export potential at leading U.S. trade shows. Specifically, through the IBP, the ITA selects domestic trade shows which will receive ITA assistance in the form of global promotion in foreign markets, provision of export counseling to exhibitors, and provision of matchmaking services at the trade show. This notice covers selection for IBP participation during calendar year 2017.

DATES: Applications for the IBP must be received by Friday, January 8, 2016.

ADDRESSES: The application form can be found at *www.export.gov/ibp.* Applications may be submitted by any of the following methods: (1) Mail/Hand Delivery Service: International Buyer Program, Trade Promotion Programs, International Trade Administration, U.S. Department of Commerce, Ronald Reagan Building, 1300 Pennsylvania Ave. NW., Suite 800M—Mezzanine Level—Atrium North, Washington, DC 20004; (2) Facsimile: (202) 482–7800; or (3) email: *IBP2017@trade.gov.* Facsimile and email applications will be accepted as interim applications, but must be followed by a signed original application that is received by the program no later than five (5) business days after the application deadline. To ensure that applications are received by the deadline, applicants are strongly urged to send applications by express delivery service (*e.g.,* U.S. Postal Service Express Delivery, Federal Express, UPS, etc.).

FOR FURTHER INFORMATION CONTACT: Vidya Desai, Acting Director, International Buyer Program, Trade Promotion Programs, International Trade Administration, U.S. Department of Commerce, 1300 Pennsylvania Ave. NW., Ronald Reagan Building, Suite 800M—Mezzanine Level—Atrium North, Washington, DC 20004; Telephone (202) 482–2311; Facsimile: (202) 482–7800; Email: *IBP2017@trade.gov.*

SUPPLEMENTARY INFORMATION: The IBP was established in the Omnibus Trade and Competitiveness Act of 1988 (Pub. L. 100–418, codified at 15 U.S.C. 4724) to bring international buyers together with U.S. firms by promoting leading U.S. trade shows in industries with high export potential. The IBP emphasizes cooperation between the DOC and trade show organizers to benefit U.S. firms exhibiting at selected events and provides practical, hands-on assistance such as export counseling and market analysis to U.S. companies interested in exporting. Shows selected for the IBP will provide a venue for U.S. companies

interested in expanding their sales into international markets.

Through the IBP, ITA selects U.S. trade shows with participation by U.S. firms interested in exporting that ITA determines to be leading international trade shows, for promotion in overseas markets by U.S. Embassies and Consulates. The DOC is authorized to provide successful applicants with assistance in the form of overseas promotion of the show; outreach to show participants about exporting; recruitment of potential buyers to attend the events; and staff assistance in setting up international trade centers at the events. Worldwide promotion is executed through ITA officers at U.S. Embassies and Consulates in more than 70 countries representing the United States' major trading partners, and also in Embassies in countries where ITA does not maintain offices.

The International Trade Administration (ITA) is accepting applications from trade show organizers for the IBP for trade events taking place between January 1, 2017, and December 31, 2017. Selection of a trade show is valid for one event, *i.e.,* a trade show organizer seeking selection for a recurring event must submit a new application for selection for each occurrence of the event. For events that occur more than once in a calendar year, the trade show organizer must submit a separate application for each event.

For the IBP in calendar year 2017, the ITA expects to select approximately 20 events from among the applicants. The ITA will select those events that are determined to most clearly meet the statutory mandate in 15 U.S.C. 4721 to promote U.S. exports, especially those of small- and medium-sized enterprises, and the selection criteria articulated below.

There is no fee required to submit an application. If accepted into the program for calendar year 2017, a participation fee of $9,800 is required for shows of five days or fewer. For trade shows more than five days in duration, or requiring more than one International Trade Center, a participation fee of $15,000 is required. For trade shows ten days or more in duration, and/or requiring more than two International Trade Centers, the participation fee will be determined by DOC and stated in the written notification of acceptance. It would be calculated on a full cost recovery basis. Successful applicants will be required to enter into a Memorandum of Agreement (MOA) with ITA within 10 days of written notification of acceptance into the program. The participation fee (by check or credit card) is due within 30 days of written notification of acceptance into the program.

The MOA constitutes an agreement between ITA and the show organizer specifying which responsibilities for international promotion and export assistance services at the trade shows are to be undertaken by ITA as part of the IBP and, in turn, which responsibilities are to be undertaken by the show organizer. Anyone requesting application information will be sent a sample copy of the MOA along with the application and a copy of this **Federal Register** Notice. Applicants are encouraged to review the MOA closely as IBP participants are required to comply with all terms, conditions, and obligations in the MOA. Trade show organizer obligations include, but are not limited to, providing waived or reduced admission fees for international attendees who are participating in the IBP, the construction of an International Trade Center at the trade show, production of an export interest directory, and provision of complimentary hotel accommodations for DOC staff as explained in the MOA. One of the most important commitments is for the trade show organizer to: include in the terms and conditions of its exhibitor contracts provisions for the protection of intellectual property rights (IPR); to have procedures in place at the trade show to address IPR infringement which, at a minimum, provide information to help U.S. exhibitors procure legal representation during the trade show; and to agree to assist the DOC to reach and educate U.S. exhibitors on the Strategy Targeting Organized Piracy (STOP!), IPR protection measures available during the show, and the means to protect IPR in overseas markets, as well as in the United States. ITA responsibilities include, but are not limited to, the worldwide promotion of the trade show and, where feasible, recruitment of international buyers to that show, provision of on-site export assistance to U.S. exhibitors at the show, and the reporting of results to the show organizer.

Selection as an IBP partner does not constitute a guarantee by DOC of the show's success. IBP partnership status is not an endorsement of the show except as to its international buyer activities. Non-selection of an applicant for IBP partnership status should not be viewed as a determination that the event will not be successful in promoting U.S. exports.

Eligibility: All 2017 U.S. trade events are eligible to apply for IBP participation through the show organizer.

Exclusions: Trade shows that are either first-time or horizontal (non-industry specific) events generally will not be considered.

General Evaluation Criteria: The ITA will evaluate shows to be International Buyer Program partners using the following criteria:

(a) *Export Potential:* The trade show promotes products and services from U.S. industries that have high export potential, as determined by DOC sources, including industry analysts' assessment of export potential, ITA best prospects lists and U.S. export statistics.

(b) *Level of International Interest:* The trade show meets the needs of a significant number of overseas markets and corresponds to marketing opportunities as identified by ITA. Previous international attendance at the show may be used as an indicator of such interest.

(c) *Scope of the Show:* The event offers a broad spectrum of U.S. made products and services for the subject industry. Trade shows with a majority of U.S. firms as exhibitors will be given priority.

(d) *U.S. Content of Show Exhibitors:* Trade shows with exhibitors featuring a high percentage of products produced in the United States or products with a high degree of U.S. content will be preferred.

(e) *Stature of the Show:* The trade show is clearly recognized by the industry it covers as a leading event for the promotion of that industry's products and services both domestically and internationally, and as a showplace for the latest technology or services in that industry.

(f) *Level of Exhibitor Interest:* U.S. exhibitors have expressed interest in receiving international business visitors during the trade show. A significant number of U.S. exhibitors should be seeking to begin exporting or to expand their sales into additional export markets.

(g) *Level of Overseas Marketing:* There has been a demonstrated effort by the applicant to market this event and prior related events. For this criterion, the applicant should describe in detail, among other information, the international marketing program to be conducted for the event, and explain how efforts should increase individual and group international attendance.

(h) *Logistics:* The trade show site, facilities, transportation services, and availability of accommodations at the site of the exhibition (*i.e.* International Trade Center, interpreters) are capable of accommodating large numbers of

attendees whose native language will not be English.

(i) *Level of Cooperation:* The applicant demonstrates a willingness to cooperate with the ITA to fulfill the program's goals and adhere to the target dates set out in the MOA and in the event timetables, both of which are available from the program office (see the **FOR FURTHER INFORMATION CONTACT** section above). Past experience in the IBP will be taken into account in evaluating the applications received.

(j) *Delegation Incentives:* The IBP Office will be evaluating the level and/or range of incentives offered to delegations and/or delegation leaders recruited by U.S. overseas Embassies and Consulates. Examples of incentives to international visitors and to organized delegations include: Special organized events, such as receptions, meetings with association executives, briefings, and site tours; and complimentary accommodations for delegation leaders (beyond those required in the MOA). Review Process: ITA will evaluate all applications received based on the criteria set out in this notice. Vetting will include soliciting input from ITA industry analysts, as well as domestic and international field offices, focusing primarily on the export potential, level of international interest, and stature of the show. In reviewing applications, ITA will also consider scheduling and sector balance in terms of the need to allocate resources to support selected events.

Application Requirements: Show organizers submitting applications for the 2017 IBP are requested to submit: (1) A narrative statement addressing each question in the application, Form OMB 0625–0143 (found at *www.export.gov/ibp*); (2) a signed statement that ''The information submitted in this application is correct and the applicant will abide by the terms set forth in the Call for Applications for the 2017 International Buyer Program (January 1, 2017 through December 31, 2017);'' and (3) two copies of the application: one copy of the application printed on company letterhead, and one electronic copy of the application submitted on a CD–RW (preferably in Microsoft Word® format), on or before the deadline noted above. There is no fee required to apply. Applications for the IBP must be received by Friday, January 8, 2016. ITA expects to issue the results of its review process in April 2016.

Legal Authority: The statutory program authority for the ITA to conduct the International Buyer Program is 15 U.S.C. 4724. The DOC has the legal authority to enter into MOAs with show organizers under the provisions of the Mutual Educational and Cultural Exchange Act of 1961 (MECEA), as amended (22 U.S.C.s 2455(f) and 2458(c)). MECEA allows ITA to accept contributions of funds and services from firms for the purposes of furthering its mission.

The Office of Management and Budget (OMB) has approved the information collection requirements of the application to this program (Form OMB 0625–0143) under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (OMB Control No. 0625–0143). Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.

For further information please contact: Vidya Desai, Acting Director, International Buyer Program (*IBP2017@trade.gov*).

Frank Spector,

Trade Promotion Programs.

[FR Doc. 2015–29859 Filed 11–23–15; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Docket No.: 151106999–5999–01]

Call for Applications for the International Buyer Program Select Service for Calendar Year 2017

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice and call for applications.

SUMMARY: The U.S. Department of Commerce (DOC), International Trade Administration (ITA) announces that it will begin accepting applications for the International Buyer Program (IBP) Select service for calendar year 2017 (January 1, 2017, through December 31, 2017). This announcement sets out the objectives, procedures and application review criteria for IBP Select. Under IBP Select, ITA recruits international buyers to U.S. trade shows to meet with U.S. suppliers exhibiting at those shows. The main difference between IBP and IBP Select is that IBP offers worldwide promotion, whereas IBP Select focuses on promotion and recruitment in up to five international markets. Specifically, through the IBP Select, the DOC selects domestic trade shows that will receive DOC assistance in the form of targeted promotion and recruitment in up to five foreign markets, export counseling to exhibitors, and export counseling and matchmaking services at the trade show. This notice covers selection for IBP Select participation during calendar year 2017.

DATES: Applications for IBP Select must be received by Friday, January 8, 2016.

ADDRESSES: The application form can be found at *www.export.gov/ibp.* Applications may be submitted by any of the following methods: (1) *Mail/Hand Delivery Service* International Buyer Program, Trade Promotion Programs, International Trade Administration, U.S. Department of Commerce, Ronald Reagan Building, 1300 Pennsylvania Ave. NW., Suite 800—Mezzanine Level—Atrium North, Washington, DC 20004; (2) *Facsimile:* (202) 482–7800; or (3) *email: IBP2017@trade.gov.* Facsimile and email applications will be accepted as interim applications, and must be followed by a signed original application that is received by the program no later than five (5) business days after the application deadline. To ensure that applications are received by the deadline, applicants are strongly urged to send applications by express delivery service (*e.g.,* U.S. Postal Service Express Delivery, Federal Express, UPS, etc.).

FOR FURTHER INFORMATION CONTACT: Vidya Desai, Acting Director, International Buyer Program, Trade Promotion Programs, International Trade Administration, U.S. Department of Commerce, 1300 Pennsylvania Ave. NW., Ronald Reagan Building, Suite 800M—Mezzanine Level—Atrium North, Washington, DC 20004; Telephone (202) 482–2311; Facsimile: (202) 482–7800; Email: *IBP2017@trade.gov.*

SUPPLEMENTARY INFORMATION: The IBP was established in the Omnibus Trade and Competitiveness Act of 1988 (Pub. L. 100–418, title II, § 2304, codified at 15 U.S.C. 4724) to bring international buyers together with U.S. firms by promoting leading U.S. trade shows in industries with high export potential. The IBP emphasizes cooperation between the DOC and trade show organizers to benefit U.S. firms exhibiting at selected events and provides practical, hands-on assistance such as export counseling and market analysis to U.S. companies interested in exporting. Shows selected for the IBP Select will provide a venue for U.S. companies interested in expanding their sales into international markets.

Through the IBP, the DOC selects trade shows that DOC determines to be

leading trade shows with participation by U.S. firms interested in exporting. DOC provides successful applicants with assistance in the form of targeted overseas promotion of the show by U.S. Embassies and Consulates; outreach to show participants about exporting; recruitment of potential buyers to attend the events; and staff assistance in setting up and staffing international trade centers at the events. Targeted promotion in up to five markets can be executed through the overseas offices of ITA or in U.S. Embassies in countries where ITA does not maintain offices.

ITA is accepting applications for IBP Select from trade show organizers of trade events taking place between January 1, 2017, and December 31, 2017. Selection of a trade show for IBP Select is valid for one event. A trade show organizer seeking selection for a recurring event must submit a new application for selection for each occurrence of the event. For events that occur more than once in a calendar year, the trade show organizer must submit a separate application for each event.

There is no fee required to submit an application. For IBP Select in calendar year 2017, ITA expects to select approximately 8 events from among the applicants. ITA will select those events that are determined to most clearly support the statutory mandate in 15 U.S.C. 4721 to promote U.S. exports, especially those of small- and medium-sized enterprises, and that best meet the selection criteria articulated below. Once selected, applicants will be required to enter into a Memorandum of Agreement (MOA) with the DOC, and submit payment of the $6,000 2017 participation fee (by check or credit card) within 30 days of written notification of acceptance into IBP Select. The MOA constitutes an agreement between the DOC and the show organizer specifying which responsibilities for international promotion and export assistance services at the trade shows are to be undertaken by the DOC as part of the IBP Select and, in turn, which responsibilities are to be undertaken by the show organizer. Anyone requesting application information will be sent a sample copy of the MOA along with the application form and a copy of this **Federal Register** Notice. Applicants are encouraged to review the MOA closely, as IBP Select participants are expected to comply with all terms, conditions, and obligations in the MOA. Trade show organizer obligations include the construction of an International Trade Center at the trade show, production of an export interest directory, and provision of complimentary hotel accommodations for DOC staff as explained in the MOA. ITA responsibilities include targeted promotion of the trade show and, where feasible, recruitment of international buyers to that show from up to five target markets identified, provision of on-site export assistance to U.S. exhibitors at the show, and the reporting of results to the show organizer.

Selection as an IBP Select show does not constitute a guarantee by DOC of the show's success. IBP Select participation status is not an endorsement of the show except as to its international buyer activities. Non-selection of an applicant for IBP Select status should not be viewed as a determination that the event will not be successful in promoting U.S. exports. Eligibility: 2017 U.S. trade events with 1,350 or fewer exhibitors are eligible to apply, through the show organizer, for IBP Select participation. First-time events will also be considered. Exclusions: U.S. trade shows with over 1,350 exhibitors will not be considered for IBP Select. General Evaluation Criteria: ITA will evaluate applicants for IBP Select using the following criteria:

(a) Export Potential: The trade show promotes products and services from U.S. industries that have high export potential, as determined by DOC sources, including industry analysts' assessment of export potential, ITA best prospects lists, and U.S. export analysis.

(b) Level of International Interest: The trade show meets the needs of a significant number of overseas markets and corresponds to marketing opportunities as identified by ITA. Previous international attendance at the show may be used as an indicator.

(c) Scope of the Show: The event must offer a broad spectrum of U.S. made products and services for the subject industry. Trade shows with a majority of U.S. firms as exhibitors are given priority.

(d) U.S. Content of Show Exhibitors: Trade shows with exhibitors featuring a high percentage of products produced in the United States or products with a high degree of U.S. content will be preferred.

(e) Stature of the Show: The trade show is clearly recognized by the industry it covers as a leading event for the promotion of that industry's products and services both domestically and internationally, and as a showplace for the latest technology or services in that industry.

(f) Level of Exhibitor Interest: There is significant interest on the part of U.S. exhibitors in receiving international business visitors during the trade show. A significant number of U.S. exhibitors should be new-to-export or seeking to expand their sales into additional export markets.

(g) Level of Overseas Marketing: There has been a demonstrated effort by the applicant to market prior shows overseas. In addition, the applicant should describe in detail the international marketing program to be conducted for the event, and explain how efforts should increase individual and group international attendance.

(h) Level of Cooperation: The applicant demonstrates a willingness to cooperate with ITA to fulfill the program's goals and adhere to the target dates set out in the MOA and in the event timetables, both of which are available from the program office (see the **FOR FURTHER INFORMATION CONTACT** section above). Past experience in the IBP will be taken into account in evaluating the applications received.

(i) Delegation Incentives: Waived or reduced (by at least 50%) admission fees are required for international attendees who are participating in IBP Select. Delegation leaders also must be provided complimentary admission to the event. In addition, show organizers should offer a range of incentives to delegations and/or delegation leaders recruited by the DOC overseas posts. Examples of incentives to international visitors and to organized delegations include: Special organized events, such as receptions, meetings with association executives, briefings, and site tours; or complimentary accommodations for delegation leaders.

Review Process: ITA will vet all applications received based on the criteria set out in this notice. Vetting will include soliciting input from ITA industry analysts, as well as domestic and international field offices, focusing primarily on the export potential, level of international interest, and stature of the show. In reviewing applications, ITA will also consider sector and calendar diversity in terms of the need to allocate resources to support selected events.

Application Requirements: Show organizers submitting applications for 2017 IBP Select are required to submit: (1) A narrative statement addressing each question in the application, OMB 0625–0143 (found at *www.export.gov/ibp*); and (2) a signed statement that ''The above information provided is correct and the applicant will abide by the terms set forth in this Call for Applications for the International Buyer Program Select (January 1, 2017 through December 31, 2017);'' on or before the deadline noted above. Applications for IBP Select must be received by Friday, January 8, 2016. There is no fee required

to apply. ITA expects to issue the results of this process in April 2016.

Legal Authority: The statutory program authority for ITA to conduct the IBP is 15 U.S.C. 4724. ITA has the legal authority to enter into MOAs with show organizers under the provisions of the Mutual Educational and Cultural Exchange Act of 1961 (MECEA), as amended (22 U.S.C.s 2455(f) and 2458(c)). MECEA allows ITA to accept contributions of funds and services from firms for the purposes of furthering its mission.

The Office of Management and Budget (OMB) has approved the information collection requirements of the application to this program (0625–0143) under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (OMB Control No. 0625–0143). Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.

For further information please contact: Vidya Desai, Acting Director, International Buyer Program (*IBP2017@trade.gov*).

Frank Spector,

Acting Director, Trade Promotion Programs.

[FR Doc. 2015–29858 Filed 11–23–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of a public workshop.

SUMMARY: The Pacific Fishery Management Council (Council) and the NMFS Northwest and Southwest Fisheries Science Centers (NWFSC and SWFSC, respectively) will hold a public workshop to review and critique its groundfish stock assessment process in 2015. The Groundfish Stock Assessment Process Review Workshop is open to the public.

DATES: The Groundfish Stock Assessment Process Review Workshop will commence at 8:30 a.m. PT, Wednesday, December 9, 2015 and continue until 5:30 p.m. or as necessary to complete business for the day. The workshop will reconvene at 8:30 a.m. PT, Thursday, December 10, 2015 and continue until 5:30 p.m. or as necessary to complete business for the day

ADDRESSES: The Groundfish Stock Assessment Process Review Workshop will be held at Room 203, Fishery Sciences Building (FSH), University of Washington, 1122 NE Boat Street, Seattle, WA 98105.

FOR FURTHER INFORMATION CONTACT: Mr. John DeVore, Pacific Council; telephone: (503) 820–2413.

SUPPLEMENTARY INFORMATION: The purpose of the Groundfish Stock Assessment Process Review Workshop webinar is for participants in the Council's 2015 stock assessment process to consider the procedures used in 2015 to assess and update groundfish stock abundance and develop recommendations for improving the process for future assessments and future assessment reviews. No management actions will be decided in this workshop. Any recommendations developed at the workshop will be submitted for consideration by the Council at its March 2016 meeting in Sacramento, CA or its April 2016 meeting in Vancouver, WA (see the Council's Web site at *www.pcouncil.org* for future Council meeting agendas).

Although non-emergency issues not identified in the workshop agenda may come before the workshop participants for discussion, those issues may not be the subject of formal action during this workshop. Formal action at the workshop will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson Stevens Fishery Conservation and Management Act, provided the public has been notified of the workshop participants' intent to take final action to address the emergency.

Special Accommodations

This workshop is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820–2425 at least 5 days prior to the workshop date.

Dated: November 19, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–29891 Filed 11–23–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No.: PTO–P–2015–0075]

Grant of Interim Extension of the Term of U.S. Patent No. 5,808,146; fluciclovine (^{18}F)

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of Interim Patent Term Extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension under 35 U.S.C. 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 5,808,146.

FOR FURTHER INFORMATION CONTACT: Mary C. Till by telephone at (571) 272–7755; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313–1450; by fax marked to her attention at (571) 273–7755; or by email to *Mary.Till@uspto.gov.*

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to one year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On October 22, 2015, Emory University, the patent owner of record, timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of U.S. Patent No. 5,808,146. The patent claims the active ingredient fluciclovine (^{18}F) of the drug product Axumin™. The application for patent term extension indicates that New Drug Application (NDA) 208054 was submitted to the Food and Drug Administration (FDA) on September 28, 2015. In a letter dated October 8, 2015, FDA acknowledged receipt of NDA 208054 for ''Axumin™ ([F–18] Fluciclovine)''.

Review of the patent term extension application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for one year as required by 35 U.S.C. 156(d)(5)(B). Because the regulatory review period

has continued beyond the original expiration date of the patent, November 9, 2015, interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 5,808,146 is granted for a period of one year from the original expiration date of the patent.

Dated: November 18, 2015.

Robert Bahr,

Acting Deputy Commissioner for Patent Examination Policy, United States Patent and Trademark Office.

[FR Doc. 2015–29887 Filed 11–23–15; 8:45 am]

BILLING CODE 3510–16–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No: CFPB–2015–0051]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (Bureau) is requesting to renew the Office of Management and Budget (OMB) titled, ''Report of Terms of Credit Card Plans (FR 2572)''.

DATES: Written comments are encouraged and must be received on or before January 25, 2016 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Electronic: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552.
- *Hand Delivery/Courier:* Consumer Financial Protection Bureau (Attention: PRA Office), 1275 First Street NE., Washington, DC 20002.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or social security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.regulations.gov.* Requests for additional information should be directed to the Consumer Financial Protection Bureau, (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552, (202) 435–9575, or email: *PRA@cfpb.gov.* Please do not submit comments to this mailbox.

SUPPLEMENTARY INFORMATION:

Title of Collection: Report of Terms of Credit Card Plans (FR 2572).

OMB Control Number: 3170–0001.

Type of Review: Extension without change of a currently approved collection.

Affected Public: Private Sector.

Estimated Number of Respondents: 150.

Estimated Total Annual Burden Hours: 75.

Abstract: Form FR 2572 collects data on credit card pricing and availability from a sample of at least 150 financial institutions that offer credit cards. The data enable the Consumer Financial Protection Bureau (CFPB or the Bureau) to present information to the public on terms of credit card plans.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Dated: November 17, 2015.

Darrin A. King,

Paperwork Reduction Act Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2015–29818 Filed 11–23–15; 8:45 am]

BILLING CODE 4810–AM–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No: CFPB–2015–0048]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (Bureau) is proposing a new information collection titled, ''Financial Well-Being National Survey.''

DATES: Written comments are encouraged and must be received on or before January 25, 2016 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Electronic: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552.
- *Hand Delivery/Courier:* Consumer Financial Protection Bureau (Attention: PRA Office), 1275 First Street NE., Washington, DC 20002.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or social security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.regulations.gov.* Requests for additional information should be directed to the Consumer Financial Protection Bureau, (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552, (202) 435–9575, or email: *PRA@cfpb.gov. Please do not submit comments to this mailbox.*

SUPPLEMENTARY INFORMATION:

Title of Collection: Financial Well-Being National Survey.

OMB Control Number: 3170–XXXX.

Type of Review: New collection (Request for a new OMB control number).

Affected Public: Individuals.

Estimated Number of Respondents: 6,000.

Estimated Total Annual Burden Hours: 2,000.

Abstract: Under the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, the Bureau's Office of Financial Education is responsible for developing and implementing a strategy to improve the financial literacy of consumers that

includes measurable goals and initiatives, in consultation with the Financial Literacy and Education Commission, consistent with the National Strategy for Financial Literacy. In addition, the Office of Financial Protection for Older Americans within the Bureau is charged with conducting research to identify methods and strategies to educate and counsel seniors, and developing goals for programs that provide seniors with financial literacy and counseling.

Through prior research, the Bureau has determined that improvement in consumer financial well-being is the ultimate goal of such financial literacy initiatives. In order to inform our identification and development of financial literacy strategies that explicitly seek to improve consumer financial well-being, the Bureau plans to conduct a nationally representative survey to measure adult financial well-being and related concepts, as well as an oversample of adults age 62 and older to gather additional data relevant to the needs and experiences of older consumers. The specific goals of the survey are to (1) measure the level of financial well-being of American adults and key sub-populations; (2) quantitatively test previously developed hypotheses about the specific types of knowledge, behavior, traits and skills that may support higher levels of financial well-being; and (3) produce fully de-identified public use data files that will allow external researchers to examine additional questions about financial well-being and its drivers.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record.

Dated: November 17, 2015.

Darrin A. King,

Paperwork Reduction Act Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2015–29816 Filed 11–23–15; 8:45 am]

BILLING CODE 4810–AM–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No: CFPB–2015–0050]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (Bureau) is requesting to renew the Office of Management and Budget (OMB) approval for an existing information collection titled, ''Homeownership Counseling Amendments to the Real Estate Settlement Procedures Act (Regulation X) 12 CFR 1024.''

DATES: Written comments are encouraged and must be received on or before January 25, 2016 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Electronic: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552.
- *Hand Delivery/Courier:* Consumer Financial Protection Bureau (Attention: PRA Office), 1275 First Street NE., Washington, DC 20002.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or social security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.regulations.gov.* Requests for additional information should be directed to the Consumer Financial Protection Bureau, (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552, (202) 435–9575, or email: *PRA@cfpb.gov. Please do not submit comments to this mailbox.*

SUPPLEMENTARY INFORMATION:

Title of Collection: Homeownership Counseling Amendments to the Real Estate Settlement Procedures Act (Regulation X) 12 CFR 1024.

OMB Control Number: 3170–0025.

Type of Review: Request approval for an existing information collection.

Affected Public: Businesses and other for-profit entities.

Estimated Number of Respondents: 2,259.

Estimated Total Annual Burden Hours: 117,500.

Abstract: Regulation X implements the Real Estate Settlement Procedures Act, ensures that consumers are provided with more helpful information about the cost of the mortgage settlement and protected from unnecessarily high settlement charges caused by certain abusive practices. Regulation X contains information collections in the form of third party disclosures and recordkeeping requirements.

This amendment to Regulation X requires lenders to provide mortgage applicants a list of certified homeownership counselors at or soon after the time of their application. This requirement is meant to help applicants be informed about the process of applying for a mortgage, and receive additional non-biased guidance if desired.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record.

Dated: November 18, 2015.

Darrin A. King,

Paperwork Reduction Act Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2015–29815 Filed 11–23–15; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Revised Non-Foreign Overseas Per Diem Rates

AGENCY: Defense Travel Management Office, DoD.

ACTION: Notice of revised non-foreign overseas per diem rates.

SUMMARY: The Defense Travel Management Office is publishing Civilian Personnel Per Diem Bulletin Number 300. This bulletin lists revisions in the per diem rates prescribed for U.S. Government employees for official travel in Alaska, Hawaii, Puerto Rico, the Northern Mariana Islands and Possessions of the United States when applicable. AEA changes announced in Bulletin Number 194 remain in effect. Bulletin Number 300 is being published in the **Federal Register** to assure that travelers are paid per diem at the most current rates.

DATES: *Effective date:* December 1, 2015.

FOR FURTHER INFORMATION CONTACT: Ms. Sonia Malik, 571–372–1276.

SUPPLEMENTARY INFORMATION: This document gives notice of revisions in per diem rates prescribed by the Defense Travel Management Office for non-foreign areas outside the contiguous United States. It supersedes Civilian Personnel Per Diem Bulletin Number 299. Per Diem Bulletins published periodically in the **Federal Register** now constitute the only notification of revisions in per diem rates to agencies and establishments outside the Department of Defense. For more information or questions about per diem rates, please contact your local travel office. Civilian Bulletin 300 includes updated rates for Puerto Rico.

Dated: November 19, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Islands and Possessions of the United States by Federal Government civilian employees.

LOCALITY	MAXIMUM LODGING AMOUNT (A)	+	MEALS AND INCIDENTALS RATE (B)	=	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
ALASKA						
[OTHER]						
01/01 - 12/31	110		99		209	03/01/2015
ADAK						
11/01 - 03/31	150		70		220	03/01/2015
04/01 - 10/31	192		74		266	03/01/2015
ANCHORAGE [INCL NAV RES]						
05/16 - 09/30	339		126		465	07/01/2015
10/01 - 05/15	99		102		201	07/01/2015
BARROW						
01/01 - 12/31	177		78		255	03/01/2015
BARTER ISLAND LRRS						
01/01 - 12/31	110		99		209	04/01/2015
BETHEL						
01/01 - 12/31	179		94		273	03/01/2015
BETTLES						
01/01 - 12/31	175		79		254	03/01/2015
CAPE LISBURNE LRRS						
01/01 - 12/31	110		99		209	03/01/2015
CAPE NEWENHAM LRRS						
01/01 - 12/31	110		99		209	03/01/2015
CAPE ROMANZOF LRRS						
01/01 - 12/31	110		99		209	03/01/2015
CLEAR AB						
01/01 - 12/31	90		82		172	10/01/2006
COLD BAY LRRS						
01/01 - 12/31	110		99		209	03/01/2015
COLDFOOT						
01/01 - 12/31	165		70		235	10/01/2006
COPPER CENTER						
05/15 - 09/15	130		79		209	03/01/2015

LOCALITY	MAXIMUM LODGING AMOUNT (A)	+	MEALS AND INCIDENTALS RATE (B)	=	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
09/16 - 05/14	89		75		164	03/01/2015
CORDOVA						
01/01 - 12/31	95		77		172	03/01/2015
CRAIG						
04/01 - 09/30	129		77		206	06/01/2014
10/01 - 03/31	85		72		157	06/01/2014
DEADHORSE						
01/01 - 12/31	170		70		240	05/01/2014
DELTA JUNCTION						
05/01 - 09/30	169		60		229	03/01/2015
10/01 - 04/30	139		57		196	03/01/2015
DENALI NATIONAL PARK						
06/01 - 08/31	185		89		274	03/01/2015
09/01 - 05/31	109		82		191	03/01/2015
DILLINGHAM						
10/16 - 05/14	169		109		278	01/01/2011
05/15 - 10/15	185		111		296	01/01/2011
DUTCH HARBOR-UNALASKA						
01/01 - 12/31	135		79		214	03/01/2015
EARECKSON AIR STATION						
01/01 - 12/31	90		77		167	06/01/2007
EIELSON AFB						
05/15 - 09/15	154		85		239	03/01/2015
09/16 - 05/14	75		77		152	03/01/2015
ELFIN COVE						
01/01 - 12/31	225		68		293	03/01/2015
ELMENDORF AFB						
05/16 - 09/30	339		126		465	07/01/2015
10/01 - 05/15	99		102		201	07/01/2015
FAIRBANKS						
09/16 - 05/14	75		77		152	03/01/2015
05/15 - 09/15	154		85		239	03/01/2015
FOOTLOOSE						
01/01 - 12/31	175		18		193	10/01/2002

LOCALITY	MAXIMUM LODGING AMOUNT (A)	+	MEALS AND INCIDENTALS RATE (B)	=	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
FORT YUKON LRRS						
01/01 - 12/31	110		99		209	03/01/2015
FT. GREELY						
05/01 - 09/30	169		60		229	03/01/2015
10/01 - 04/30	139		57		196	03/01/2015
FT. RICHARDSON						
05/16 - 09/30	339		126		465	07/01/2015
10/01 - 05/15	99		102		201	07/01/2015
FT. WAINWRIGHT						
05/15 - 09/15	154		85		239	03/01/2015
09/16 - 05/14	75		77		152	03/01/2015
GAMBELL						
01/01 - 12/31	133		59		192	03/01/2015
GLENNALLEN						
05/15 - 09/15	130		79		209	03/01/2015
09/16 - 05/14	89		75		164	03/01/2015
HAINES						
01/01 - 12/31	107		101		208	01/01/2011
HEALY						
06/01 - 08/31	185		89		274	03/01/2015
09/01 - 05/31	109		82		191	03/01/2015
HOMER						
05/01 - 09/30	159		91		250	03/01/2015
10/01 - 04/30	89		84		173	03/01/2015
JB ELMENDORF-RICHARDSON						
05/16 - 09/30	339		126		465	07/01/2015
10/01 - 05/15	99		102		201	07/01/2015
JUNEAU						
05/01 - 09/30	159		90		249	03/01/2015
10/01 - 04/30	135		88		223	03/01/2015
KAKTOVIK						
01/01 - 12/31	165		86		251	10/01/2002
KAVIK CAMP						
01/01 - 12/31	250		71		321	03/01/2015

LOCALITY	MAXIMUM LODGING AMOUNT (A)	+	MEALS AND INCIDENTALS RATE (B)	=	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
KENAI-SOLDOTNA						
05/01 - 10/31	194		107		301	03/01/2015
11/01 - 04/30	84		96		180	03/01/2015
KENNICOTT						
01/01 - 12/31	229		102		331	03/01/2015
KETCHIKAN						
04/01 - 10/01	140		90		230	03/01/2015
10/02 - 03/31	99		85		184	03/01/2015
KING SALMON						
05/01 - 10/01	225		91		316	10/01/2002
10/02 - 04/30	125		81		206	10/01/2002
KING SALMON LRRS						
01/01 - 12/31	110		99		209	03/01/2015
KLAWOCK						
10/01 - 03/31	85		72		157	06/01/2014
04/01 - 09/30	129		77		206	06/01/2014
KODIAK						
10/01 - 04/30	100		74		174	03/01/2015
05/01 - 09/30	180		82		262	03/01/2015
KOTZEBUE						
01/01 - 12/31	219		95		314	03/01/2015
KULIS AGS						
05/16 - 09/30	339		126		465	07/01/2015
10/01 - 05/15	99		102		201	07/01/2015
MCCARTHY						
01/01 - 12/31	229		102		331	03/01/2015
MCGRATH						
01/01 - 12/31	160		82		242	07/01/2014
MURPHY DOME						
05/15 - 09/15	154		85		239	03/01/2015
09/16 - 05/14	75		77		152	03/01/2015
NOME						
01/01 - 12/31	165		108		273	03/01/2015
NUIQSUT						

LOCALITY	MAXIMUM LODGING AMOUNT (A)	+	MEALS AND INCIDENTALS RATE (B)	=	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
01/01 - 12/31	233		69		302	03/01/2015
OLIKTOK LRRS						
01/01 - 12/31	110		99		209	03/01/2015
PETERSBURG						
01/01 - 12/31	110		99		209	03/01/2015
POINT BARROW LRRS						
01/01 - 12/31	110		99		209	03/01/2015
POINT HOPE						
01/01 - 12/31	181		81		262	06/01/2014
POINT LAY						
01/01 - 12/31	265		72		337	07/01/2014
POINT LAY LRRS						
01/01 - 12/31	265		72		337	04/01/2015
POINT LONELY LRRS						
01/01 - 12/31	110		99		209	03/01/2015
PORT ALEXANDER						
01/01 - 12/31	155		61		216	03/01/2015
PORT ALSWORTH						
01/01 - 12/31	135		88		223	10/01/2002
PRUDHOE BAY						
01/01 - 12/31	170		70		240	05/01/2014
SELDOVIA						
10/01 - 04/30	89		84		173	03/01/2015
05/01 - 09/30	159		91		250	03/01/2015
SEWARD						
10/01 - 04/30	169		100		269	03/01/2015
05/01 - 09/30	207		104		311	03/01/2015
SITKA-MT. EDGECUMBE						
05/15 - 09/15	200		99		299	03/01/2015
09/16 - 05/14	139		93		232	03/01/2015
SKAGWAY						
04/01 - 10/01	140		90		230	03/01/2015
10/02 - 03/31	99		85		184	03/01/2015
SLANA						

LOCALITY	MAXIMUM LODGING AMOUNT (A)	+	MEALS AND INCIDENTALS RATE (B)	=	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
05/01 - 09/30	139		55		194	02/01/2005
10/01 - 04/30	99		55		154	02/01/2005
SPARREVOHN LRRS						
01/01 - 12/31	110		99		209	03/01/2015
SPRUCE CAPE						
10/01 - 04/30	100		74		174	03/01/2015
05/01 - 09/30	180		82		262	03/01/2015
ST. GEORGE						
01/01 - 12/31	220		68		288	03/01/2015
TALKEETNA						
01/01 - 12/31	100		89		189	10/01/2002
TANANA						
01/01 - 12/31	165		108		273	03/01/2015
TATALINA LRRS						
01/01 - 12/31	110		99		209	03/01/2015
TIN CITY LRRS						
01/01 - 12/31	110		99		209	03/01/2015
TOK						
05/15 - 09/30	100		72		172	03/01/2015
10/01 - 05/14	79		70		149	03/01/2015
UMIAT						
01/01 - 12/31	350		80		430	03/01/2015
VALDEZ						
04/16 - 09/16	189		98		287	03/01/2015
09/17 - 04/15	109		90		199	03/01/2015
WAINWRIGHT						
01/01 - 12/31	175		83		258	01/01/2011
WASILLA						
05/01 - 09/30	125		92		217	03/01/2015
10/01 - 04/30	90		89		179	03/01/2015
WRANGELL						
10/02 - 03/31	99		85		184	03/01/2015
04/01 - 10/01	140		90		230	03/01/2015
YAKUTAT						

LOCALITY		MAXIMUM LODGING AMOUNT (A)	+	MEALS AND INCIDENTALS RATE (B)	=	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
	01/01 - 12/31	105		94		199	01/01/2011
AMERICAN SAMOA							
AMERICAN SAMOA							
	01/01 - 12/31	139		69		208	06/01/2015
GUAM							
GUAM (INCL ALL MIL INSTAL)							
	01/01 - 12/31	159		87		246	07/01/2015
JOINT REGION MARIANAS (ANDERSEN)							
	01/01 - 12/31	159		87		246	07/01/2015
JOINT REGION MARIANAS (NAVAL BASE)							
	01/01 - 12/31	159		87		246	07/01/2015
HAWAII							
[OTHER]							
	01/01 - 12/31	142		108		250	06/01/2015
CAMP H M SMITH							
	01/01 - 12/31	177		117		294	06/01/2015
EASTPAC NAVAL COMP TELE AREA							
	01/01 - 12/31	177		117		294	06/01/2015
FT. DERUSSEY							
	01/01 - 12/31	177		117		294	06/01/2015
FT. SHAFTER							
	01/01 - 12/31	177		117		294	06/01/2015
HICKAM AFB							
	01/01 - 12/31	177		117		294	06/01/2015
HONOLULU							
	01/01 - 12/31	177		117		294	06/01/2015
ISLE OF HAWAII: HILO							
	01/01 - 12/31	142		108		250	06/01/2015
ISLE OF HAWAII: OTHER							
	01/01 - 12/31	189		142		331	06/01/2015
ISLE OF KAUAI							
	01/01 - 12/31	305		146		451	06/01/2015
ISLE OF MAUI							
	01/01 - 12/31	259		146		405	06/01/2015

LOCALITY	MAXIMUM LODGING AMOUNT (A)	+	MEALS AND INCIDENTALS RATE (B)	=	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
ISLE OF OAHU						
01/01 - 12/31	177		117		294	06/01/2015
JB PEARL HARBOR-HICKAM						
01/01 - 12/31	177		117		294	06/01/2015
KEKAHA PACIFIC MISSILE RANGE FAC						
01/01 - 12/31	305		146		451	06/01/2015
KILAUEA MILITARY CAMP						
01/01 - 12/31	142		108		250	06/01/2015
LANAI						
01/01 - 12/31	229		103		332	06/01/2015
LUALUALEI NAVAL MAGAZINE						
01/01 - 12/31	177		117		294	06/01/2015
MCB HAWAII						
01/01 - 12/31	177		117		294	06/01/2015
MOLOKAI						
01/01 - 12/31	157		86		243	06/01/2015
NAS BARBERS POINT						
01/01 - 12/31	177		117		294	06/01/2015
PEARL HARBOR						
01/01 - 12/31	177		117		294	06/01/2015
PMRF BARKING SANDS						
01/01 - 12/31	305		146		451	06/01/2015
SCHOFIELD BARRACKS						
01/01 - 12/31	177		117		294	06/01/2015
TRIPLER ARMY MEDICAL CENTER						
01/01 - 12/31	177		117		294	06/01/2015
WHEELER ARMY AIRFIELD						
01/01 - 12/31	177		117		294	06/01/2015
MIDWAY ISLANDS						
MIDWAY ISLANDS						
01/01 - 12/31	125		81		206	06/01/2015
NORTHERN MARIANA ISLANDS						
[OTHER]						
01/01 - 12/31	99		102		201	07/01/2015

LOCALITY		MAXIMUM LODGING AMOUNT (A)	+	MEALS AND INCIDENTALS RATE (B)	=	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
ROTA							
	01/01 - 12/31	130		107		237	07/01/2015
SAIPAN							
	01/01 - 12/31	140		98		238	07/01/2015
TINIAN							
	01/01 - 12/31	99		102		201	07/01/2015
PUERTO RICO							
[OTHER]							
	01/01 - 12/31	109		112		221	06/01/2012
AGUADILLA							
	01/01 - 12/31	171		84		255	11/01/2015
BAYAMON							
	06/01 - 11/30	167		88		255	12/01/2015
	12/01 - 05/31	195		88		283	12/01/2015
CAROLINA							
	06/01 - 11/30	167		88		255	12/01/2015
	12/01 - 05/31	195		88		283	12/01/2015
CEIBA							
	01/01 - 12/31	139		92		231	10/01/2012
CULEBRA							
	01/01 - 12/31	150		98		248	03/01/2012
FAJARDO [INCL ROOSEVELT RDS NAVSTAT]							
	01/01 - 12/31	139		92		231	10/01/2012
FT. BUCHANAN [INCL GSA SVC CTR, GUAYNABO]							
	12/01 - 05/31	195		88		283	12/01/2015
	06/01 - 11/30	167		88		255	12/01/2015
HUMACAO							
	01/01 - 12/31	139		92		231	10/01/2012
LUIS MUNOZ MARIN IAP AGS							
	06/01 - 11/30	167		88		255	12/01/2015
	12/01 - 05/31	195		88		283	12/01/2015
LUQUILLO							
	01/01 - 12/31	139		92		231	10/01/2012
MAYAGUEZ							

LOCALITY		MAXIMUM LODGING AMOUNT (A)	+	MEALS AND INCIDENTALS RATE (B)	=	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
	01/01 - 12/31	109		112		221	09/01/2010
PONCE							
	01/01 - 12/31	149		89		238	09/01/2012
RIO GRANDE							
	01/01 - 12/31	169		123		292	06/01/2012
SABANA SECA [INCL ALL MILITARY]							
	06/01 - 11/30	167		88		255	12/01/2015
	12/01 - 05/31	195		88		283	12/01/2015
SAN JUAN & NAV RES STA							
	12/01 - 05/31	195		88		283	12/01/2015
	06/01 - 11/30	167		88		255	12/01/2015
VIEQUES							
	01/01 - 12/31	175		95		270	03/01/2012
VIRGIN ISLANDS (U.S.)							
ST. CROIX							
	04/15 - 12/14	247		110		357	06/01/2015
	12/15 - 04/14	299		116		415	06/01/2015
ST. JOHN							
	05/01 - 12/03	170		107		277	08/01/2015
	12/04 - 04/30	230		113		343	08/01/2015
ST. THOMAS							
	01/01 - 12/31	240		112		352	08/01/2015
WAKE ISLAND							
WAKE ISLAND							
	01/01 - 12/31	173		66		239	07/01/2014

[FR Doc. 2015–29875 Filed 11–23–15; 8:45 am]
BILLING CODE 5001–06–C

DEPARTMENT OF EDUCATION

[Docket No.: ED–2015–ICCD–0097]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Natural Experiments and Model Career-Focused Schools: An Environmental Scan

AGENCY: Technical and Adult Education (OCTAE), Office of Career, Department of Education.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before December 24, 2015.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2015–ICCD–0097. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E105, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Braden Goetz, 202–245–7405.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Natural Experiments and Model Career-Focused Schools: An Environmental Scan.

OMB Control Number: 1830–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local and Tribal Governments.

Total Estimated Number of Annual Responses: 100.

Total Estimated Number of Annual Burden Hours: 25.

Abstract: The purpose of this collection is to determine the extent to which there are natural circumstances that approximate random assignment among a group of college- and career-focused schools that belong to one or more school reform networks. A survey will be administered to principals of these schools to determine if they are oversubscribed and use lotteries for student admission. If a sufficient number of schools with such practices are identified, future research could use these naturally occurring experimental conditions to investigate differences in the outcomes achieved by students who attend these types of schools.

Dated: November 18, 2015.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2015–29847 Filed 11–23–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–306–B]

Application To Export Electric Energy; MAG Energy Solutions, Inc.

AGENCY: Office of Electricity Delivery and Energy Reliability, DOE.

ACTION: Notice of application.

SUMMARY: MAG Energy Solutions, Inc. (Applicant or MAG E.S.) has applied to renew its authority to transmit electric energy from the United States to Canada pursuant to section 202(e) of the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before December 24, 2015.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed to: Office of Electricity Delivery and Energy Reliability, Mail Code: OE–20, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585–0350. Because of delays in handling conventional mail, it is recommended that documents be transmitted by overnight mail, by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to 202–586–8008.

SUPPLEMENTARY INFORMATION: Exports of electricity from the United States to a foreign country are regulated by the Department of Energy (DOE) pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b), 7172(f)) and require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On March 30, 2011, DOE issued Order No. EA–306–A to MAG E.S., which authorized the Applicant to transmit electric energy from the United States to Canada as a power marketer for a five-year term using existing international transmission facilities. That authority expires on April 6, 2016. On November 3, 2015, MAG E.S. filed an application with DOE for renewal of the export authority contained in Order No. EA–306 for an additional five-year term.

In its application, MAG E.S. states that it does not own or operate any electric generation or transmission facilities, and it does not have a franchised service area. The electric energy that MAG E.S. proposes to export to Canada would be surplus energy purchased from third parties such as electric utilities and Federal power marketing agencies pursuant to voluntary agreements. The existing international transmission facilities to be utilized by MAG E.S. have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC)

Rules of Practice and Procedures (18 CFR 385.211). Any person desiring to become a party to these proceedings should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214). Five copies of such comments, protests, or motions to intervene should be sent to the address provided above on or before the date listed above.

Comments and other filings concerning MAG E.S.'s application to export electric energy to Canada should be clearly marked with OE Docket No. EA–306–B. An additional copy is to be provided directly to both Ruta Kalvaitis Skucas, Pierce Atwood LLC., 900 17th Street NW., Suite 350, Washington, DC 20006 and Simon Pelletier, MAG Energy Solutions, Inc., 999 de Maisonneuve Boulevard West, Suite 875, Montreal, Quebec H3A 3L4 Canada.

A final decision will be made on this application after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after a determination is made by DOE that the proposed action will not have an adverse impact on the sufficiency of supply or reliability of the U.S. electric power supply system.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above, by accessing the program Web site at *http://energy.gov/node/11845,* or by emailing Angela Troy at *Angela.Troy@hq.doe.gov.*

Issued in Washington, DC, on November 18, 2015.

Christopher Lawrence,

Electricity Policy Analyst, Office of Electricity Delivery and Energy Reliability.

[FR Doc. 2015–29885 Filed 11–23–15; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9939–18–ORD; Docket ID No. EPA–HQ–ORD–2013–0357]

Draft Integrated Science Assessment for Sulfur Oxides—Health Criteria

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 60-day public comment period for the draft document titled, ''External Review Draft Integrated Science Assessment for Sulfur Oxides—Health Criteria'' (EPA/600/R–15/066). The draft document was prepared by the National Center for Environmental Assessment (NCEA) within the EPA's Office of Research and Development as part of the review of the primary (health-based) National Ambient Air Quality Standards (NAAQS) for sulfur dioxide (SO_2). The Integrated Science Assessment (ISA), in conjunction with additional technical and policy assessments, provides the scientific basis for the EPA's decisions on the adequacy of the current NAAQS and the appropriateness of possible alternative standards. EPA intends to develop a separate ISA as part of an independent review for the secondary (welfare-based) NAAQS for oxides of nitrogen and sulfur.

EPA is releasing this draft document to seek review by the Clean Air Scientific Advisory Committee (CASAC) and the public (meeting date and location to be specified in a separate **Federal Register** notice). This draft document is not final as described in EPA's information quality guidelines, and it does not represent, and should not be construed to represent, Agency policy or views. When revising the document, EPA will consider any public comments submitted during the 60-day comment period in response to this notice.

DATES: The 60-day public comment period begins on November 24, 2015, and ends on January 25, 2016. Comments must be received on or before January 25, 2016.

ADDRESSES: The ''External Review Draft Integrated Science Assessment for Sulfur Oxides—Health Criteria'' will be available primarily via the Internet on EPA's Integrated Science Assessment for Sulfur Dioxide (Health Criteria) home page at *http://www2.epa.gov/isa/integrated-science-assessment-isa-sulfur-dioxide-health-criteria* or the public docket at *http://www.regulations.gov,* Docket ID: EPA–HQ–ORD–2013–0357. A limited number of CD–ROM copies will be available. Contact Ms. Marieka Boyd by phone: 919–541–0031; fax: 919–541–5078; or email: *boyd.marieka@epa.gov* to request a CD–ROM, and please provide your name, your mailing address, and the document title, ''External Review Draft Integrated Science Assessment for Sulfur Oxides—Health Criteria'' to facilitate processing of your request.

FOR FURTHER INFORMATION CONTACT: For information on the public comment period, contact the ORD Docket at the EPA Headquarters Docket Center; telephone: 202–566–1752; facsimile: 202–566–9744; or email: *Docket_ORD@epa.gov.*

For technical information, contact Dr. Tom Long, NCEA; telephone: 919–541–1880; facsimile: 919–541–1818; or email: *long.tom@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Information About the Document

Section 108(a) of the Clean Air Act directs the Administrator to identify certain pollutants which, among other things, ''cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare'' and to issue air quality criteria for them. These air quality criteria are to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air. . . .'' Under section 109 of the Act, EPA is then to establish NAAQS for each pollutant for which EPA has issued criteria. Section 109(d) of the Act subsequently requires periodic review and, if appropriate, revision of existing air quality criteria to reflect advances in scientific knowledge on the effects of the pollutant on public health or welfare. EPA is also required to review and, if appropriate, revise the NAAQS, based on the revised air quality criteria (for more information on the NAAQS review process, see *http://www.epa.gov/ttn/naaqs/review.html*).

Sulfur oxides are one of six criteria pollutants for which EPA has established NAAQS. Periodically, EPA reviews the scientific basis for these standards by preparing an ISA (formerly called an Air Quality Criteria Document). The ISA, in conjunction with additional technical and policy assessments, provides the scientific basis for the EPA's decisions on the adequacy of the current NAAQS and the appropriateness of possible alternative standards. The CASAC, an independent science advisory committee whose review and advisory functions are mandated by Section 109(d)(2) of the Clean Air Act, is charged (among other things) with independent scientific review of the EPA's air quality criteria.

On May 10, 2013 (78 FR 27387), EPA formally initiated its current review of the air quality criteria for the health effects of sulfur oxides and the primary (health-based) SO_2 NAAQS, requesting the submission of recent scientific information on specified topics. EPA held a workshop on June 12 and 13, 2013, to discuss with invited scientific experts, both internal and external to the EPA, key science and policy issues relevant to the review of the health effects of sulfur oxides (78 FR 27387). These science and policy issues were incorporated in EPA's ''Integrated Review Plan for the Primary National

Ambient Air Quality Standard for Sulfur Dioxide'' (EPA–452/R–14–007), which was finalized in October 2014 with a prior draft available for public comment (79 FR 14035) and discussion by the CASAC via publicly accessible teleconference consultations (79 FR 16325, 79 FR 30137, 79 FR 34739). On June 23–24, 2014, EPA held a workshop to discuss, with invited internal and external scientific experts, initial draft materials prepared in the development of the ISA (79 FR 33750).

The ''External Review Draft Integrated Science Assessment for Sulfur Oxides—Health Criteria'' will be discussed at a public meeting for review by CASAC and the public. In addition to the public comment period announced in this notice, the public will have an opportunity to address CASAC. A separate **Federal Register** notice will inform the public of the exact date and time of the CASAC meeting and of the procedures for public participation.

II. How To Submit Technical Comments to the Docket at www.regulations.gov

Submit your comments, identified by Docket ID No. EPA–HQ–ORD–2013–0357, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: Docket_ORD@epa.gov.*
- *Fax:* 202–566–9744.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center (ORD Docket), Mail Code: 28221T, 1200 Pennsylvania Avenue NW., Washington, DC 20460. The phone number is 202–566–1752.
- *Hand Delivery:* The ORD Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202–566–1744. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. If you provide comments by mail or hand delivery, please submit three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

Instructions: Direct your comments to Docket ID No. EPA–HQ–ORD–2013–0357. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked ''late,'' and may only be considered if time permits. It is the EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at *www.regulations.gov,* including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information through *www.regulations.gov* or email that you consider to be CBI or otherwise protected. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket visit the EPA Docket Center homepage at *http://www2.epa.gov/dockets.*

Docket: Documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the ORD Docket in the EPA Headquarters Docket Center.

Dated: November 6, 2015.

Mary A. Ross,

Deputy Director, National Center for Environmental Assessment.

[FR Doc. 2015–29800 Filed 11–23–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

FCC To Hold Open Commission Meeting Thursday, November 19, 2015

November 12, 2015.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, November 19, 2015, 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	Public Safety and Homeland Security	Title: Improving Wireless Emergency Alerts and Community-Initiated Alerting (PS Docket No. 15–91). Summary: The Commission will consider a Notice of Proposed Rulemaking that would improve the effectiveness of WEA message content and the geographic targeting of WEA messages, and facilitate WEA testing and proficiency training.
2	Wireless Tele-Communications	Title: Amendment of the Commission's Rules Governing Hearing Aid Compatible Mobile Handsets (WT Docket No. 07–250). Summary: The Commission will consider a Report and Order and Notice of Proposed Rulemaking that would update the scope of the wireless hearing aid compatibility rules and seek comment on additional measures that would ensure greater deployment of hearing aid compatible wireless handsets.

Item No.	Bureau	Subject
3	Media	Title: Accessibility of User Interfaces, and Video Programming Guides and Menus (MB Docket No. 12–108). Summary: The Commission will consider a Second Report and Order, Order on Reconsideration, and Second Further Notice of Proposed Rulemaking to provide consumers with better information about the availability of accessible devices and features, and create easier access to video programming and closed captioning on devices.
*	*	* * * *
Consent Agenda		
The Commission will consider the following subjects listed below as a consent agenda and these items will not be presented individually:		
1	Enforcement	Title: Enforcement Bureau Order. Summary: The Commission will consider an Order concerning an Application for Review.
2	Media	Title: Bellizzi Broadcasting Network, Inc. Station WEYW–LP, Key West, Florida Summary: The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by Bellizzi Broadcasting Network, Inc. seeking review of a Media Bureau Order on Reconsideration finding WEYW is not a qualified low-power television station.
3	Media	Title: Hawaii Public Radio, Inc. for a New Noncommercial Educational FM station at Kailua, Hawaii, et al. Summary: The Commission will consider a Memorandum Opinion and Order concerning Applications for Review filed by Wren Communications, Inc., Cedar Cove Broadcasting, Inc. and Kanu O Ka Aina Learning Ohana seeking review the Media Bureau's decisions regarding NCE MX Group 510.
4	Media	Title: Susquehanna Radio Corp. and Whitley Media, LLC Application for Consent to Assignment of License and Cancellation of License for DKTDK(FM), Sanger, Texas. Summary: The Commission will consider a Memorandum Opinion and Order concerning Petitions for Reconsideration filed by Whitley Media and North Texas Radio Group seeking review of a Commission Order regarding the Petitioners standing to challenge the cancellation of DKTDK(FM).
5	Media	Title: Christian Broadcasting of East Point, Inc. Applications to Renew and Assign the License of DWTJH(AM), East Point, GA. Summary: The Commission will consider a Memorandum Opinion and Order concerning two Applications for Review filed by Praise 95, Inc. and Christian Broadcasting of East Point, Inc. seeking review of a Media Bureau decision finding that the license of DWTJH(AM) had forfeited.

The meeting site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, and assistive listening devices will be provided on site. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted, but may be impossible to fill. Send an email to: *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Additional information concerning this meeting may be obtained from the Office of Media Relations, (202) 418–0500; TTY 1–888–835–5322. Audio/Video coverage of the meeting will be broadcast live with open captioning over the Internet from the FCC Live Web page at *www.fcc.gov/live.*

For a fee this meeting can be viewed live over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the Internet. To purchase these services, call (703) 993–3100 or go to *www.capitolconnection.gmu.edu.*

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2015–29849 Filed 11–23–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0349]

Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communication Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to

any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before December 24, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@omb.eop.gov;* and to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page <*http://www.reginfo.gov/public/do/PRAMain*>, (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0349.

Title: Equal Employment Opportunity (''EEO'') Policy, 47 CFR Sections 73.2080, 76.73, 76.75, 76.79 and 76.1702.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; not for profit institutions.

Number of Respondents and Responses: 14,179 respondents; 14,179 responses.

Estimated Time per Response: 42 hours.

Frequency of Response: Recordkeeping requirement; annual reporting requirement; five year reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority which covers this information collection is contained in Section 154(i) and 303 of the Communications Act of 1934, as amended, and Section 634 of the Cable Communications Policy Act of 1984.

Total Annual Burden: 595,518 hours.

Total Annual Cost: No cost.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: 47 CFR Section 73.2080 provides that equal opportunity in employment shall be afforded by all broadcast stations to all qualified persons and no person shall be discriminated against in employment by such stations because of race, color, religion, national origin or sex. Section 73.2080 requires that each broadcast station employment unit with 5 or more full-time employees shall establish, maintain and carry out a program to assure equal opportunity in every aspect of a broadcast station's policy and practice. These same requirements also apply to Satellite Digital Audio Radio Service (''SDARS'') licensees.

Revised Information Collection Requirement: In 1997, the Commission determined that SDARS licensees must comply with the Commission's EEO requirements. See Establishment of Rules and Policies for the Digital Audio Radio Satellite Service in the 2310–2360 MHz Frequency Band, 12 FCC Rcd 5754, 5791,) 91 (1997) (''1997 SDARS Order''), FCC 97–70. In 2008, the Commission clarified that SDARS licensees must comply with the Commission's EEO broadcast rules and policies, including the same recruitment, outreach, public file, Web site posting, record-keeping, reporting, and self-assessment obligations required of broadcast licensees, consistent with 47 CFR 73.2080, as well as any other Commission EEO policies. See Applications for Consent to the Transfer of Control of Licenses, SM Satellite Radio Holdings Inc., Transferor, to Sirius Satellite Radio Inc., Transferee, 23 FCC Rcd 12348, 12426,) 174, and note 551 (2008) (''XM-Sirius Merger Order'').

The Commission is making this submission to the Office of Management and Budget for approval to add SDARS licensees to this information collection.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer. Office of the Secretary.

[FR Doc. 2015–29850 Filed 11–23–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

[Docket No. 15–11]

Igor Ovchinnikov, Irina Rzaeva, and Denis Nekipelov v. Michael Hitrinov a/k/a Michael Khitrinov, Empire United Lines Co., Inc., and Carcont, Ltd.; Notice of Filing of Complaint and Assignment

Notice is given that a complaint has been filed with the Federal Maritime Commission (Commission) by Igor Ovchinnikov, Irina Rzaeva, and Denis Nekipelov, hereinafter ''Complainants,'' against Michael Hitrinov (''Hitrinov''), Empire United Lines Co., Inc. (''EUL'') and CarCont Ltd. (''CarCont''), hereinafter ''Respondents.'' Complainants state that they are individuals residing in the Russian Federation. Complainants allege that Respondent EUL is a New York corporation and a licensed non-vessel-operating common carrier, Respondent CarCont is a company in Finland, and Respondent Hitrinov is the owner of both EUL and CarCont.

Complainants allege that Respondents have violated the Shipping Act, 46 U.S.C. 40301, 40302, 40501, 40701, 41102, 41104, 41106, and the Commission's regulations at 46 CFR part 515, in connection with shipment of 3 vehicles. Complainants allege that each Complainant purchased a vehicle, which vehicles were shipped to Finland but never released or delivered because of unpaid loans due Respondents by the seller of the vehicles, affiliates G-Auto Sales, Inc. and Effect Auto Sales Inc. Complainant Igor Ovchinnikov seek damages in excess of $28,960. Complainant Irina Rzaeva seek damages in excess of $32,101. Complainant Denis Nekipelov seek damages in excess of $19,920.

Complainants request that: ''(1) Respondents be required to answer the charges herein; (2) that after due hearing, an order be made commanding said Respondent to pay to Complainants by way of reparations for the unlawful conduct . . . with interest and attorney's fees or such other sum as the Commission may determine to be proper as an award of reparation; (3) that the Commission issue an Order holding that the Respondents . . . violated the Shipping Act of 1984; (4) that the Commission Order the Respondents to provide Empire United Lines Co., Inc.'s house bills of lading for the shipments described herein; and (5) that the Commission issue such other and further order or orders as the Commission determines to be just and proper.''

The full text of the complaint can be found in the Commission's Electronic Reading Room at *www.fmc.gov/15-11.*

This proceeding has been assigned to the Office of Administrative Law Judges. The initial decision of the presiding officer in this proceeding shall be issued by November 17, 2016, and the final decision of the Commission shall be issued by May 16, 2017.

Karen V. Gregory,

Secretary.

[FR Doc. 2015–29856 Filed 11–23–15; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than December 9, 2015.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Thomas P. Haleas, Clarendon Hills, Illinois, Peter J. Haleas, Evanston, Illinois, Peter E. Haleas Sarasota, Florida, and Sophia M. Haleas,* Clarendon Hills, Illinois, as a group acting in concert; to retain voting shares of Bridgeview Bancorp, Inc., and thereby indirectly retain voting shares of Bridgeview Bank Group, both in Bridgeview, Illinois.

Board of Governors of the Federal Reserve System, November 19, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–29869 Filed 11–23–15; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–AD–2015–01; Docket 2015–0002; Sequence 31]

Notice of the 2016 Presidential Transition Directory

AGENCY: Presidential Transition, General Services Administration.

ACTION: Notice of availability of the General Services Administration 2016 Presidential Transition Directory.

SUMMARY: The Presidential Transition Directory Web site is designed to help candidates in the 2016 Presidential election get quick and easy access to key resources about the federal government structure and key policies related to Presidential Transition. The creation of the Presidential Transition Directory is mandated by the Presidential Transition Act of 1963, as amended.

DATES: *Effective:* November 24, 2015.

FOR FURTHER INFORMATION CONTACT: The GSA Presidential Transition Team at *presidentialtransition@gsa .gov.*

SUPPLEMENTARY INFORMATION: The Presidential Transition Directory (*presidentialtransition.usa.gov*) Web site is designed to help candidates in the 2016 Presidential election get quick and easy access to key resources about the Federal Government structure and key policies related to Presidential Transition. The creation of the Presidential Transition Directory is mandated by the Presidential Transition Act of 1963, as amended. Connecting resources from the Government Printing Office, Office of Personnel Management, National Archives and Records Administration, U.S. Office of Government Ethics and others, the site will also help future political appointees better understand key aspects of their roles and some of the key policies and aspects of federal service. Additionally, the Directory will be connecting to not-for-profit resources about Presidential Transition to help acquaint potential appointees with the types of problems and challenges that most typically confront new political appointees when they make the transition from prior activities to assuming the responsibility for governance. The site will be continuously updated as new information becomes available to help ensure candidates and their staffs have access to the best information possible as they begin their planning to establish the next management of the Executive Branch of the federal government.

Dated: November 17, 2015.

Mary D. Gibert,

Director, Presidential Transition, U.S. General Services Administration.

[FR Doc. 2015–29920 Filed 11–23–15; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–00XX; Docket No. 2015–0001; Sequence No. 26]

Information Collection; Simplifying Federal Award Reporting

AGENCY: Federal Acquisition Service; General Services Administration (GSA).

ACTION: Notice of request for comments regarding a new request for an OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve a new information collection requirement regarding OMB Control No: 3090–00XX; Simplifying Federal Award Reporting.

DATES: Submit comments on or before: January 25, 2016.

ADDRESSES: Submit comments identified by Information Collection 3090–00XX; Simplifying Federal Award Reporting by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching for ''Information Collection 3090–00xx; Simplifying Federal Award Reporting''. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 3090–00XX; Simplifying Federal Award Reporting''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 3090–00xx; Simplifying Federal Award Reporting'' on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 3090–00XX, Simplifying Federal Award Reporting.

Instructions: Please submit comments only and cite Information Collection 3090–00XX; Simplifying Federal Award Reporting, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To

confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Goldman, GSA, at telephone 202–779–2265.

SUPPLEMENTARY INFORMATION:

A. Purpose

The President's Management Agenda includes objectives for creating a twenty-first century government that delivers better results to the American people in a more efficient manner. Leveraging information technology capabilities to reduce reporting burden is key to achieving these goals. Section 5 of the Digital Accountability and Transparency Act (Pub. L. 113–101) requires a pilot program to develop recommendations for standardizing reporting, eliminating unnecessary duplication, and reducing compliance costs for recipients of Federal awards. The pilot participants are required to provide requested reports as well as the cost to collect the data via the pilot. The proposed pilot program will provide an alternative submission method for existing Federal Acquisition Regulation (FAR) requirements, and assess the pilot results against the existing FAR-required method.

B. Annual Reporting Burden

Respondents: 720.

Responses per Respondent: 3 each week.

Total Annual Responses: 2,160.

Hours per Response: .5.

Total Burden Hours: 56,160.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755.

Please cite OMB Control No. 3090–XXXX, Simplifying Federal Award Reporting, in all correspondence.

Dated: November 18, 2015.

David A. Shive,

Chief Information Officer.

[FR Doc. 2015–29896 Filed 11–23–15; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–16–1067; Docket No. CDC–2015–0106]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, 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. This notice invites comment on a proposed revision of the information collection entitled *Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics—College of American Pathologists,* which will allow for a fuller exploration of the factors that underlie the reasons why laboratorians adhere to the College of American Pathologists' laboratory practice guideline for immunohistochemistry test validation.

DATES: Written comments must be received on or before January 25, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0106 by any of the following methods:

- *Federal eRulemaking Portal:* Regulation.gov. Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing

and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Improving the Impact of Laboratory Practice Guidelines (LPGs): A New Paradigm for Metrics—College of American Pathologists, REVISION (OMB Control No. 0920–1067, Expiration 05/31/16)—Center for Surveillance, Epidemiology and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention is funding three 5-year projects collectively entitled ''Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics''. An ''LPG'' is defined as written recommendations for voluntary, standardized approaches for medical laboratory testing that takes into account processes for test selection, sample procurement and processing, analytical methods, and results reporting for effective diagnosis and management of disease and health conditions. LPGs may be disseminated to, and used by, laboratorians and clinicians to assist with test selection and test result interpretation. The overall purpose of these cooperative agreements is to increase the effectiveness of LPGs by defining measures and collecting information to inform better LPG creation, revision, dissemination, promotion, uptake, and impact on clinical testing and public health. The project will explore how these processes and their impediments and facilitators differ among various intended users of LPGs. Through this demonstration project, CDC seeks to understand how to customize LPG creation and promotion to better serve these intended users of LPGs. An important goal is to help organizations that sponsor the development of LPGs create a sustainable approach for continuous quality improvement to evaluate and improve an LPG's impact through better collection of information.

The CDC selected three organizations that currently create and disseminate LPGs to support activities under a cooperative agreement funding mechanism to improve the impact of their LPGs. The American Society for Microbiology, the Clinical and Laboratory Standards Institute, and the College of American Pathologists (CAP), will each use their LPGs as models to better understand how to improve uptake and impact of these and future LPGs. Only the CAP submission will be described in this notice.

The CAP project will address two LPGs that are important to clinical testing: immunohistochemistry test validation (IHC) and an algorithm for diagnosing acute leukemia (ALA). As part of the completed survey collections that was conducted under OMB Control Number 0920–1067, the intended users of the CAP's IHC LPG included pathologists, clinical laboratory directors, and laboratory managers overseeing the IHC staining department; the intended users of the CAP's ALA LPG were pathologists and hematologists overseeing testing for acute leukemia. For this revision request, CDC is proposing information collections to conduct qualitative studies of the survey respondents of the IHC post-survey with the intent to include representation from the laboratory professionals who submitted the IHC post-survey results (pathologists, clinical laboratory directors, and laboratory managers).

Prior to entering into this cooperative agreement project with the CDC, the CAP had already completed a baseline IHC LPG information collection from laboratories that used IHC testing. Because of this prior baseline assessment, the CAP only needed to collect post-dissemination data. This has been completed using the information approved under OMB Control Number 0920–1067. Similarly, the CAP also completed an ALA baseline survey under this clearance.

We are submitting a revision request to allow for a fuller exploration of the factors that underlie the reasons why laboratorians adhere to the College of American Pathologists' laboratory practice guideline for IHC. We propose to conduct telephone interviews that will explore the impediments and facilitators that affect uptake and use of the CAP IHC LPG, both generally and concerning specific recommendations. This will be followed by two focus groups, arranged by peer group of pathologists and non-pathologists (referred to as laboratory directors and managers for the purpose of estimating burden), which will allow us to collect information on the current usage of CAP's tools and resources (toolkit) to facilitate implementation of the IHC guideline for its future improvement. To the extent possible, we will include non-adopters of the CAP's IHC LPG, but this fraction won't be known until the information collection occurs. We propose to collect information for the telephone interviews and focus groups combined, from 64 of the IHC post-survey respondents which include pathologists and non-pathologist laboratory directors and laboratory managers.

For this request, the CAP will collect information via telephone interviews from 40 laboratorians. The time it will take each respondent to complete the interview is 20 minutes. Because the CAP anticipates that as many as 121 individuals may need to be contacted to reach 40 individuals who will voluntarily participate, and the burden for those individuals who will not go on to participate (81) in the telephone interview is one minute, the anticipated total burden for individuals who decline participation is 1.35 hours (81 minutes). The telephone interview respondents will be targeted from two primary segments: (1) Laboratories exclusively using CAP Proficiency Testing (PT) products, and (2) laboratories identified by Centers for Medicare and Medicaid Services billing codes that perform IHC testing but are not enrolled in CAP PT products. The telephone interview respondents will be randomly sampled from the submitted post-survey results and will be cross-checked for appropriate distribution of laboratory type and size. Because there are fewer of them, all of the non-CAP PT customer respondents will be included. The CAP estimates that the individuals who complete the telephone interview will be comprised of 20 pathologists, 10 laboratory directors, and 10 laboratory managers and will each take 20 minutes and the 40 respondents combined will take approximately 13 hours (800 minutes) total burden.

The two in-person focus group sessions will include some of the probe questions from the telephone interview survey and a specific subset concentrating on evaluating CAP's current tools and resources (toolkit). It is anticipated that 200 individuals will be contacted to determine their availability to participate in one of two focus group sessions and each will take no longer than five minutes to read and respond to the invitation letter (~17 hours or 1,000 minutes total). Among the 200 individuals contacted, only the 24 who are selected to participate in a focus group session will each be asked to read and submit a signed consent form prior to the session (5 minutes each) (2 hours or 120 minutes total). Twelve participants will be selected to participate in each of the two focus groups (pathologist peers and laboratory director/manager peers) and will last no more than 90 minutes each (36 hours or 2,160 minutes total). Thus, the total

burden for the focus group is estimated to be ~55 hours (3,280 minutes) total.

Including both telephone interviews and focus group sessions, the total new burden for this revision request will be an additional ~68 hours (321 individuals) at $4,421 total, compared with the original OMB approved burden of 1,570 hours (4,435 individuals) at $97,460 total.

There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Pathologist	IHC telephone interview	20	1	20/60	7
	IHC telephone interview—contacted	27	1	1/60	0.45
	IHC focus group	12	1	1.50	18
	IHC focus group—invitation	100	1	5/60	8
	IHC focus group—consent form	12	1	5/60	1
Laboratory Directors	IHC telephone interview	10	1	20/60	3
	IHC telephone interview—contacted	27	1	1/60	0.45
	IHC focus group	6	1	1.50	9
	IHC focus group—invitation	50	1	5/60	4
	IHC focus group—consent form	6	1	5/60	0.50
Laboratory Managers	IHC telephone interview	10	1	20/60	3
	IHC telephone interview—contacted	27	1	1/60	0.45
	IHC focus group	6	1	1.50	9
	IHC focus group—invitation	50	1	5/60	4
	IHC focus group—consent form	6	1	5/60	0.50
Total					68.00

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–29867 Filed 11–23–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–16–0968; Docket No. CDC–2015–0104]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, 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. This notice invites comment on a proposed information collection entitled ''Monitoring and Reporting System for DELTA FOCUS Awardees''. CDC will use the information collected to monitor cooperative agreement awardees and to identify challenges to program implementation and achievement of outcomes.

DATES: Written comments must be received on or before January 25, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0104 by any of the following methods:

Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.

Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation,

maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Monitoring and Reporting System for DELTA FOCUS Awardees, (OMB Control No. 0920–0968, expiration 5/31/2016)—Extension—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Intimate Partner Violence (IPV) is a serious, preventable public health problem that affects millions of Americans and results in serious consequences for victims, families, and communities. IPV occurs between two people in a close relationship. The term ''intimate partner'' describes physical, sexual, or psychological harm by a current or former partner or spouse. IPV can impact health in many ways, including long-term health problems, emotional impacts, and links to negative health behaviors. Given these factors, the Family Violence Prevention and Services Act (42 U.S.C. 10401) provides an important opportunity for the advancement of public health and reduction of IPV. Support and guidance for programs addressing IPV have been provided through cooperative agreement funding and technical assistance administered by CDC's National Center for Injury Prevention and Control (NCIPC). CDC seeks to continue collecting information needed to monitor cooperative agreement programs funded under Domestic Violence Prevention Enhancement and Leadership through Alliances, Focusing on Outcomes for Communities United with States DELTA FOCUS (FOA CDC–RFA–CE13–130).

Information to be collected will provide crucial data for program performance monitoring and provide CDC with the capacity to respond in a timely manner to requests for information about the program from the Department of Health and Human Services (HHS), the White House, Congress, and other sources. Awardees will report progress and activity information to CDC on an annual schedule using the Program Management Information System (PMIS) consisting of fillable electronic templates and submitted via Grant Solutions.

CDC will use the information collected to monitor each awardee's progress and to identify facilitators and challenges to program implementation and achievement of outcomes. Monitoring allows CDC to determine whether an awardee is meeting performance goals and to make adjustments in the type and level of technical assistance provided to them, as needed, to support attainment of their objectives. CDC's monitoring and evaluation activities also allow CDC to provide oversight of the use of federal funds, and to identify and disseminate information about successful prevention and control strategies implemented by awardees. These functions are central to the NCIPC's broad mission of reducing the burden of injury and violence. Finally, the information collection allows CDC to monitor the increased emphasis on partnerships and programmatic collaboration, and is expected to reduce duplication of effort, enhance program impact and maximize the use of federal funds.

This is an extension request for three years. Participation in the information collection is required as a condition of funding. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State Domestic Violence Coalitions ..	DELTA FOCUS PMIS: Semi-annual reporting.	10	2	3	60
Total	.....	.....	.....	.....	60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–29866 Filed 11–23–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Nominations of Candidates To Serve as Members of the Community Preventive Services Task Force (CPSTF); Reopening of Nomination Period

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) announces the reopening of the nomination period for individuals qualified to serve as members of the Community Preventive Services Task Force (CPSTF). The nomination period originally closed on November 9, 2015.

DATES: Nomination packages must be received by December 8, 2015. Complete nomination packages must be submitted by the deadline in order to be considered. Individuals who submitted a nomination package during the original nomination period do not need to re-submit their nomination package to be considered.

ADDRESSES: Nomination packages should be submitted electronically to *cpstf@cdc.gov* or by U.S. mail to the address provided below in **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Donyelle Russ, Center for Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS E–69, Atlanta, Georgia 30329. Phone (404) 498–3971, email: *cpstf@cdc.gov.*

SUPPLEMENTARY INFORMATION: On September 25, 2015 HHS/CDC published a notice in the **Federal Register** (80 FR 57820) requesting nomination of individuals to serve on the Community Preventive Services Task Force (CPSTF). The closing date for nominations was November 9, 2015. Today, CDC is reopening the nomination period to provide the public an additional opportunity to nominate individuals to serve on the CPSTF. The submission process and qualification requirements, the selection process, and the time commitment of Task Force members are described below. Individuals who submitted a nomination package during the original nomination period do not need to re-submit their nomination package to be considered.

Nomination Submissions

Nomination packages must be submitted electronically, and should include:

(1) The nominee's current curriculum vitae;

(2) A brief biographic sketch of the nominee;

(3) The nominee's contact information, including mailing address, email address, and telephone number; and

(4) A brief explanation of how the nominee meets the qualification requirements and how he/she would contribute to the CPSTF. The information provided should also attest to the nominee's willingness to serve as a member of the CPSTF.

HHS/CDC will later ask persons under serious consideration for CPSTF membership to provide detailed information that will permit evaluation of possible significant conflicts of interest.

To obtain diverse perspectives, HHS/CDC encourages nominations of all races, genders, ages and persons living with disabilities. Interested individuals can self-nominate. Organizations and individuals may nominate one or more persons qualified for membership on the CPSTF. Federal employees are not eligible to be CPSTF members. Individuals nominated prior to this round, who continue to have interest in serving on the CPSTF, should be re-nominated.

Qualification Requirements

To qualify for the CPSTF and support its mission, a nominee must, at a minimum, demonstrate knowledge, experience, and national leadership in the following areas:

- The critical evaluation of research or policy, and/or in the methods of evidence review; and
- Research, evaluation, or implementation of community and/or health system-based programs, policies, or services to improve population health.

Strongest consideration will be given to individuals with expertise and experience:

- That is applied, with practical applications for public health action;
- That addresses broad public health considerations, or is beyond one or two highly defined areas;
- In state and/or local health departments; and
- With policy.

In the current round of nominations, the strongest consideration will also be given to people with expertise and experience in systematic review methods, minority health, and aging. The CPSTF will also benefit from members with expertise and experience in the following areas: Youth populations; environmental health; injury (in particular substance abuse and violence prevention); media, communications, and marketing; public health nursing; and economic analysis.

Candidates with experience and skills in any of these areas should highlight them in their nomination materials.

All nominated individuals will be considered for CPSTF membership.

Applicants must have no substantial conflicts of interest, whether financial, professional, or intellectual, that would impair the scientific integrity of the work of the CPSTF and must be willing to complete regular conflict of interest disclosures.

Applicants must have the ability to work collaboratively with a team of diverse professionals who support the mission of the CPSTF. Applicants must have adequate time to contribute substantively to the work products of the CPSTF.

Nominee Selection

Appointments to the CPSTF will be made on the basis of qualifications as outlined above (see Qualification Requirements) and the current expertise needs of the CPSTF.

Background of the CPSTF

The CPSTF was established in 1996 by the U.S. Department of Health and Human Services (HHS) to identify population health interventions that are scientifically proven to save lives, increase lifespans, and improve quality of life. The CPSTF produces recommendations (and identifies evidence gaps) to help inform the decision making of federal, state, and local health departments, other government agencies, communities, healthcare providers and organizations, employers, schools and research organizations.

The CPSTF (*http://www.thecommunityguide.org/about/task-force-members.html*), is an independent, nonpartisan, nonfederal, unpaid panel of public health and prevention experts that is statutorily mandated to provide evidence-based findings and recommendations about community preventive services, programs, and policies to improve health (Public Health Service Act § 399U(a)). Its members represent a broad range of research, practice, and policy expertise in community preventive services, public health, health promotion, and disease prevention. The CPSTF members are appointed by the CDC Director and serve five year terms, with extensions possible in order to maintain a full scope of expertise, complete specific work, and ensure consistency of CPSTF methods and recommendations. CDC provides ''ongoing administrative, research, and technical support for the operations of the Task Force'' as directed by the Public Health Service Act § 399U(c).

The CPSTF bases its recommendations on rigorous, replicable systematic reviews of the scientific literature, which do all of the following:

- Evaluate the strength and limitations of published scientific studies about community-based health promotion and disease prevention programs, services, and policies;
- Assess whether the programs, services, and policies are effective in promoting health and preventing disease, injury, and disability;
- Examine the applicability of these programs, services, and policies to varied populations and settings; and
- Conduct economic analyses of recommended interventions.

These systematic reviews are conducted, with CPSTF oversight, by scientists and subject matter experts from HHS/CDC in collaboration with a wide range of government, academic, policy, and practice-based partners.

CPSTF findings and recommendations and the systematic reviews on which they are based are available at *http://www.thecommunityguide.org/index.html.*

Time Commitment

The CPSTF conducts three, two-day meetings each year that are open to the public. In addition, a significant portion of the CPSTF's work occurs between meetings during conference calls and via email discussions. Member duties include overseeing the process of prioritizing Task Force work, participating in the development and refinement of systematic review methods, serving as members of individual review teams, and issuing recommendations and findings to help inform the decision making process about policy, practice, research, and research funding in a wide range of U.S. settings. The estimated workload for CPSTF members is approximately 168 hours a year in addition to the three in-person meetings. The members are all volunteers and do not receive any compensation beyond support for travel to in-person meetings.

Dated: November 19, 2015.

Sandra Cashman,

Acting Director, Division of the Executive Secretariat, Office of the Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2015–29882 Filed 11–23–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4272]

Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon: Guidance for Industry.'' We developed the draft guidance to assist food manufacturers that wish to voluntarily label their food product or ingredients (for humans or animals) derived from Atlantic salmon as either containing or not containing products from genetically engineered (GE) Atlantic salmon.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on the draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 25, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–4272 for ''Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Office of Nutrition, Labeling, and Dietary Supplements (HFS–820), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist the office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: *Regarding human food issues:* Andrea Krause, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371. *Regarding animal food issues:* Kathleen Jones, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–7077.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

On November 19, 2015, FDA approved a new animal drug application (NADA) related to AquAdvantage Salmon, a GE Atlantic salmon. This is FDA's first approval of an NADA in support of a GE animal for use as food. According to information in the NADA, AquAdvantage Salmon is genetically engineered to reach market size in a shorter period than non-GE farm-raised Atlantic salmon. FDA's Center for Veterinary Medicine reviewed the NADA and made a determination concerning the safety and effectiveness of the new animal drug in AquAdvantage Salmon.

In terms of labeling of food derived from AquAdvantage Salmon, the law requires, among other things, that the label includes a name that accurately describes the basic nature of a food and any other information that is considered material with regard to consequences that may result from the use of the food. In a 1992 policy on foods derived from new plant varieties and a 2001 draft guidance on voluntary labeling of food from GE plants, we explained that: Name changes are appropriate when a food from a GE plant is *materially* different from its traditional counterpart, such that the common or usual name no longer adequately describes the new food; or when there are other material differences that affect the food's nutritional or functional characteristics.[1] (Elsewhere in this issue of the **Federal Register**, we are announcing the availability of a final guidance entitled ''Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants.'') Changes to the name of the product or other additional labeling are not required if the resulting food is not materially different from its non-genetically engineered counterpart.

In the process of deciding whether or not to require additional labeling of AquAdvantage Salmon, FDA considered whether food from AquAdvantage Salmon is materially different from non-GE, farm-raised Atlantic salmon. As part of our evaluation, we assessed data and information submitted in response to our August 26, 2010, **Federal Register** document entitled ''Food Labeling; Labeling of Food Made From AquAdvantage Salmon; Public Hearing; Request for Comments'' (75 FR 52602), as well as data and information submitted by the sponsor.

Based on our review of the sponsor's data and information, and other information available to the Agency (*e.g.,* FDA's laboratory analyses establishing that AquAdvantage Salmon meets the criteria for Atlantic salmon established for the Regulatory Fish Encyclopedia), we found that the composition, nutritional profile, and safety of food from AquAdvantage Salmon do not differ from food from non-GE, farm-raised Atlantic salmon in any material way, and thus it is as safe and nutritious as food from non-GE, farm-raised Atlantic salmon. For these reasons, we concluded that there is no basis to require additional labeling of food derived from AquAdvantage Salmon.[2] [3]

II. Guidance on Voluntary Labeling

Recognizing that some consumers are interested in whether a food contains GE Atlantic salmon and some manufacturers may want to respond to this consumer interest, we developed this draft guidance to assist food manufacturers that wish to voluntarily label their food product or ingredients (for humans or animals) as either containing or not containing products from GE Atlantic salmon. FDA's main concern within the context of this guidance is that any voluntary labeling be truthful and not misleading.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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. This draft guidance contains proposed collections of information. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to publish a 60-day notice in the **Federal Register** soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA will publish a 60-day notice on the proposed collections of information in this draft guidance in a future issue of the **Federal Register**.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: November 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29904 Filed 11–23–15; 8:45 am]

BILLING CODE 4164–01–P

[1] See 57 FR 22984, May 29, 1992.

[2] We note that, if a different GE salmon is developed in the future, we will separately assess the data and information about that salmon to determine whether it differs materially from non-GE salmon and, as such, whether additional labeling would be required on food derived from that salmon.

[3] Memorandum to File: Office of Nutrition, Labeling and Dietary Supplements, CFSAN: Evaluation of data and information and recommendations related to the labeling of food from AquAdvantage Salmon.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–D–0075]

Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled ''Voluntary Labeling Indicating Whether

Foods Have or Have Not Been Derived from Genetically Engineered Plants.'' The guidance is intended to help food manufacturers that wish to voluntarily label their plant-derived food products or ingredients (for humans or for animals) as having been made with or without bioengineering.

DATES: Submit either electronic or written comments on the guidance at any time. Fax written comments on the collection of information by December 24, 2015.

ADDRESSES: To ensure that comments on the information collection are received, the Office of Management and Budget (OMB) recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–New and title ''Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants.'' Also include the FDA docket number found in brackets in the heading of this document.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2000–D–0075 for ''Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Office of Nutrition, Labeling, and Dietary Supplements (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: *Regarding human food issues:* Andrea Krause, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371. *Regarding animal food issues:* Kathleen Jones, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–7077. *Regarding the information collection:* FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 403 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343) generally governs the labeling of foods. Under section 403(a)(1) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular.

Section 201(n) of the FD&C Act (21 U.S.C. 321(n)) provides that labeling is misleading if, among other things, it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual.

In the **Federal Register** of May 29, 1992 (57 FR 22984), we published a ''Statement of Policy: Foods Derived from New Plant Varieties'' (1992 Policy). The 1992 Policy applies to foods for humans and animals that are developed from new plant varieties, including varieties that are developed using recombinant deoxyribonucleic acid (rDNA) technology. This technology has long been referred to as ''rDNA technology,'' ''genetic

engineering,'' or ''bioengineering,'' and more recently, as ''modern biotechnology.''

In the 1992 Policy, we addressed, among other things, the labeling of foods derived from new plant varieties, including plants developed by bioengineering. In the 1992 Policy, we explained that we were not establishing special labeling requirements for foods from bioengineered plants as a class of foods because we did not find any basis for concluding that foods from bioengineered plants, as a class, differ from other foods in any meaningful or uniform way, or that foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding.

In the **Federal Register** of January 18, 2001 (66 FR 4839), we announced the availability of a draft guidance for industry entitled ''Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering.'' We received more than 155,000 comments on the draft guidance. Most comments were submitted by consumers. Other comments represented the views of advocacy groups, trade organizations, organic grocers/food co-ops, private sector business, farming/farm bureaus, food manufacturers, crop developers, local governments, and academic researchers. We have considered the comments and revised the guidance as appropriate. We understand that consumers may want information about whether or not a food is developed through genetic engineering. Thus, we are providing guidance on voluntary labeling that will help manufacturers that would like to provide consumers with additional information about the foods they consume.

We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. In addition, this guidance does not preempt State food labeling requirements that are consistent with the Federal requirements described in the guidance and that are not otherwise expressly preempted by the FD&C Act.

II. Paperwork Reduction Act of 1995

This final guidance contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). Under the PRA, Federal Agencies must obtain approval from 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, in the **Federal Register** of January 18, 2001, we gave interested persons 60 days to comment on the information collection provisions in the draft guidance (66 FR 4839 at 4840).

After publishing the 60-day notice requesting public comment, section 3507 of the PRA (44 U.S.C. 3507) requires Federal Agencies to submit the proposed collection to OMB for review and clearance. In compliance with 44 U.S.C. 3507, we have submitted the following proposed collection of information to OMB for review and clearance. FDA is issuing this final guidance subject to OMB approval of the collection of information. If the collection is approved, FDA will publish a notice in the **Federal Register** concerning OMB approval and providing an OMB control number.

Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants

OMB Control Number 0910–New

As noted, in the **Federal Register** of January 18, 2001, we announced the availability of the draft guidance document and requested public comment on the information collection provisions. Subsequently, we published a document in the **Federal Register** of October 31, 2003 (68 FR 62086), informing interested parties that the proposed collection of information had been submitted to the OMB for review and clearance under the PRA. However, we determined that the request for comments was issued prematurely. Thus, we withdrew the notice on November 21, 2003 (68 FR 65717). We are now reissuing the request for comments and submitting the proposed collection of information to OMB.

The guidance entitled ''Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants'' is intended to assist manufacturers that wish to voluntarily label their foods (human or animal) as being made with or without genetic engineering or the use of genetically engineered ingredients, to ensure that such labeling is truthful and not misleading. The information that the manufacturers will collect is documentation of handling practices so that they can truthfully label their products to indicate, if they so choose, whether the food has or has not been developed using genetic engineering.

In general, we anticipate that manufacturers claiming that a product is not developed using genetically engineered material would substantiate the claim. We suggest that manufacturers document practices and procedures to substantiate a claim that a food was not developed using genetic engineering. Examples of documentation that we anticipate will demonstrate practices and procedures are recordkeeping, and certifications or affidavits from farmers, processors, and others in the food production and distribution chain. We are neither suggesting that firms maintain a certain set list of documents nor are we suggesting that anything less or different would likely be considered unacceptable. Rather, we are leaving it to each firm's judgment to maintain appropriate documentation to demonstrate that the food was produced using traditional methods.

Description of Respondents: The respondents to the proposed collection of information are manufacturers of foods that were or were not derived from genetically engineered plants who wish to voluntarily label their food products.

As noted, in the **Federal Register** of January 18, 2001, we published a 60-day notice requesting public comment on the proposed collection of information. We received more than 155,000 comments, each containing one or more issues. The following is a discussion of the comments we received on the information collection and our response to those comments.

(Comment 1) Most comments agreed that labeling food products as genetically engineered or non-genetically engineered would result in costs due to segregation, testing, or third-party validation, in addition to label changes. However, some comments said the producers that choose to label their products as non-genetically engineered and the consumers that choose to purchase these products should incur these costs. Other comments said that these costs should be borne by the growers, manufacturers, processors, and

marketers of genetically engineered foods.

(Response) We disagree that it would be necessary to incur costs due to segregation, testing, or third-party validation to substantiate a claim that a food was not developed using genetic engineering. We also note that the question of who should bear the paperwork burden is not within the scope of the guidance.

(Comment 2) One comment stated that we underestimated the number of small firms that will choose to label their product as not genetically engineered, but will not attempt to make an organic claim.

(Response) We disagree that we underestimated the number of respondents in the 2001 60-day **Federal Register** notice. The comment did not offer any evidence to substantiate this claim or give an estimate of how many small firms will choose to make a non-genetically engineered claim. We based our estimate of the number of firms that would label their products with a genetically engineered claim on the number of products making an organic claim and the number of products that were not currently making an organic claim on their label, but were making a statement about genetic engineering on their Web site, through a press release, or other venue when the 2001 60-day notice was published. We have, however, updated in this notice the estimated number of recordkeepers to reflect new information on the number of foods that are labeled as not genetically engineered.

(Comment 3) Numerous comments pointed out that mandatory labeling would have high costs for additional activities such as segregation, testing, labeling, quality control, and certification. One comment estimated that these costs could be as high as 6 to 17 percent of the farmgate price.

(Response) The paperwork reduction analysis only estimates the paperwork burden associated with *voluntary* labeling. The estimates related to mandatory labeling are outside the scope of the guidance, and we have not included them in the analysis.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping per the Guidance	85	4	340	1	340

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have updated the number of recordkeepers and respondents to reflect new information on the number of food products that are labeled using the terms ''biotechnology'' and ''GMO'' (genetically modified organism) since the 2001 issuance of the 60-day notice and draft guidance. We estimate a recordkeeping burden, to retain paperwork to substantiate that the food or ingredient is produced without genetic engineering, only for products that are not also already labeled using the term ''organic.'' We did not include products that are labeled ''organic'' in the estimated annual recordkeeping burden because, according to a final rule in the **Federal Register** of December 21, 2000 (65 FR 80548), issued by the Agriculture Marketing Service of the U.S. Department of Agriculture, a food labeled as ''organic'' would not be permitted to contain genetically engineered materials. Thus, there is no additional paperwork burden to substantiate a claim that a product is not developed using genetic engineering for these certified organic products.

We based our revised estimates of the recordkeeping burden (table 1 of this document) on data from Labelbase by FoodEssentials. Labelbase is a custom online system for accessing a consumer packaged goods product data; the database contains more than 250,000 product labels that can be searched by keyword, ingredient, nutrient, allergen, label claim, or food additive, for example. Using this database, we have identified 540 food manufacturers who produce 2,160 products with the term ''bioengineered'' or ''GMO'' on their labels; this estimate includes manufacturers of human food and pet food. In addition, the National Center for Appropriate Technology's National Sustainable Agriculture Information Center maintains on its Web site a list of Organic Livestock Feed Suppliers. Using this list, we have identified 54 livestock feed suppliers that would be likely to include a statement about bioengineering on the label of their products and thus would have documentation to substantiate their claim.

Of the 2,160 human food and pet food products that we have identified as using the term ''bioengineered'' or ''GMO'' on their labels (presumably used in a context to designate foods that are not bioengineered), 1,140 of these products (285 manufacturers) also use the term ''organic'' on the label; 1,020 products do not use the term ''organic'' on the label (2,160 − 1,140 = 1,020 products not organics; 540 − 285 = 255 manufacturers of not organic products). In addition, the 54 livestock feed suppliers are also organic producers, thus the 216 products attributed to these manufacturers already are considered to be labeled ''organic.'' Thus, there are 1,020 products made by 255 human food and pet food manufacturers that would need to substantiate that their product or ingredient was not genetically engineered.

We estimate that the burden of maintaining the documentation is a one-time burden; the document to substantiate that the product or ingredient was produced without genetic engineering only needs to be generated once and then kept on file. To annualize this one-time burden, we divide by 3 because paperwork burden collections are approved on a 3-year cycle (255/3 = 85). Thus, we estimate in table 1 that, on average, 85 manufacturers annually will collect and keep information that substantiates their label claim for four products (1,020 products/3 = 340 products/85 manufacturers = 4 products per manufacturer).

We estimate this one-time recordkeeping burden to be 1 hour per product that makes use of a labeling claim which results in a burden of 1 hour for a total annualized recordkeeping burden of 340 hours (85 manufacturers × 4 records per manufacturer × 1 hour per record). In the 2001 notice, we estimated $53,040 as ''operating and maintenance costs'' associated with this recordkeeping burden. These costs were reported in error and have been removed from table 1. We estimate no capital costs or operating and maintenance costs associated with this recordkeeping burden.

We do not estimate any reporting burden or third party disclosure burden associated with this information collection. Manufacturers who want to make use of this voluntary labeling claim option are considered to be those that already have such wording on their products' labels. We do not expect that this guidance will cause labels already in the marketplace to need to be re-worded.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: November 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29903 Filed 11–23–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, NIAID Investigator Initiated Program Project Applications (P01).

Date: December 17, 2015.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 4H200 A/B, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Kelly Y. Poe, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3F40B, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5036, *poeky@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 18, 2015.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–29854 Filed 11–23–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Physiology and Pathobiology of Cardiovascular and Respiratory Systems.

Date: November 23–24, 2015.

Time: 8:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: The St. Regis Washington, DC, 923 16th St.NW., Washington, DC 20006.

Contact Person: Abdelouahab Aitouche, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4222, MSC 7812, Bethesda, MD 20892, 301–435–2365, *aitouchea@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 18, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–29853 Filed 11–23–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2015–1005]

Merchant Mariner Medical Advisory Committee; Vacancies

AGENCY: Coast Guard, DHS.

ACTION: Request for applications.

SUMMARY: The Coast Guard seeks applications for membership on the Merchant Mariner Medical Advisory Committee. The Merchant Mariner Medical Advisory Committee provides advice and recommendations to the Secretary on matters related to medical certification determinations for issuance of licenses, certificates of registry, and merchant mariners' documents; medical standards and guidelines for the physical qualifications of operators of commercial vessels; medical examiner education; and medical research. Applicants selected for service on the Merchant Mariner Medical Advisory Committee via this solicitation will not begin their respective term until August 8, 2016.

DATES: Completed applications should reach the Coast Guard on or before January 25, 2016.

ADDRESSES: Applicants should send a cover letter expressing interest in an appointment to the Merchant Mariner Medical Advisory Committee that also identifies which membership category the applicant is applying under, along with a resume detailing the applicant's experience via one of the following methods:

- *By Email: ashley.e.holm@uscg.mil.*
- *By Fax:* 202–372–4908.
- *By Mail:* Lieutenant Ashley Holm, Alternate Designated Federal Officer of the Merchant Mariner Medical Advisory Committee, Commandant, Mariner Credentialing Program Policy Division (CG–CVC–4), U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE., Stop 7501 Washington, DC 20593–7501.

FOR FURTHER INFORMATION CONTACT: Lieutenant Ashley Holm, Alternate Designated Federal Officer of the Merchant Mariner Medical Advisory Committee, Commandant, Mariner Credentialing Program Policy Division (CG–CVC–4), U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE., Stop 7501 Washington, DC 20593–7501, *ashley.e.holm@uscg.mil,* phone: 202–372–1128, fax: 202–372–4908.

SUPPLEMENTARY INFORMATION: The Merchant Mariner Medical Advisory Committee was established under Section 210 of the Coast Guard

Authorization Act of 2010, Public Law 111–281 and operates in accordance with the provisions of the Federal Advisory Committee Act, (5 U.S.C. Appendix). The Committee's purpose is to provide advice and recommendations to the Secretary on matters related to medical certification determinations for issuance of licenses, certificates of registry, and merchant mariners' documents; medical standards and guidelines for the physical qualifications of operators of commercial vessels; medical examiner education; and medical research.

The Merchant Mariner Medical Advisory Committee is expected to meet at least twice a year at various locations around the country. It may also meet intercessionally for extraordinary purposes. Working groups may also meet to consider specific tasks as required.

The Coast Guard will consider applications for seven positions that expire on August 8, 2016. These positions include two professional mariners with knowledge and experience in mariners' occupational requirements, and five health care professionals with particular expertise, knowledge, or experience regarding the medical examinations of merchant mariners or occupational medicine.

The members appointed will serve a term of office of five years. The members are limited to serving no more than two consecutive terms. All members serve without compensation from the Federal Government; however, members may be reimbursed for travel and per diem depending on fiscal budgetary constraints.

Members of the Merchant Mariner Medical Advisory Committee will be appointed and serve as Special Government Employees as defined in section 202(a) of Title 18 United States Code. As candidates for appointment as Special Government Employees, applicants are required to complete Confidential Financial Disclosure Reports (OGE Form 450). Coast Guard may not release the reports or the information in them to the public except under an order issued by a Federal court or as otherwise provided under the Privacy Act (5 U.S.C. 552a). Only the Designated Coast Guard Ethics Official or his designee may release a Confidential Financial Disclosure Report. Applicants can obtain this form by going to the Web site of the Office of Government Ethics (*www.oge.gov*), or by contacting the individual listed above in **FOR FURTHER INFORMATION CONTACT**. Applications for a Special Government Employees that are not accompanied by a completed OGE Form 450 will not be considered.

Registered lobbyists are not eligible to serve on Federal advisory committees in an individual capacity. Registered lobbyists are lobbyists required to comply with provisions contained in the Lobbying Disclosure Act of 1995 (2 U.S.C. 1605; Pub. L. 104–65; as amended by Title II of Pub. L. 110–81).

The Merchant Mariner Medical Advisory Committee members are appointed in their individual capacity and would be designated as a Special Government Employee as defined in 202(a) of Title 18, U.S.C. See ''Revised Guidance on Appointment of Lobbyist to Federal Advisory Committees, Boards and Commissions'' (79 FR 47482, August 13, 2014).

The Department of Homeland Security does not discriminate in selection of Committee members on the basis of race, color, religion, sex, national origin, political affiliation, sexual orientation, gender identity, marital status, disabilities and genetic information, age, membership in an employee organization, or any other non-merit factor. The Department of Homeland Security strives to achieve a widely diverse candidate pool for all of its recruitment actions.

If you are interested in applying to become a member of the Committee, send your cover letter and resume to Lieutenant Ashley Holm, Designated Alternate Federal Officer of the Merchant Mariner Medical Advisory Committee by email or mail according to instructions in the **ADDRESSES** section by the deadline in the **DATES** section of this notice.

All email submittals will receive email receipt confirmation.

To visit our online docket, go to *http://www.regulations.gov* enter the docket number (for this notice (USCG–2015–1005) in the Search box, and click ''Search''. Please do not post your resume or OGE 450 Form on this site.

Dated: November 17, 2015.

V.B. Gifford, Jr.,

Captain, U.S. Coast Guard, Director, Inspections and Compliance.

[FR Doc. 2015–29836 Filed 11–23–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2015–1018]

Merchant Mariner Medical Advisory Committee's Response to Task Statement 1, Navigation and Vessel Inspection Circular 04–08 Revision

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability.

SUMMARY: The Coast Guard announces the availability of the Merchant Mariner Medical Advisory Committee's response to Task Statement 1, ''Navigation and Vessel Inspection Circular 04–08 Revision Working Group.'' This document recommends various changes to NVIC 04–08, ''Medical and Physical Evaluation Guidelines for Merchant Mariner Credentials,'' which the Coast Guard uses when making decisions on mariner credentialing. The Coast Guard has not adopted this document as policy, but will consider it in future policy development.

ADDRESSES: Task Statement 1 and the Merchant Mariner Medical Advisory Committee's response to the task are available on the Coast Guard's Web site at: *https://homeport.uscg.mil.* To locate the documents on the Web site, select Missions/Ports and Waterways/Safety Advisory Committees/MEDMAC/Announcements/MEDMAC's Response to Task Statement 1—Navigation and Vessel Inspection Circular 04–08 Revision.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, email *MMCPolicy@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

The Merchant Mariner Medical Advisory Committee (the Committee) is authorized under 46 United States Code 7115 and operates in accordance with the Federal Advisory Committee Act (Title 5 U.S.C., Appendix). The Committee advises the Secretary on matters related to (a) medical certification determinations for issuances of licenses, certificates of registry, and merchant mariners' documents; (b) medical standards and guidelines for the physical qualifications of operators of commercial vessels; (c) medical examiner education; and (d) medical research.

The Committee voted to accept Task Statement 1 during the second public meeting held on May 8–9, 2012 in Martinsburg, WV. This task requested

that the Committee review sections of NVIC 04–08, ''Medical and Physical Evaluation Guidelines for Merchant Mariner Credentials,'' to ensure that the Coast Guard's guidance is in compliance with all current regulations and reflects medical considerations that are appropriate for merchant mariners.

Task Statement 1 required the following inputs. First, it required the working group to review the introduction and Enclosures 1, 2, 5, and 6 of NVIC 04–08 to ensure compliance with existing Coast Guard regulations in the Code of Federal Regulations. Second, it required the working group to review all medical conditions listed in Enclosures 3 and 4 of the NVIC and perform the following actions:

—Identify circumstances defining inordinate risk for the condition.
—Identify circumstances which would decrease the risk from inordinate.
—Determine appropriate amplifying information and testing required to assess the condition.
—Identify the standards used to determine the suitability of the condition.
—Determine the minimum compliance for the condition that should allow safe operation.
—Determine whether or not a waiver is required and define waiver parameters.
—Work with the Top Mariner Conditions working group to incorporate their recommendations for the top medical conditions.

Subsequently, a working group was established. The working group was comprised of individual members of MEDMAC and the public, although the composition of the working group changed over time. The Committee voted to accept the response to Task Statement 1 provided by the working group during the sixth public meeting held on September 29–30, 2014 in Piney Point, MD. All working group meetings were open to the public.

The response to Task Statement 1 is in the form of a revised NVIC 04–08. This revision includes both the introduction to NVIC 04–08 as well as revised versions of each of the enclosures. In accordance with the task statement, the working group has made revisions to each enclosure, but made substantial revisions to enclosures 3 and 4. These enclosures, entitled ''Vision and Hearing Standards'' and ''Guidance on Specific Medical Conditions,'' provide detailed guidelines that can help the Coast Guard make fitness determinations for mariners to maintain their credentials.

The Merchant Mariner Medical Advisory Committee's response to Task Statement 1 is a work product of the Committee and therefore is not an official Coast Guard policy and may not be cited as an official agency position. The Coast Guard may use the response, or portions of the response, for development of future policy.

Authority

This notice is issued under the authority of 5 U.S.C. 552(a), 46 U.S.C. 7101 *et seq.,* 46 CFR 10.215, and Department of Homeland Security Delegation No. 0710.1.

Dated: November 17, 2015.

V. B. Gifford, Jr.,

Captain, U.S. Coast Guard, Director of Inspections and Compliance.

[FR Doc. 2015–29837 Filed 11–23–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0047]

Agency Information Collection Activities: Employment Eligibility Verification, Form I–9; Revision of a Currently Approved Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until January 25, 2016.

ADDRESSES: All submissions received must include the Office of Management and Budget (OMB) Control Number 1615–0047 in the subject box, the agency name, and Docket ID USCIS–2006–0068. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at *http://www.regulations.gov* under e-Docket ID number USCIS–2006–0068;

(2) *Email.* Submit comments to *USCISFRComment@uscis.dhs.gov;*

(3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Laura Dawkins, Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, telephone number 202–272–8377. (This is not a toll-free number.) Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information, by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2006–0068 in the search box. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the

functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

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

(2) *Title of the Form/Collection:* Employment Eligibility Verification.

(3) *Agency form number, if any, and the applicable DHS component sponsoring the collection:* I–9; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Employers, employees, recruiters and referrers for a fee (limited to agricultural associations, agricultural employers, or farm labor contractors), and state employment agencies. This form was developed to facilitate compliance with section 274A of the Immigration and Nationality Act, which prohibits the knowing employment of unauthorized aliens. This information collection is necessary for employers, agricultural recruiters and referrers for a fee, and state employment agencies to verify the identity and employment authorization of individuals hired (or recruited or referred for a fee, if applicable) for employment in the United States.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–9 is 55,400,000 for employers and recruiters and referrers with an estimated hour burden per response is .33 hours; 55,400,000 for individuals/households with an estimated hour burden response of .17 hour; and 20,000,000 for record keepers with an estimated hour burden response of .08 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 29,300,000 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $0.

Dated: November 19, 2015.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2015–29909 Filed 11–23–15; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5898–N–01]

Statutorily Mandated Designation of Difficult Development Areas and Qualified Census Tracts for 2016

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: This document designates ''Difficult Development Areas'' (DDAs) and ''Qualified Census Tracts'' (QCTs) for purposes of the Low-Income Housing Tax Credit (LIHTC) under Internal Revenue Code (IRC) Section 42 (26 U.S.C. 42). The United States Department of Housing and Urban Development (HUD) makes new DDA and QCT designations annually. As previously announced, the 2016 metropolitan DDA designations use for the first time Small Area Fair Market Rents (SAFMRs), rather than metropolitan-area Fair Market Rents (FMRs), for designating metropolitan DDAs. Compared to previous designations, this notice: (1) Describes a strengthening of the data quality standard HUD uses in designating the 2016 QCTs, (2) extends from 365 days to 730 days the period for which the 2016 lists of QCTs and DDAs are effective for projects located in areas not on a subsequent list of DDAs or QCTs but having submitted applications while the area was a 2016 QCT or DDA, and (3) establishes the effective date of the new QCTs and DDAs as July 1, 2016 rather than January 1.

FOR FURTHER INFORMATION CONTACT: For questions on how areas are designated and on geographic definitions, contact Michael K. Hollar, Senior Economist, Economic Development and Public Finance Division, Office of Policy Development and Research, Department of Housing and Urban Development, 451 Seventh Street SW., Room 8234, Washington, DC 20410–6000; telephone number 202–402–5878, or send an email to *Michael.K.Hollar@hud.gov.* For specific legal questions pertaining to Section 42, contact Branch 5, Office of the Associate Chief Counsel, Passthroughs and Special Industries, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224; telephone number 202–317–4137, fax number 202–317–6731. For questions about the ''HUB Zone'' program, contact Mariana Pardo, Director, HUBZone Program, Office of Government Contracting and Business Development, U.S. Small Business Administration, 409 Third Street SW., Suite 8800, Washington, DC 20416; telephone number 202–205–2985, fax number 202–481–6443, or send an email to *hubzone@sba.gov.* A text telephone is available for persons with hearing or speech impairments at 800–877–8339. (These are not toll-free telephone numbers.) Additional copies of this notice are available through HUD User at 800–245–2691 for a small fee to cover duplication and mailing costs.

Copies Available Electronically: This notice and additional information about DDAs and QCTs are available electronically on the Internet at *http://www.huduser.org/datasets/qct.html.*

SUPPLEMENTARY INFORMATION:

This Document

This notice designates DDAs for each of the 50 states, the District of Columbia, Puerto Rico, American Samoa, Guam, the Northern Mariana Islands, and the U.S. Virgin Islands. The designations of DDAs in this notice are based on modified Fiscal Year (FY) 2015 Small Area Fair Market Rents (SAFMRs), FY2015 income limits, and 2010 Census population counts, as explained below.

This notice also designates QCTs based on new income and poverty data released in the American Community Survey (ACS). HUD relies on the most recent three sets of ACS estimates to ensure that anomalous estimates, due to sampling, do not affect the QCT status of tracts.

2010 Census and 2007–2011, 2008–2012 and 2009–2013 American Community Survey Data

Data from the 2010 Census on total population of metropolitan areas and nonmetropolitan areas are used in the designation of DDAs. The Office of Management and Budget (OMB) first published new metropolitan area definitions incorporating 2000 Census data in OMB Bulletin No. 03–04 on June 6, 2003, and updated them periodically through OMB Bulletin No. 10–02 on

December 1, 2009. FY2015 FMRs and FY2015 income limits used to designate DDAs are based on these metropolitan statistical area (MSA) definitions, with modifications to account for substantial differences in rental housing markets (and, in some cases, median income levels) within MSAs. SAFMRs are calculated for the ZIP Code Tabulation Areas (ZCTAs), or portions of ZCTAs within the metropolitan areas defined by OMB Bulletin No. 10–02.

Data from the 2010 Census on total population of census tracts, metropolitan areas, and the nonmetropolitan parts of states are used in the designation of QCTs. The FY2015 income limits used to designate QCTs are based on these MSA definitions with modifications to account for substantial differences in rental housing markets (and in some cases median income levels) within MSAs. This QCT designation uses the OMB metropolitan area definitions published in OMB Bulletin No. 10–02 on December 1, 2009, without modification for purposes of evaluating how many census tracts can be designated under the population cap, but uses the HUD-modified definitions and their associated area median incomes for determining QCT eligibility.

Because the 2010 Decennial Census did not include questions on respondent household income, HUD uses ACS data to designate QCTs. The ACS tabulates data collected over 5 years to provide estimates of socioeconomic variables for small areas containing fewer than 20,000 persons, such as census tracts. Due to anomalies in estimates from year-to-year, HUD incorporates three sets of ACS tabulations to ensure that anomalous estimates do not affect QCT status.

Background

The U.S. Department of the Treasury (Treasury) and its Internal Revenue Service (IRS) are authorized to interpret and enforce the provisions of the LIHTC found at IRC Section 42. The Secretary of HUD is required to designate DDAs and QCTs by IRC Section 42(d)(5)(B). In order to assist in understanding HUD's mandated designation of DDAs and QCTs for use in administering IRC Section 42, a summary of the section is provided. The following summary does not purport to bind Treasury or the IRS in any way, nor does it purport to bind HUD, since HUD has authority to interpret or administer the IRC only in instances where it receives explicit statutory delegation.

Summary of the Low-Income Housing Tax Credit

The LIHTC is a tax incentive intended to increase the availability of low-income housing. IRC Section 42 provides an income tax credit to owners of newly constructed or substantially rehabilitated low-income rental housing projects. The dollar amount of the LIHTC available for allocation by each state (credit ceiling) is limited by population. Each state is allowed a credit ceiling based on a statutory formula indicated at IRC Section 42(h)(3). States may carry forward unallocated credits derived from the credit ceiling for one year; however, to the extent such unallocated credits are not used by then, the credits go into a national pool to be redistributed to states as additional credit. State and local housing agencies allocate the state's credit ceiling among low-income housing buildings whose owners have applied for the credit. Besides IRC Section 42 credits derived from the credit ceiling, states may also provide IRC Section 42 credits to owners of buildings based on the percentage of certain building costs financed by tax-exempt bond proceeds. Credits provided under the tax-exempt bond ''volume cap'' do not reduce the credits available from the credit ceiling.

The credits allocated to a building are based on the cost of units placed in service as low-income units under particular minimum occupancy and maximum rent criteria. In general, a building must meet one of two thresholds to be eligible for the LIHTC; either: (1) 20 percent of the units must be rent-restricted and occupied by tenants with incomes no higher than 50 percent of the Area Median Gross Income (AMGI), or (2) 40 percent of the units must be rent-restricted and occupied by tenants with incomes no higher than 60 percent of AMGI. A unit is ''rent-restricted'' if the gross rent, including an allowance for tenant-paid utilities, does not exceed 30 percent of the imputed income limitation (*i.e.,* 50 percent or 60 percent of AMGI) applicable to that unit. The rent and occupancy thresholds remain in effect for at least 15 years, and building owners are required to enter into agreements to maintain the low-income character of the building for at least an additional 15 years.

The LIHTC reduces income tax liability dollar-for-dollar. It is taken annually for a term of 10 years and is intended to yield a present value of either: (1) 70 Percent of the ''qualified basis'' for new construction or substantial rehabilitation expenditures that are not federally subsidized (as defined in IRC Section 42(i)(2)), or (2) 30 percent of the qualified basis for the cost of acquiring certain existing buildings or projects that are federally subsidized. The actual credit rates are adjusted monthly for projects placed in service after 1987 under procedures specified in IRC Section 42. Individuals can use the credits up to a deduction equivalent of $25,000 (the actual maximum amount of credit that an individual can claim depends on the individual's marginal tax rate). For buildings placed in service after December 31, 2007, individuals can use the credits against the alternative minimum tax. Corporations, other than S or personal service corporations, can use the credits against ordinary income tax, and, for buildings placed in service after December 31, 2007, against the alternative minimum tax. These corporations also can deduct losses from the project.

The qualified basis represents the product of the building's ''applicable fraction'' and its ''eligible basis.'' The applicable fraction is based on the number of low-income units in the building as a percentage of the total number of units, or based on the floor space of low-income units as a percentage of the total floor space of residential units in the building. The eligible basis is the adjusted basis attributable to acquisition, rehabilitation, or new construction costs (depending on the type of LIHTC involved). These costs include amounts chargeable to a capital account that are incurred prior to the end of the first taxable year in which the qualified low-income building is placed in service or, at the election of the taxpayer, the end of the succeeding taxable year. In the case of buildings located in designated DDAs or designated QCTs, eligible basis can be increased up to 130 percent from what it would otherwise be. This means that the available credits also can be increased by up to 30 percent. For example, if a 70 percent credit is available, it effectively could be increased to as much as 91 percent.

IRC Section 42 defines a DDA as an area designated by the Secretary of HUD that has high construction, land, and utility costs relative to the AMGI. All designated DDAs in metropolitan areas (taken together) may not contain more than 20 percent of the aggregate population of all metropolitan areas, and all designated areas not in metropolitan areas may not contain more than 20 percent of the aggregate population of all nonmetropolitan areas.

IRC Section 42(d)(5)(B)(v) allows states to award an increase in basis up

to 30 percent to buildings located outside of federally designated DDAs and QCTs if the increase is necessary to make the building financially feasible. This state discretion applies only to buildings allocated credits under the state housing credit ceiling and is not permitted for buildings receiving credits in connection with tax-exempt bonds. Rules for such designations shall be set forth in the LIHTC-allocating agencies' qualified allocation plans (QAPs).

Explanation of HUD Designation Method

A. 2016 Difficult Development Areas

In developing the list of DDAs, HUD compared housing costs with incomes. HUD used 2010 Census population for ZCTAs, and nonmetropolitan areas, and the MSA definitions, as published in OMB Bulletin No. 10–02 on December 1, 2009, with modifications, as described below. In keeping with past practice of basing the coming year's DDA designations on data from the preceding year, the basis for these comparisons is the FY2015 HUD income limits for very low-income households (very low-income limits, or VLILs), which are based on 50 percent of AMGI, and modified FMRs based on the FY2015 FMRs used for the Housing Choice Voucher (HCV) program. For metropolitan DDAs, HUD used SAFMRs based on 3 annual releases of ACS data, to avoid statistical anomalies which affect estimates for some ZCTAs. For non-metropolitan DDAs, HUD used the final FY2015 FMRs as published on October 3, 2014 (79 FR 59786) and updated on January 12, 2015 (80 FR 1511).

In formulating the FY2015 FMRs and VLILs, HUD modified the current OMB definitions of MSAs to account for substantial differences in rents among areas within each current MSA that were in different FMR areas under definitions used in prior years. HUD formed these ''HUD Metro FMR Areas'' (HMFAs) in cases where one or more of the parts of newly defined MSAs that previously were in separate FMR areas had 2000 Census based 40th-percentile recent-mover rents that differed, by 5 percent or more, from the same statistic calculated at the MSA level. In addition, a few HMFAs were formed on the basis of very large differences in AMGIs among the MSA parts. All HMFAs are contained entirely within MSAs. All nonmetropolitan counties are outside of MSAs and are not broken up by HUD for purposes of setting FMRs and VLILs. (Complete details on HUD's process for determining FY2015 FMR areas and FMRs are available at *http://www.huduser.org/portal/datasets/fmr/fmrs/docsys.html&data=fmr15*. Complete details on HUD's process for determining FY2015 income limits are available at *http://www.huduser.org/portal/datasets/il/il15/index.html*.)

HUD's unit of analysis for designating metropolitan DDAs consists of ZCTAs, whose SAFMRs are compared to metropolitan VLILs. For purposes of computing VLILs in metropolitan areas, HUD considers entire MSAs, in cases where these were not broken up into HMFAs for purposes of computing VLILs; and HMFAs within the MSAs that were broken up for such purposes. Hereafter in this notice, the unit of analysis for designating metropolitan DDAs will be called the ZCTA, and the unit of analysis for nonmetropolitan DDAs will be the nonmetropolitan county or county equivalent area. The procedure used in making the DDA calculations follows:

1. For each metropolitan ZCTA and each nonmetropolitan county, HUD calculated a ratio. HUD used a modified FY2015 two-bedroom SAFMR for ZCTAs, the final FY2015 two-bedroom FMR as published for non-metropolitan counties, and the FY2015 four-person VLIL for this calculation. The modified FY2015 two-bedroom SAFMRs for ZCTAs differ from the final FY2015 SAFMRs in 5 ways.

First, three years of median rents from the American Community Survey (ACS) were deflated and averaged. Three years of ACS releases are averaged to avoid anomalies that occur due to statistical sampling in some ZCTAs. The modified SAFMRs rely on the 2006–2010, 2007–2011 and 2008–2012 5-year ACS estimates. Only rents with margins of error less than 50 percent of the rent estimate were considered.[1] Second, HUD did not limit the median gross ZCTA rent to 150 percent of the median gross Core-Based Statistical Area (CBSA) rent, as in the SAFMR calculations used in HUD's demonstration project. Third, for a small percentage of ZCTAs with median rents exceeding $2,000, the census releases only a value of ''$2,000+''. HUD's modified FY2015 SAFMRs includes an interpolated value above $2,000 for these areas. Fourth, HUD adjusted median rent values in New York City to correct for the downward-bias resulting from rent control and stabilization regulations using the New York City Housing and Vacancy Survey, which is conducted by the U.S. Census Bureau.[2] Finally, the adjustment for recent mover rents is calculated at the HMFA-level rather than CBSA-level.

a. The numerator of the ratio, representing the development cost of housing, was the area's FY2015 FMR, or SAFMR in metropolitan areas. In general, the FMR is based on the 40th-percentile gross rent paid by recent movers to live in a two-bedroom apartment.

b. The denominator of the ratio, representing the maximum income of eligible tenants, was the monthly LIHTC income-based rent limit, which was calculated as 1/12 of 30 percent of 120 percent of the area's VLIL (where the VLIL was rounded to the nearest $50 and not allowed to exceed 80 percent of the AMGI in areas where the VLIL is adjusted upward from its 50 percent-of-AMGI base).

2. The ratios of the FMR, or SAFMR, to the LIHTC income-based rent limit were arrayed in descending order, separately, for ZCTAs and for nonmetropolitan counties.

3. The DDAs are those with the highest ratios cumulative to 20 percent of the 2010 population of all metropolitan areas and all nonmetropolitan areas. For purposes of applying this population cap, HUD excluded the population in areas designated as 2016 QCTs. Thus, an area can be designated as a QCT or DDA, but not both.

B. Application of Population Caps to DDA Determinations

In identifying DDAs, HUD applied caps, or limitations, as noted above. The cumulative population of metropolitan DDAs cannot exceed 20 percent of the cumulative population of all metropolitan areas, and the cumulative population of nonmetropolitan DDAs cannot exceed 20 percent of the cumulative population of all nonmetropolitan areas.

In applying these caps, HUD established procedures to deal with how to treat small overruns of the caps. The remainder of this section explains those procedures. In general, HUD stops selecting areas when it is impossible to choose another area without exceeding the applicable cap. The only exceptions to this policy are when the next eligible excluded area contains either a large absolute population or a large

[1] HUD is moving to a tighter margin of error ratio for most uses of ACS data (base rents, recent mover rents, median rents used in the Small Area FMR calculations, etc.) in order to make the FMRs more reliable and stable. ACS data with a coefficient of variation (CV) greater than 30 percent, which coincides with a margin of error ratio of 50 percent, is highly suspect.

[2] HUD encourages other jurisdictions with rent control laws that affect rents paid by recent movers into existing units to contact HUD about what data might be provided or collected to adjust SAFMRs in those jurisdictions.

percentage of the total population, or the next excluded area's ranking ratio, as described above, was identical (to four decimal places) to the last area selected, and its inclusion resulted in only a minor overrun of the cap. Thus, for both the designated metropolitan and nonmetropolitan DDAs, there may be minimal overruns of the cap. HUD believes the designation of additional areas in the above examples of minimal overruns is consistent with the intent of the IRC. As long as the apparent excess is small due to measurement errors, some latitude is justifiable, because it is impossible to determine whether the 20 percent cap has been exceeded. Despite the care and effort involved in a Decennial Census, the Census Bureau and all users of the data recognize that the population counts for a given area and for the entire country are not precise. Therefore, the extent of the measurement error is unknown. There can be errors in both the numerator and denominator of the ratio of populations used in applying a 20 percent cap. In circumstances where a strict application of a 20 percent cap results in an anomalous situation, recognition of the unavoidable imprecision in the census data justifies accepting small variances above the 20 percent limit.

C. Qualified Census Tracts

In developing this list of QCTs, HUD used 2010 Census 100-percent count data on total population, total households, and population in households; the median household income and poverty rate as estimated in the 2007–2011, 2008–2012 and 2009–2013 ACS tabulations; the FY2015 Very Low-Income Limits (VLILs) computed at the HUD Metropolitan FMR Area (HMFA) level [3] to determine tract eligibility; and the MSA definitions published in OMB Bulletin No. 10–02 on December 1, 2009, for determining how many eligible tracts can be designated under the statutory 20 percent population cap.

HUD uses the HMFA-level AMGIs to determine QCT eligibility because the statute, specifically IRC Section 42(d)(5)(B)(iv)(II), refers to the same section of the IRC that defines income for purposes of tenant eligibility and unit maximum rent, specifically IRC Section 42(g)(4). By rule, the IRS sets these income limits according to HUD's VLILs, which, starting in FY2006 and thereafter, are established at the HMFA level. Similarly, HUD uses the entire MSA to determine how many eligible tracts can be designated under the 20 percent population cap as required by the statute (IRC Section 42(d)(5)(B)(ii)(III)), which states that MSAs should be treated as singular areas. The QCTs were determined as follows:

1. To be eligible to be designated a QCT, a census tract must have 50 percent of its households with incomes below 60 percent of the AMGI or have a poverty rate of 25 percent or more. Due to potential statistical anomalies in the ACS 5-year estimates, one of these conditions must be met in at least 2 of the 3 evaluation years for a tract to be considered eligible for QCT designation. HUD calculates 60 percent of AMGI by multiplying by a factor of 1.2 the HMFA or nonmetropolitan county FY2015 VLIL adjusted for inflation to match the ACS estimates. For example, the FY2015 VLILs were adjusted for inflation to 2012 dollars to compare with the median income estimate from the 2008–2012 ACS estimates. The inflation-adjusted 2012 VLIL was then deflated to 2011 for comparison with the 2007–2011 ACS estimates and inflated to 2013 to compare with the 2009–2013 ACS estimates.

2. For each census tract, whether or not 50 percent of households have incomes below the 60 percent income standard (income criterion) was determined by: (a) Calculating the average household size of the census tract, (b) applying the income standard after adjusting it to match the average household size, and (c) comparing the average-household-size-adjusted income standard to the median household income for the tract reported in each of the three years of ACS tabulations (2007–2011, 2008–2012 and 2009–2013). HUD did not consider estimates of median household income to be statistically reliable unless the margin of error was less than half of the estimate (or a Margin of Error Ratio, MoER, of 50 percent or less). If at least two of the three estimates were not statistically reliable by this measure, HUD determined the tract to be ineligible under the income criterion due to lack of consistently reliable median income statistics across the 3 ACS tabulations. In prior designations of QCTs, HUD accepted ACS data with MoERs of up to, but not including 100 percent. The higher data quality standard used for the 2016 QCTs is consistent with current thinking about the reliability of ACS data.[4] Since 50 percent of households in a tract have incomes above and below the tract median household income, if the tract median household income is less than the average-household-size-adjusted income standard for the tract, then more than 50 percent of households have incomes below the standard.

3. For each census tract, the poverty rate was determined in each of the three releases of ACS tabulations (2007–2011, 2008–2012 and 2009–2013) by dividing the population with incomes below the poverty line by the population for whom poverty status has been determined. As with the evaluation of tracts under the income criterion, HUD uses a higher data quality standard for evaluating ACS poverty rate data in designating the 2016 QCTs than HUD used in previous designations. HUD did not consider estimates of the poverty rate to be statistically reliable unless both the population for whom poverty status has been determined and the number of persons below poverty had MoERs of less than 50 percent of the respective estimates. In prior designations of QCTs, HUD accepted ACS data with MoERs of up to, but not including 100 percent. If at least two of the three poverty rate estimates were not statistically reliable, HUD determined the tract to be ineligible under the poverty rate criterion due to lack of reliable poverty statistics across the ACS tabulations.

4. QCTs are those census tracts in which 50 percent or more of the households meet the income criterion in at least two of the three years evaluated, or 25 percent or more of the population is in poverty in at least two of the three years evaluated, such that the population of all census tracts that satisfy either one or both of these criteria does not exceed 20 percent of the total population of the respective area.

5. In areas where more than 20 percent of the population resides in

[3] HUD income limits for very low-income households (very low-income limits, or VLILs) are based on 50 percent of AMGI. In formulating the Fair Market Rents (FMRs) and VLILs, HUD modified the current OMB definitions of MSAs to account for substantial differences in rents among areas within each new MSA that were in different FMR areas under definitions used in prior years. HUD formed these ''HUD Metro FMR Areas'' (HMFAs) in cases where one or more of the parts of newly defined MSAs that previously were in separate FMR areas had 2000 Census based 40th-percentile recent-mover rents that differed, by 5 percent or more, from the same statistic calculated at the MSA level. In addition, a few HMFAs were formed on the basis of very large differences in AMGIs among the MSA parts. All HMFAs are contained entirely within MSAs. All nonmetropolitan counties are outside of MSAs and are not broken up by HUD for purposes of setting FMRs and VLILs. (Complete details on HUD's process for determining FMR areas and FMRs are available at *http://www.huduser.org/portal/datasets/fmr.html*. Complete details on HUD's process for determining income limits are available at *http://www.huduser.org/portal/datasets/il.html*.)

[4] For a discussion of ACS data quality measures, see: *https://www.census.gov/content/dam/Census/library/publications/2008/acs/ACSGeneralHandbook.pdf*.

eligible census tracts, census tracts are designated as QCTs in accordance with the following procedure:

a. The income and poverty criteria are each averaged over the three ACS tabulations (2007–2011, 2008–2012 and 2009–2013). Statistically reliable values that did not exceed the income and poverty rate thresholds were included in the average.

b. Eligible tracts are placed in one of two groups based on the averaged values of the income and poverty criteria. The first group includes tracts that satisfy both the income and poverty criteria for QCTs for at least two of the three evaluation years. The second group includes tracts that satisfy either the income criterion or the poverty criterion in at least two of three years, but not both. A tract must qualify by at least one of the criteria in at least two of the three evaluation years to be eligible, although it does not need to be the same criterion.

c. Tracts in the first group are ranked from highest to lowest by the average of the ratios of the tract average-household-size-adjusted income limit to the median household income. Then, tracts in the first group are ranked from highest to lowest by the average of the poverty rates. The two ranks are averaged to yield a combined rank. The tracts are then sorted on the combined rank, with the census tract with the highest combined rank being placed at the top of the sorted list. In the event of a tie, more populous tracts are ranked above less populous ones.

d. Tracts in the second group are ranked from highest to lowest by the average of the ratios of the tract average-household-size-adjusted income limit to the median household income. Then, tracts in the second group are ranked from highest to lowest by the average of the poverty rates. The two ranks are then averaged to yield a combined rank. The tracts are then sorted on the combined rank, with the census tract with the highest combined rank being placed at the top of the sorted list. In the event of a tie, more populous tracts are ranked above less populous ones.

e. The ranked first group is stacked on top of the ranked second group to yield a single, concatenated, ranked list of eligible census tracts.

f. Working down the single, concatenated, ranked list of eligible tracts, census tracts are identified as designated until the designation of an additional tract would cause the 20 percent limit to be exceeded. If a census tract is not designated because doing so would raise the percentage above 20 percent, subsequent census tracts are then considered to determine if one or more census tract(s) with smaller population(s) could be designated without exceeding the 20 percent limit.

D. Exceptions to OMB Definitions of MSAs and Other Geographic Matters

As stated in OMB Bulletin 10–02, defining metropolitan areas:

> OMB establishes and maintains the definitions of Metropolitan . . . Statistical Areas, . . . solely for statistical purposes. . . . OMB does not take into account or attempt to anticipate any non-statistical uses that may be made of the definitions[.] In cases where . . . an agency elects to use the Metropolitan . . . Area definitions in nonstatistical programs, it is the sponsoring agency's responsibility to ensure that the definitions are appropriate for such use. An agency using the statistical definitions in a nonstatistical program may modify the definitions, but only for the purposes of that program. In such cases, any modifications should be clearly identified as deviations from the OMB statistical area definitions in order to avoid confusion with OMB's official definitions of Metropolitan . . . Statistical Areas.

Following OMB guidance, the estimation procedure for the FMRs and income limits incorporates the current OMB definitions of metropolitan areas based on the CBSA standards, as implemented with 2000 Census data, but makes adjustments to the definitions, in order to separate subparts of these areas in cases where FMRs (and in a few cases, VLILs) would otherwise change significantly if the new area definitions were used without modification. In CBSAs where subareas are established, it is HUD's view that the geographic extent of the housing markets are not yet the same as the geographic extent of the CBSAs, but may approach becoming so as the social and economic integration of the CBSA component areas increases.

The geographic baseline for the FMR and income limit estimation procedure is the CBSA Metropolitan Areas (referred to as Metropolitan Statistical Areas or MSAs) and CBSA Non-Metropolitan Counties (nonmetropolitan counties include the county components of Micropolitan CBSAs where the counties are generally assigned separate FMRs). The HUD-modified CBSA definitions allow for subarea FMRs within MSAs based on the boundaries of ''Old FMR Areas'' (OFAs) within the boundaries of new MSAs. (OFAs are the FMR areas defined for the FY2005 FMRs. Collectively, they include the June 30, 1999, OMB definitions of MSAs and Primary MSAs (old definition MSAs/PMSAs), metropolitan counties deleted from old definition MSAs/PMSAs by HUD for FMR-setting purposes, and counties and county parts outside of old definition MSAs/PMSAs referred to as nonmetropolitan counties). Subareas of MSAs are assigned their own FMRs and Income Limits when the subarea 2000 Census Base FMR differs significantly from the MSA 2000 Census Base FMR (or, in some cases, where the 2000 Census base AMGI differs significantly from the MSA 2000 Census Base AMGI). MSA subareas, and the remaining portions of MSAs after subareas have been determined, are referred to as ''HUD Metro FMR Areas (HMFAs),'' to distinguish such areas from OMB's official definition of MSAs.

In the New England states (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont), HMFAs are defined according to county subdivisions or minor civil divisions (MCDs), rather than county boundaries. However, since no part of an HMFA is outside an OMB-defined, county-based MSA, all New England nonmetropolitan counties are kept intact for purposes of designating Nonmetropolitan DDAs.

For the convenience of readers of this notice, the geographical definitions of designated Metropolitan DDAs are included in the list of DDAs.

Future Designations

DDAs are designated annually as updated income and FMR data are made public. QCTs are designated annually as new income and poverty rate data are released.

Effective Date

The 2016 lists of QCTs and DDAs are effective:

(1) for allocations of credit after June 30, 2016; or

(2) for purposes of IRC Section 42(h)(4), if the bonds are issued and the building is placed in service after June 30, 2016.

If an area is not on a subsequent list of QCTs or DDAs, the 2016 lists are effective for the area if:

(1) the allocation of credit to an applicant is made no later than the end of the 730-day period after the applicant submits a complete application to the LIHTC-allocating agency, and the submission is made before the effective date of the subsequent lists; or

(2) for purposes of IRC Section 42(h)(4), if:

(a) the bonds are issued or the building is placed in service no later than the end of the 730-day period after the applicant submits a complete application to the bond-issuing agency, and

(b) the submission is made before the effective date of the subsequent lists,

provided that both the issuance of the bonds and the placement in service of the building occur after the application is submitted.

An application is deemed to be submitted on the date it is filed if the application is determined to be complete by the credit-allocating or bond-issuing agency. A ''complete application'' means that no more than de minimis clarification of the application is required for the agency to make a decision about the allocation of tax credits or issuance of bonds requested in the application.

In the case of a ''multiphase project,'' the DDA or QCT status of the site of the project that applies for all phases of the project is that which applied when the project received its first allocation of LIHTC. For purposes of IRC Section 42(h)(4), the DDA or QCT status of the site of the project that applies for all phases of the project is that which applied when the first of the following occurred: (a) The building(s) in the first phase were placed in service, or (b) the bonds were issued.

For purposes of this notice, a ''multiphase project'' is defined as a set of buildings to be constructed or rehabilitated under the rules of the LIHTC and meeting the following criteria:

(1) The multiphase composition of the project (*i.e.,* total number of buildings and phases in project, with a description of how many buildings are to be built in each phase and when each phase is to be completed, and any other information required by the agency) is made known by the applicant in the first application of credit for any building in the project, and that applicant identifies the buildings in the project for which credit is (or will be) sought;

(2) The aggregate amount of LIHTC applied for on behalf of, or that would eventually be allocated to, the buildings on the site exceeds the one-year limitation on credits per applicant, as defined in the Qualified Allocation Plan (QAP) of the LIHTC-allocating agency, or the annual per-capita credit authority of the LIHTC allocating agency, and is the reason the applicant must request multiple allocations over 2 or more years; and

(3) All applications for LIHTC for buildings on the site are made in immediately consecutive years.

Members of the public are hereby reminded that the Secretary of Housing and Urban Development, or the Secretary's designee, has legal authority to designate DDAs and QCTs, by publishing lists of geographic entities as defined by, in the case of DDAs, the Census Bureau, the several states and the governments of the insular areas of the United States and, in the case of QCTs, by the Census Bureau; and to establish the effective dates of such lists. The Secretary of the Treasury, through the IRS thereof, has sole legal authority to interpret, and to determine and enforce compliance with the IRC and associated regulations, including **Federal Register** notices published by HUD for purposes of designating DDAs and QCTs. Representations made by any other entity as to the content of HUD notices designating DDAs and QCTs that do not precisely match the language published by HUD should not be relied upon by taxpayers in determining what actions are necessary to comply with HUD notices.

Interpretive Examples of Effective Date

For the convenience of readers of this notice, interpretive examples are provided below to illustrate the consequences of the effective date in areas that gain or lose DDA status. The examples covering DDAs are equally applicable to QCT designations.

(Case A) Project A is located in a 2016 DDA that is NOT a designated DDA in 2017 or 2018. A complete application for tax credits for Project A is filed with the allocating agency on November 15, 2016. Credits are allocated to Project A on October 30, 2018. Project A is eligible for the increase in basis accorded a project in a 2016 DDA because the application was filed BEFORE January 1, 2017 (the assumed effective date for the 2017 DDA lists), and because tax credits were allocated no later than the end of the 730-day period after the filing of the complete application for an allocation of tax credits.

(Case B) Project B is located in a 2016 DDA that is NOT a designated DDA in 2017 or 2018. A complete application for tax credits for Project B is filed with the allocating agency on December 1, 2016. Credits are allocated to Project B on March 30, 2019. Project B is NOT eligible for the increase in basis accorded a project in a 2016 DDA because, although the application for an allocation of tax credits was filed BEFORE January 1, 2017 (the assumed effective date of the 2017 DDA lists), the tax credits were allocated later than the end of the 730-day period after the filing of the complete application.

(Case C) Project C is located in a 2016 DDA that was not a DDA in 2015. Project C was placed in service on November 15, 2015. A complete application for tax-exempt bond financing for Project C is filed with the bond-issuing agency on January 15, 2016. The bonds that will support the permanent financing of Project C are issued on September 30, 2016. Project C is NOT eligible for the increase in basis otherwise accorded a project in a 2016 DDA, because the project was placed in service BEFORE July 1, 2016.

(Case D) Project D is located in an area that is a DDA in 2016, but is NOT a DDA in 2017 or 2018. A complete application for tax-exempt bond financing for Project D is filed with the bond-issuing agency on October 30, 2016. Bonds are issued for Project D on April 30, 2018, but Project D is not placed in service until January 30, 2019. Project D is eligible for the increase in basis available to projects located in 2016 DDAs because: (1) One of the two events necessary for triggering the effective date for buildings described in Section 42(h)(4)(B) of the IRC (the two events being bonds issued and buildings placed in service) took place on April 30, 2018, within the 730-day period after a complete application for tax-exempt bond financing was filed, (2) the application was filed during a time when the location of Project D was in a DDA, and (3) both the issuance of the bonds and placement in service of Project D occurred after the application was submitted.

(Case E) Project E is a multiphase project located in a 2016 DDA that is NOT a designated DDA or QCT in 2017. The first phase of Project E received an allocation of credits in 2016, pursuant to an application filed July 15, 2016, which describes the multiphase composition of the project. An application for tax credits for the second phase of Project E is filed with the allocating agency by the same entity on July 15, 2017. The second phase of Project E is located on a contiguous site. Credits are allocated to the second phase of Project E on October 30, 2017. The aggregate amount of credits allocated to the two phases of Project E exceeds the amount of credits that may be allocated to an applicant in one year under the allocating agency's QAP and is the reason that applications were made in multiple phases. The second phase of Project E is, therefore, eligible for the increase in basis accorded a project in a 2016 DDA, because it meets all of the conditions to be a part of a multiphase project.

(Case F) Project F is a multiphase project located in a 2016 DDA that is NOT a designated DDA in 2017 or 2018. The first phase of Project F received an allocation of credits in 2016, pursuant to an application filed July 15, 2016, which does not describe the multiphase composition of the project. An application for tax credits for the second

phase of Project F is filed with the allocating agency by the same entity on March 15, 2018. Credits are allocated to the second phase of Project F on October 30, 2018. The aggregate amount of credits allocated to the two phases of Project F exceeds the amount of credits that may be allocated to an applicant in one year under the allocating agency's QAP. The second phase of Project F is, therefore, NOT eligible for the increase in basis accorded a project in a 2016 DDA, since it does not meet all of the conditions for a multiphase project, as defined in this notice. The original application for credits for the first phase did not describe the multiphase composition of the project. Also, the application for credits for the second phase of Project F was not made in the year immediately following the first phase application year.

Findings and Certifications

Environmental Impact

This notice involves the establishment of fiscal requirements or procedures that are related to rate and cost determinations and do not constitute a development decision affecting the physical condition of specific project areas or building sites. Accordingly, under 40 CFR 1508.4 of the regulations of the Council on Environmental Quality and 24 CFR 50.19(c)(6) of HUD's regulations, this notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Federalism Impact

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any policy document that has federalism implications if the document either imposes substantial direct compliance costs on state and local governments and is not required by statute, or the document preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the executive order. This notice merely designates DDAs as required under IRC Section 42, as amended, for the use by political subdivisions of the states in allocating the LIHTC. This notice also details the technical method used in making such designations. As a result, this notice is not subject to review under the order.

Dated: November 19, 2015.

Katherine M. O'Regan,

Assistant Secretary for Policy Development and Research.

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BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2015–0166; FXIA16710900000–156–FF09A30000]

Endangered Species; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (ESA) prohibits activities with listed species unless Federal authorization is acquired that allows such activities.

DATES: We must receive comments or requests for documents on or before December 24, 2015.

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

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–IA–2015–0166.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2015–0166; U.S. Fish and Wildlife Service Headquarters, MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

When submitting comments, please indicate the name of the applicant and the PRT# you are commenting on. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information). *Viewing Comments:* Comments and materials we receive will be available for public inspection on *http://www.regulations.gov,* or by appointment, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays, at the U.S. Fish and Wildlife Service, Division of Management Authority, 5275 Leesburg Pike, Falls Church, VA 22041–3803; telephone 703–358–2095.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2281 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

II. Background

To help us carry out our conservation responsibilities for affected species, and

in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), along with Executive Order 13576, ''Delivering an Efficient, Effective, and Accountable Government,'' and the President's Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken.

III. Permit Applications

Endangered Species

Applicant: Big Cat Rescue Corporation, Tampa, FL; PRT–75301B

The applicant requests a permit to import one captive-bred male tiger (*Bengal tigris*) for the purpose of enhancement of the survival of the species through conservation education and zoological display.

Applicant: Tanganyika Wildlife Park, Goddard, KS; PRT–68465B

The applicant requests a permit to import 16 captive-bred African penguins (*Spheniscus demersus*) for the purpose of enhancement of the survival of the species through zoological display.

Applicant: Disney's Animal Kingdom, Bay Lake, FL; PRT–80902B

The applicant requests a permit to import three captive-bred lion-tailed macaques (*Macaca Silenus*) for the purpose of enhancement of the survival of the species through captive breeding. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: SOS Ranch, LLC, Crystal City, TX; PRT–66741B

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species to enhance species propagation or survival: barasingha (*Cervus duvaucelii*), Eld's deer (*Cervus eldii*), Arabian oryx (*Oryx leucoryx*), and red lechwe (*Kobus lechwe*). This notification covers activities to be conducted by the applicant over a 5-year period.

Multiple Applicants

The following applicants each request a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Jeffrey Scherer, Beemer, NE; PRT–78213B

Applicant: Kevin Poynter, Houston, TX; PRT–80785B

Applicant: Daniel Danell, Hanford, CA; PRT–80787B

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2015–29864 Filed 11–23–15; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[167 A2100DD/AAKC001030/ A0A501010.999900]

Indian Gaming; Extension of Tribal-State Class III Gaming Compact (Yankton Sioux Tribe and the State of South Dakota)

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice announces the extension of the Class III gaming compact between the Yankton Sioux Tribe and the State of South Dakota.

DATES: November 24, 2015.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: An extension to an existing tribal-state Class III gaming compact does not require approval by the Secretary if the extension does not include any amendment to the terms of the compact. See 25 CFR 293.5. The Yankton Sioux Tribe and the State of South Dakota have reached an agreement to extend the expiration of their existing Tribal-State Class III gaming compact until April 19, 2016. This publishes notice of the new expiration date of the compact.

Dated: November 17, 2015.

Kevin K. Washburn,

Assistant Secretary—Indian Affairs.

[FR Doc. 2015–29911 Filed 11–23–15; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR83570000, 167R5065C6, RX.59389832.1009676]

Agency Information Collection Activities Under OMB Review; Renewal of a Currently Approved Information Collection

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Reclamation (Reclamation) has forwarded the following Information Collection Request to the Office of Management and Budget (OMB) for review and approval: Recreation Use Data Reports, OMB Control Number: 1006–0002. As part of its continuing effort to reduce paperwork and respondent burdens, Reclamation invites State, local, or tribal governments that manage recreation sites at Reclamation projects; concessionaires, and not-for-profit organizations who operate concessions on Reclamation lands; and the public, to comment on this information collection.

DATES: OMB has up to 60 days to approve or disapprove this information collection request, but may respond after 30 days; therefore, public comments must be received on or before December 24, 2015.

ADDRESSES: Send written comments to the Desk Officer for the Department of the Interior at the Office of Management and Budget, Office of Information and Regulatory Affairs, via facsimile to (202) 395–5806, or email to *oira_submissions@omb.eop.gov.* A copy of your comments should also be directed to the Mr. Jerome Jackson, Bureau of Reclamation, 84–57000, P.O. Box 25007, Denver, CO 80225–0007; or via email to *jljackson@usbr.gov.* Please reference OMB Control Number 1006–0002 in your comments.

FOR FURTHER INFORMATION CONTACT: Mr. Jerome Jackson at (303) 445–2712. You may also view the information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

Reclamation collects agency-wide recreation and concession information to fulfill congressional reporting requirements pursuant to current public laws, including Public Law 89–72, as amended through 106–580, Federal Water Project Recreation Act of 1965; and Public Law 102–575, Title XXVIII, Reclamation Recreation Management Act of 1992. In addition, collected

information will permit relevant program assessments of resources managed by Reclamation, its recreation managing partners, and/or concessionaires for the purpose of contributing to the implementation of Reclamation's mission. More specifically, the collected information enables Reclamation to (1) evaluate the effectiveness of program management based on existing recreation and concessionaire resources and facilities, and (2) validate the efficiency of resources for public use within partner managed recreation resources, located on Reclamation project lands in the 17 Western States. No changes are being made to this information collection.

II. Data

OMB Control Number: 1006–0002.
Title: Recreation Use Data Reports.
Form Numbers: 7–2534, Part I, Managing Partners and Direct Managed Recreation Areas; 7–2535, Part II, Concessionaires.
Frequency: Annually.
Respondents: State, local, or tribal governments; agencies who manage Reclamation's recreation resources and facilities; and commercial concessions, and nonprofit organizations located on Reclamation lands with associated recreation services.

Estimated Total Number of Respondents: 270.

Estimated Number of Responses per Respondent: 1.

Estimated Total Number of Annual Responses: 270.

Estimated Total Annual Burden on Respondents: 136 hours.

Form No.	Burden estimate per form (in minutes)	Annual number of respondents	Annual burden on respondents (in hours)
7–2534 (Part I, Managing Partners and Direct Managed Recreation Areas)	30	155	78
7–2535 (Part II, Concessionaires)	30	115	58
Total Burden Hours	.....	.....	136

III. Request for Comments

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on September 3, 2015 (80 FR 53326). No comments were received.

We invite comments concerning this information collection on:

(a) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical use;

(b) The accuracy of our burden estimate for the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, usefulness, and clarity of the information to be collected; and

(d) Ways to minimize the burden of the collection of information on respondents.

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. Reclamation will display a valid OMB control number on the forms.

IV. Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: November 13, 2015.

Roseann Gonzales,

Director, Policy and Administration.

[FR Doc. 2015–29872 Filed 11–23–15; 8:45 am]

BILLING CODE 4332–90–P–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–930]

Certain Laser Abraded Denim Garments; Commission Decision Terminating the Remaining Respondents From the Investigation; Setting the Date for the Commission To Determine Whether To Grant the Petition for Review of Order Nos. 43 and 83

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (''ALJ'') initial determinations (''IDs'') (Order No. 105 and 106), which terminated the investigation as to the remaining three respondents in the investigation. The Commission has determined to set January 20, 2016 as the date by which to determine whether to grant the petition for review of Order Nos. 43 and 83 by intervenor Dentons US LLP.

FOR FURTHER INFORMATION CONTACT: Sidney A. Rosenzweig, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–2532. Copies of non-confidential documents filed in connection with this investigation are or 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 *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on September 23, 2014, based on a complaint filed by RevoLaze, LLC and TechnoLines, LLC, both of Westlake, Ohio. 79 Fed. Reg. 56828 (Sept. 23, 2014). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, by reason of the importation into the United States, the sale for importation, and the sale within the United States after importation of certain laser abraded denim garments. The complaint alleged

the infringement of seventy-one claims of six United States patents. The notice of institution named twenty respondents. On January 23, 2015, the ALJ granted the complainants' motion to amend the complaint and notice of investigation to add nine respondents. Order No. 20 at 3–4 (Jan. 23, 2015), not reviewed, Notice at 2 (Feb. 20, 2015). As a result of numerous unreviewed initial determinations terminating various respondents, only three respondents remain in the investigation: H&M Hennes & Mauritz AB of Stockholm, Sweden; H&M Hennes & Mauritz LP of New York, New York (collectively, ''H&M''); and Eroglu Giyin San Tic AS of Istanbul, Turkey (''Eroglu'').

On October 1, 2015, the complainants moved to terminate H&M based upon a withdrawal of the complaint. See 19 CFR 210.21(a). The Commission investigative attorney (''IA'') supported the motion. On October 20, 2015, the ALJ granted the motion as an ID (Order No. 105). She found that the complainants complied with Commission Rule 210.21(a) and that good cause for withdrawal had been shown. Order No. 105 at 2.

Also on October 1, 2015, the complainants moved to terminate Eroglu on the basis of a settlement. *See* 19 CFR 210.21(b). The IA supported the motion. The ALJ found that termination as to Eroglu was in the public interest, and granted the motion. Order No. 106 at 3; *see* 19 CFR 210.50(b)(2).

One respondent was previously found to be in default. *See* Order No. 81 (Aug. 7, 2015), *not reviewed,* Notice (Sept. 1, 2015) (respondent Martelli Lavorazioni Tessili S.p.A. of Toscanella, Italy). On October 6, 2015, the complainants filed a contingent motion to terminate the investigation, explaining that they do not seek relief as to the defaulting respondent. The ALJ found the contingent motion to terminate to be moot in view of the issuance of Order Nos. 105 and 106 and in view of complainants' decision not to seek relief against the defaulting respondent. Order No. 106 at 3.

No petitions for review of the foregoing terminations (including as to the defaulting party) were filed. The Commission has determined not to review the IDs. The Commission notes that in granting termination as to Eroglu in Order No. 106, the ALJ observed the ''unconventional state of the Agreements'' demonstrating the settlement between the complainants and Eroglu. Order No. 106 at 2. That characterization is accurate, but the Commission finds that in view of the unique circumstances of this investigation, the ALJ's determination to terminate the investigation as to Eroglu was appropriate.

However, previously in the investigation, the then-presiding ALJ disqualified complainants' former counsel Dentons US LLP (''Dentons'') in a non-ID order. Order No. 43 (May 7, 2015). Subsequently, the ALJ granted (as an ID) Dentons' motion to intervene regarding its disqualification, Order No. 82 (Aug. 7, 2013), but denied (as an order) Dentons' motion for reconsideration of Order No. 43 as well as Dentons' request for leave to seek interlocutory review before the Commission, Order No. 83 (Aug. 7, 2015); *see* 19 CFR 210.24 (interlocutory review by the Commission). The Commission determined not to review Order No. 82. Notice (Aug. 26, 2015).

In response to the issuance of Order No. 106, which terminated the investigation before the ALJ, on October 27, 2015, Dentons filed a petition for Commission review of Order Nos. 43 and 83. *See* 19 CFR 210.24 (rulings by the ALJ ''on motions may not be appealed to the Commission prior to the administrative law judge's issuance of an initial determination''). On November 9, 2015, former respondent the Gap opposed Dentons' motion.

Commission Rule 210.42 does not impose a deadline upon the Commission for ruling on Dentons' petition for review, which arises from previously unreviewable orders in the investigation. The target date for completion of the investigation is September 26, 2016. The Commission has determined that Order Nos. 43 and 83 shall become the determination of the Commission on January 20, 2016, unless the Commission shall have ordered review of those orders or certain issues therein or by order has changed that date.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

Issued: November 18, 2015.

By order of the Commission.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–29846 Filed 11–23–15; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–936]

Certain Footwear Products; Notice of Request for Statements on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the presiding administrative law judge (''ALJ'') has issued a Final Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bonding in the above-captioned investigation. The Commission is soliciting comments on public interest issues raised by the recommended relief should the Commission find a violation of section 337, as amended, 19 U.S.C. 1337. The ALJ recommended a general exclusion order directed to footwear products that infringe the asserted trademarks, and recommended cease and desist orders directed against those respondents found to infringe. This notice is soliciting public interest comments from the public only. Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

FOR FURTHER INFORMATION CONTACT: Clint A. Gerdine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–2310. Copies of non-confidential documents filed in connection with this investigation are or 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 *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://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: Section 337 of the Tariff Act of 1930 provides that if the Commission finds a violation it shall exclude the articles concerned from the United States:

unless, after considering the effect of such exclusion upon the public health and welfare, competition conditions in the United States economy, the production of

like or directly competitive articles in the United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1).

The Commission is interested in further development of the record on the public interest in its investigations. Accordingly, members of the public are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the administrative law judge's Recommended Determination on Remedy and Bonding issued in this investigation on November 17, 2015. Comments should address whether issuance of an exclusion order and/or cease and desist orders in this investigation could 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 recommended orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;

(iii) indicate the extent to which like or directly competitive articles are produced in the United States or are otherwise available in the United States, with respect to the articles potentially subject to the recommended orders;

(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 recommended orders within a commercially reasonable time; and

(v) explain how the recommended orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on December 28, 2015.

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 Commission rule 210.4(f), 19 CFR 210.4(f). Submissions should refer to the investigation number (''Inv. No. 337–TA–936'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document (or portion thereof) to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of 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 sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under authority of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: November 18, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–29805 Filed 11–23–15; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–926]

Certain Marine Sonar Imaging Systems, Products Containing the Same, and Components Thereof; Commission's Final Determination Finding a Violation of Section 337; Issuance of Limited Exclusion Order and Cease and Desist Orders; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found a violation of section 337 in this investigation and has (1) issued a limited exclusion order prohibiting importation of infringing marine sonar imaging systems, products containing the same, and components thereof and (2) issued cease and desist orders directed to the domestic respondents. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–205–3042. Copies of non-confidential documents filed in connection with this investigation are or 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 (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on August 21, 2014, based on a complaint filed by Johnson Outdoors lnc. of Racine, Wisconsin and Johnson Outdoors Marine Electronics, Inc. of Eufaula, Alabama (collectively, ''Johnson Outdoors''). 79 FR 49536 (Aug. 21, 2014). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended (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 marine sonar imaging systems, products containing the same, and components thereof by reason of infringement of one or more of claims 1, 2, 17, 25, 26, 31, 32, 35, 36, 41–43, 53, and 56 of U.S. Patent No. 7,652,952 (''the '952 patent''); claims 1, 5, 7, 8, 21, 22, 24, 25, 28, and 29 of U.S. Patent No. 7,710,825 (''the '825 patent''); and claims 14, 18, 21–23, 25, and 33 of U.S. Patent No. 7,755,974 (''the '974 patent''). *Id.* The notice of investigation named the following respondents: Garmin International, Inc.; Garmin North America, Inc.; Garmin USA, Inc. all of Olathe, Kansas; and Garmin Corporation of New Taipei City, Taiwan (collectively, ''Garmin''). *Id.* The Office of Unfair Import Investigations is not a party to the investigation.

On January 30, 2015, the parties entered into a stipulation that the domestic industry requirement was met. The parties also agreed to a stipulation regarding importation of Garmin accused products. That same day, Johnson Outdoors filed two unopposed motions for summary determination: (1) That Garmin's importation and sales satisfy the importation requirement and (2) that Johnson Outdoors satisfies the

domestic industry requirement. On March 24, 2015, the ALJ granted Johnson Outdoors' summary determination motions in Order Nos. 14 and 15, respectively. The Commission determined not to review these orders. *See* Notice of Commission Determination Not to Review Two Initial Determinations Granting Unopposed Motions for Summary Determinations of Importation and the Existence of a Domestic Industry That Practices the Asserted Patents (April 22, 2015).

On July 13, 2015, the ALJ issued his final ID, finding a violation of section 337 by Garmin in connection with claims 14, 18, 21, 22, 23, and 33 of the '974 patent. The ID found no violation of section 337 in connection with the asserted claims of the '952 and '825 patents; and claim 25 of the '974 patent. Specifically, the ID found that the Commission has subject matter jurisdiction, *in rem* jurisdiction over the accused products, and *in personam* jurisdiction over Garmin. ID at 21. The ID further found that the accused products infringe asserted claims 14, 18, 21, 22, 23, and 33 of the '974 patent but do not infringe the asserted claims of the '952 and '825 patents or claim 25 of the '974 patent. *See* ID at 55–57, 58–59, and 60–62. The ID also found that Garmin failed to establish by clear and convincing evidence that the asserted claims of the '952, '825, or '974 patents were anticipated or rendered obvious by the cited prior art references. *See id.* at 68–80, 89–100. Finally, the ID found that the '952, '825, and '974 patents are not unenforceable due to inequitable conduct and that the '952 patent is not invalid under 35 U.S.C. 102(f) for derivation. ID at 80–83, 100–109.

On July 27, 2015, Garmin filed a petition for review of the ID. That same day, Johnson Outdoors filed a contingent petition for review of the ID. On August 4, 2015, the parties filed responses to the petitions.

On August 25, 2015, the Commission determined to review the final ID on all issues petitioned. 80 FR 55872–74 (Sept. 17, 2015). Specifically, the Commission asked the parties to discuss any impact on the ID's findings if it were to construe the claim term ''mounted to a boat'' to mean ''proximately secured to the boat in a fixed manner.''

On September 21, 2015, the parties filed written submissions on the issues under review, remedy, the public interest, and bonding. On September 28, 2015, the parties filed reply submissions.

Having examined the record of this investigation, including the final ID, and the parties' submissions, the Commission has determined to modify the ID's construction of the claim term ''mounted to a boat,'' a claim term recited in each of the asserted claims of the '952, '974, and '825 patents (save for asserted claim 29 of the '825 patent), which the ID construed as ''attached to a bottom surface of the boat.'' Instead, the Commission adopts the construction proposed by complainants before the ALJ and construes the limitation to mean ''proximately secured to the boat in a fixed manner.'' The Commission finds that the record evidence supports the ID's findings on infringement and invalidity based on this construction. The Commission has determined to affirm the ID's finding of no violation of section 337 in connection with the asserted claims of the'952 patent, '825 patent, and claim 25 of the '974 patent. The Commission further finds a violation of Section 337 with respect to claims 14, 18, 21–23, and 33 of the '974 patent. The Commission adopts the ID's findings to the extent they are not inconsistent with the Commission opinion issued herewith.

Having found a violation of section 337 in this investigation, the Commission has determined that the appropriate form of relief is: (1) A limited exclusion order prohibiting the unlicensed entry of marine sonar imaging systems, products containing the same, and components thereof that infringe one or more of claims 14, 18, 21, 22, 23, and 33 of the '974 patent that are manufactured by, or on behalf of, or are imported by or on behalf of Garmin or any of its affiliated companies, parents, subsidiaries, agents, or other related business entities, or their successors or assigns; and (2) cease and desist orders prohibiting domestic respondents Garmin International, Inc.; Garmin North America, Inc.; and Garmin USA, Inc. from conducting any of the following activities in the United States: Importing, selling, marketing, advertising, distributing, transferring (except for exportation), and soliciting U.S. agents or distributors for, marine sonar imaging systems, products containing the same, and components thereof covered by claims 14, 18, 21, 22, 23 and 33 of the '974 patent. The proposed cease and desist orders include the following exemptions: (1) If in a written instrument, the owner of the patents authorizes or licenses such specific conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States.

The Commission has also determined that the public interest factors enumerated in section 337(d) and (f) (19 U.S.C. 1337(d) and (f)) do not preclude issuance of the limited exclusion order or cease and desist orders. Finally, the Commission has determined that a bond in the amount of zero is required to permit temporary importation during the period of Presidential review (19 U.S.C. 1337(j)) of marine sonar imaging systems, products containing the same, and components thereof that are subject to the remedial orders. The Commission's orders and opinion were delivered to the President and to the United States Trade Representative on the day of their issuance.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

Issued: November 18, 2015.

By order of the Commission.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–29857 Filed 11–23–15; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States et al. v. Springleaf Holdings, Inc., et al.; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Asset Preservation Stipulation and Order, and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States et. al.* v. *Springleaf Holdings, Inc., et. al.*, Civil Action No. 15–1992 (RMC). On November 13, 2015, the United States filed a Complaint alleging that the proposed acquisition by Springleaf Holdings, Inc. of OneMain Financial Holdings, LLC would violate Section 7 of the Clayton Act, 15 U.S.C. 18. The proposed Final Judgment, filed at the same time as the Complaint, requires Springleaf Holdings to divest 127 branches in Arizona, California, Colorado, Idaho, North Carolina, Ohio, Pennsylvania, Texas, Virginia, Washington and West Virginia.

Copies of the Complaint, proposed Final Judgment and Competitive Impact Statement are available for inspection on the Antitrust Division's Web site at *http://www.justice.gov/atr*, and at the Office of the Clerk of the United States District Court for the District of

Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division's Web site, filed with the Court and, under certain circumstances, published in the **Federal Register**. Comments should be directed to Maribeth Petrizzi, Chief, Litigation II Section, Antitrust Division, Department of Justice, 450 Fifth Street NW., Suite 8700, Washington, DC 20530 (telephone: 202–307–0924).

Patricia A. Brink,

Director of Civil Enforcement.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

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and

STATE OF WEST VIRGINIA
Office of the Attorney General of West Virginia
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Martinsburg, WV 25404

Plaintiffs,

v.

SPRINGLEAF HOLDINGS, INC.
601 NW. Second Street
Evansville, IN 47708,

ONEMAIN FINANCIAL HOLDINGS, LLC
300 Saint Paul Place
Baltimore, MD 21202,

and

CITIFINANCIAL CREDIT COMPANY
c/o CITIGROUP INC.
399 Park Avenue
New York, NY 10022

Defendants.

CASE NO.: 1:15–cv–01992
JUDGE: Rosemary M. Collyer
FILED: 11/13/2015

Complaint

The United States of America (''United States''), acting under the direction of the Attorney General of the United States, and the States of Colorado, Idaho, Texas, Washington and West Virginia and the Commonwealths of Pennsylvania and Virginia (collectively, ''Plaintiff States''), acting by and through their respective Offices of the Attorney General, bring this civil action to enjoin the proposed acquisition of OneMain Financial Holdings, LLC (''OneMain'') by Springleaf Holdings, Inc. (''Springleaf'') and to obtain other equitable relief.

I. Nature of the Action

1. OneMain and Springleaf are the two largest lenders that offer personal installment loans to subprime borrowers in the United States, and the only two with a nationwide branch network. Personal installment loans to subprime borrowers are fixed-rate, fixed-term and fully amortized loan products that appeal to borrowers who have limited access to credit from traditional banking institutions. OneMain and Springleaf specialize in the same products (large installment loans typically ranging from $3,000 to $6,000), target the same customer base, and often operate branches within close proximity to one another.

2. In local markets across Arizona, California, Colorado, Idaho, North Carolina, Ohio, Pennsylvania, Texas, Virginia, Washington, and West Virginia, Springleaf and OneMain face limited competition for the provision of personal installment loans to subprime borrowers and serve as each other's closest—and often only—competitor. Elimination of the competition between Springleaf and OneMain would leave subprime borrowers seeking personal installment loans with few choices. This reduction in consumer choice may drive many financially struggling borrowers to much more expensive forms of credit or, worse, leave them with no reasonable alternative. As a result, Springleaf's proposed acquisition of OneMain likely would substantially lessen competition in the provision of personal installment loans to subprime borrowers in numerous local markets, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

II. The Defendants and the Transaction

3. Defendant Springleaf is a Delaware corporation headquartered in Evansville, Indiana. Springleaf is the second-largest provider of personal installment loans to subprime borrowers in the United States, with approximately 830 branches in 27 states. Springleaf has a consumer loan portfolio that totals $4.0 billion.

4. Defendant OneMain, a Delaware limited liability company headquartered in Baltimore, Maryland, is the largest provider of personal installment loans to subprime borrowers in the United States, with 1,139 branch locations in 43 states. OneMain has a consumer loan portfolio that totals $8.4 billion. OneMain is a subsidiary of Defendant CitiFinancial Credit Company (''CitiFinancial''), a Delaware corporation headquartered in Dallas, Texas. CitiFinancial is a holding company that is a wholly owned subsidiary of Citigroup, Inc.

5. Pursuant to a Purchase Agreement dated March 2, 2015, Springleaf agreed to purchase OneMain from CitiFinancial for $4.25 billion.

III. Jurisdiction and Venue

6. The United States brings this action pursuant to Section 15 of the Clayton Act, 15 U.S.C. 25, as amended, to prevent and restrain Defendants from violating Section 7 of the Clayton Act, 15 U.S.C. 18.

7. The Plaintiff States bring this action under Section 16 of the Clayton Act, 15 U.S.C. 26, to prevent and restrain Springleaf and OneMain from violating Section 7 of the Clayton Act, 15 U.S.C. 18. The Plaintiff States, by and through their respective Offices of the Attorney General, bring this action as *parens patriae* on behalf of the citizens, general welfare, and economy of each of their states.

8. The Court has subject matter jurisdiction over this action pursuant to Section 15 of the Clayton Act, 15 U.S.C. 25, and 28 U.S.C. 1331, 1337(a), and 1345. Defendants offer personal installment loans to customers in the United States in a regular, continuous, and substantial flow of interstate commerce. Defendants' activities in the provision of personal installment loans have had a substantial effect upon interstate commerce.

9. Defendants have consented to venue and personal jurisdiction in this District. Therefore, venue in this District is proper under Section 12 of the Clayton Act, 15 U.S.C. 22, and 28 U.S.C. 1391(b) and (c).

IV. Trade and Commerce

A. Personal Installment Loans to Subprime Borrowers

10. The average size of a personal installment loan typically falls in the range of $3,000 to $6,000. Personal installment loans to subprime borrowers are closed-end, fixed-rate, fixed-term, and fully amortized loan products. In a fully amortized loan, both principal and interest are paid fully through scheduled installments by the end of the loan term, which typically is between 18 and 60 months in duration. Each monthly payment is the same amount and the schedule of payments is clear. If the borrower makes each scheduled payment, at the end of the loan term, the loan is repaid in full.

11. Personal installment lenders target a unique segment of borrowers who may not be able to obtain cheaper sources of credit from other financial institutions but have enough cash flow to afford the monthly payments of personal installment loans. Borrowers of personal installment loans are considered ''subprime'' because of blemishes in their credit histories, such as serious delinquencies or defaults. These borrowers likely have been denied credit by a bank in the past and turn to personal installment lenders for the speed, ease, and likelihood of success in obtaining credit. Their borrowing needs vary, for example, from paying for unexpected expenses, such as car repairs or medical bills, to consolidating debts. A typical subprime borrower's annual income is in the range of $35,000 to $45,000.

12. The blemished credit histories of subprime borrowers suggest a higher propensity for default on future loans relative to so-called ''prime'' borrowers. Personal installment lenders mitigate this credit risk by closely analyzing a borrower's characteristics and ability to repay the loan. The lender examines several categories of information about the borrower, including, among other criteria, credit history, income and outstanding debts, stability of employment, and availability or value of collateral. Lenders typically require borrowers to meet face-to-face at a branch location to close the loan, even if the application begins online. This face-to-face meeting allows the lender to efficiently collect information used in underwriting and verify key documents (reducing the risk of fraud). Subprime borrowers seeking installment loans also value having a branch office close to where they live or work; a nearby branch reduces the borrower's travel cost to close the loan and allows convenient and timely access to loan proceeds. If approved, borrowers immediately obtain the funds at the branch.

13. Local branch presence also helps lenders and borrowers establish close customer relationships during the life of the loan. Local branch employees monitor delinquent payments of existing customers and assist borrowers in meeting their payment obligations to minimize loan loss. Borrowers also benefit from knowing the local branch employees. Borrowers may visit a branch to make payments, refinance their loans, or speak with a branch employee at times of financial difficulties. Lenders place branches where their target borrowers live or work so that it is convenient for their borrowers to come into a branch.

14. The interest rate on a personal installment loan is the largest component of the total cost of a loan. Other costs, such as origination fees, maintenance fees, and closing fees, increase the effective interest rate that a borrower will pay. The Annual Percentage Rate (''APR'') combines the two components, interest rates and fees, to indicate the annual charges associated with the loan. Although the maximum interest rates and fees charged on personal installment loans vary by state, Springleaf and OneMain have a self-imposed interest rate cap of 36 percent on their respective loans.

15. While borrowers consider APR in selecting a loan, subprime borrowers typically focus most on the monthly payment and on the ease and speed of obtaining approval. Subprime borrowers' main concerns are whether the payment will fit into their monthly budget and whether they can obtain the money quickly to meet their needs. For these reasons, negotiations between borrowers and lenders tend to focus more on the amount of the loan, the repayment terms, and collateral requirements than on the rates and fees. When a subprime borrower needs or wants a lower monthly payment, personal installment lenders generally lower the amount of the loan or lengthen the term of the loan.

16. Every state requires personal installment lenders to obtain licenses to offer loans to subprime borrowers. Many states also have regulations governing the interest rates and fees on loans charged by consumer finance companies licensed to operate in the state. Some states impose a maximum rate and fee for all personal installment loans, while others have a tiered-rate system that establishes different interest rates and fees for different loan amounts. State regulations significantly affect the number of personal installment lenders offering loans to subprime lenders in the state.

B. Relevant Product Market

17. Subprime borrowers turn to personal installment loans when they need cash but have limited access to credit from banks, credit card companies, and other lenders. The products offered by these lenders are not meaningful substitutes for personal installment loans for a substantial number of subprime borrowers.

18. Banks and credit unions offer personal installment loans at rates and terms much better than those offered by personal installment lenders, but subprime borrowers typically do not meet the underwriting criteria of those institutions and are unlikely to be approved. Further, the loan application and underwriting process at banks and credit unions typically take much longer than that of personal installment lenders, who can provide subprime borrowers with funds on a far quicker timetable. For these and other reasons, subprime borrowers would not turn to banks and credit unions as an alternative in the event personal installment lenders were to increase the interest rate or otherwise make their loan terms less appealing by a small but significant amount.

19. Payday and title lenders provide short-term cash, but charge much higher rates and fees, usually lend in amounts well below $1,000, and require far quicker repayment than personal installment lenders. Specifically, rates and fees for these types of short-term cash advances can exceed 250 percent APR with repayment generally due in less than 30 days. Given these key differences, subprime borrowers likely would not turn to payday and title loans as an alternative in the event personal installment lenders were to increase the interest rate or otherwise make their loan terms less appealing by a small but significant amount.

20. Most subprime borrowers also cannot turn to credit cards as an alternative to personal installment loans. Subprime borrowers frequently have difficulty obtaining credit cards, and those who have credit cards have often reached their maximum available credit limits (which are much lower than those given to prime borrowers), or have limited access to additional credit extensions. Although subprime borrowers may use credit cards for everyday purchases, such as groceries or dining out, they typically have insufficient remaining credit to pay for larger expenses such as major car repairs or significant medical bills. Subprime borrowers therefore could not

generally turn to credit cards as an alternative in the event lenders offering personal installment loans to subprime borrowers were to increase the interest rate or otherwise make their loan terms less appealing by a small but significant amount.

21. Finally, although online lenders have been successful in making loans to prime borrowers, they face challenges in meeting the needs of and mitigating the credit risk posed by subprime borrowers. Without a local branch presence, online lenders do not maintain close customer relationships, nor can they conduct face-to-face meetings to verify key documents, measures which reduce the risk of fraud and borrower default. Online lenders tend to focus on borrowers with better credit profiles or higher incomes than the borrowers typically served by personal installment lenders with branches in local markets. Furthermore, online lenders are unable to process an application and distribute loan proceeds as quickly as local personal installment lenders. For these reasons, subprime borrowers generally would not turn to loans offered by online lenders in the event lenders offering personal installment loans to subprime borrowers were to increase the interest rate or otherwise make their loan terms less appealing by a small but significant amount.

22. Accordingly, the provision of personal installment loans to subprime borrowers is a line of commerce and a relevant product market within the meaning of Section 7 of the Clayton Act.

C. Relevant Geographic Market

23. Subprime borrowers seeking personal installment loans value convenience, which includes quick access to the borrowed funds and minimal travel time. Consequently, subprime borrowers considering a personal installment lender look for a branch near where they live or where they work. While the distance a borrower is willing to travel may vary by geography, the vast majority of subprime borrowers travel less than twenty miles to a branch for a personal installment loan.

24. Personal installment lenders have established local trade areas for their branches. Lenders usually rely on direct mail solicitations as the primary means of marketing and solicit customers who live within close proximity to their branches. Lenders who place branches in the same areas compete to serve the same target borrower base. Borrowers view lenders with branches in close proximity to each other as close substitutes.

25. For these reasons, the overlapping trade areas of competing personal installment lenders form geographic markets where the lenders located within the trade areas compete for subprime borrowers who live or work near the branches. The size and shape of the overlapping trade areas of these branches may vary as the distance borrowers are willing to travel depends on factors specific to each local area. Even so, typically more than three-quarters of the personal installment loans to subprime borrowers made by a given branch are made to borrowers residing within twenty miles of the branch. Personal installment lenders with branches located outside these trade areas usually are not convenient alternatives for borrowers.

26. Springleaf and OneMain have a high degree of geographic overlap between their branch networks. In local areas within and around 126 towns and municipalities in eleven states—Arizona, California, Colorado, Idaho, North Carolina, Ohio, Pennsylvania, Texas, Virginia, Washington, and West Virginia—Springleaf and OneMain have branches located within close proximity of one another, often within five miles. In these overlapping trade areas of Springleaf's and OneMain's branches, few other lenders have branches offering personal installment loans to subprime borrowers. In many of these overlapping trade areas, Springleaf and OneMain are the only two personal installment lenders.

27. In local areas within and around 126 towns and municipalities in Arizona, California, Colorado, Idaho, North Carolina, Ohio, Pennsylvania, Texas, Virginia, Washington, and West Virginia, subprime borrowers of personal installment loans would not seek such loans outside the local areas in the event lenders offering personal installment loans to subprime borrowers were to increase the interest rate or otherwise make their loans less appealing by a small but significant amount. Accordingly, the overlapping trade areas located in the 126 towns and municipalities identified in the Appendix hereto constitute relevant geographic markets within the meaning of Section 7 of the Clayton Act.

D. Anticompetitive Effects

28. Springleaf and OneMain are the two largest providers of personal installment loans to subprime borrowers in the United States. Both companies have a long history in the business of providing personal installment loans to subprime borrowers, have built an extensive branch network, and have established close ties to the local communities. Leveraging their years of experience and large customer base, both companies have developed sophisticated risk analytics that allow them to minimize expected credit losses when extending loans to borrowers with blemished credit histories.

29. Compared to Springleaf and OneMain, other lenders that offer personal installment loans to subprime borrowers have much smaller branch footprints and are present in a more limited number of states and local markets. These personal installment lenders may operate in states with regulations that permit higher interest rates and fees, rather than in those with low interest rate caps. State regulations, lack of scale, and other economic factors have limited the competitive presence of these lenders in many states and local areas.

30. In local markets within and around the 126 towns and municipalities in Arizona, California, Colorado, Idaho, North Carolina, Ohio, Pennsylvania, Texas, Virginia, Washington, and West Virginia identified in the Appendix, the market for the provision of personal installment loans to subprime borrowers is highly concentrated. In the local areas within these states, Springleaf and OneMain are the largest providers of personal installment loans to subprime borrowers, and face little, if any, competition from other personal installment lenders. Even if other providers of personal installment loans to subprime borrowers have a branch presence in these states, these lenders compete in a limited number of local markets or in communities located far from a Springleaf or OneMain branch. As a result, these local markets are highly concentrated.

31. In local markets within and around the 126 towns and municipalities in Arizona, California, Colorado, Idaho, North Carolina, Ohio, Pennsylvania, Texas, Virginia, Washington, and West Virginia identified in the Appendix, the proposed acquisition would substantially increase concentration in the market for personal installment loans to subprime borrowers. Without the benefit of head-to-head competition between Springleaf and OneMain, subprime borrowers are likely to face higher interest rates or fees, greater limits on the amount they can borrow and restraints on their ability to obtain loans, and more onerous loan terms. The proposed acquisition therefore likely will substantially lessen competition in the provision of personal installment loans to subprime borrowers.

E. Entry

32. Entry of additional competitors into the provision of personal installment loans to subprime borrowers in local markets in Arizona, California, Colorado, Idaho, North Carolina, Ohio, Pennsylvania, Texas, Virginia, Washington, and West Virginia is unlikely to be timely or sufficient to defeat the likely anticompetitive effects of the proposed acquisition. In some states, the state regulatory rate caps create unattractive markets for entry. In others, lenders face entry barriers in terms of cost and time to establish a local branch presence. Personal installment lenders need experienced branch employees with knowledge of the local market to build a base of customer relationships. A new lender in a local market faces more risks as it does not have knowledge of local market conditions. A lender also must obtain funding and devote resources to building a successful local presence.

33. As a result of these barriers, entry into the provision of personal installment loans to subprime borrowers in the local markets identified above would not be timely, likely, or sufficient to defeat the substantial lessening of competition that likely would result from Springleaf's acquisition of OneMain.

V. Violation Alleged

34. The acquisition of OneMain by Springleaf likely would substantially lessen competition in the provision of personal installment loans to subprime borrowers in the relevant geographic markets identified the Appendix, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

35. Unless enjoined, the proposed acquisition likely would have the following anticompetitive effects, among others:

a. actual and potential competition between Springleaf and OneMain in the provision of personal installment loans to subprime borrowers in local markets in Arizona, California, Colorado, Idaho, North Carolina, Ohio, Pennsylvania, Texas, Virginia, Washington, and West Virginia would be eliminated;

b. competition generally in the provision of personal installment loans to subprime borrowers in local markets in Arizona, California, Colorado, Idaho, North Carolina, Ohio, Pennsylvania, Texas, Virginia, Washington, and West Virginia would be substantially lessened; and

c. prices and other terms for personal installment loans to subprime borrowers in local markets in Arizona, California, Colorado, Idaho, North Carolina, Ohio, Pennsylvania, Texas, Virginia, Washington, and West Virginia would become less favorable to consumers and access to such loans by subprime borrowers would decrease.

VI. Requested Relief

36. Plaintiffs request that the Court:

a. adjudge and decree that Springleaf's proposed acquisition of OneMain is unlawful and in violation of Section 7 of the Clayton Act, 15 U.S.C. 18;

b. preliminarily and permanently enjoin and restrain Defendants and all persons acting on their behalf from entering into any other agreement, understanding, or plan by which Springleaf would acquire OneMain;

c. award Plaintiffs their costs for this action; and

d. grant Plaintiffs such other and further relief as the Court deems just and proper.

DATED: November 13, 2015

Respectfully submitted,

FOR PLAINTIFF UNITED STATES OF AMERICA:

_____/s/_____

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_____/s/_____

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Director of Civil Enforcement.

_____/s/_____

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_____/s/_____

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APPENDIX

City	State
PHOENIX	AZ
TEMPE	AZ
TUCSON	AZ
ANAHEIM	CA
ANTIOCH	CA
BAKERSFIELD	CA
CHICO	CA
CHULA VISTA	CA
SACRAMENTO	CA
ESCONDIDO	CA
FREMONT	CA
FRESNO	CA
HANFORD	CA
LEMON GROVE	CA
LONG BEACH	CA
MADERA	CA
MERCED	CA
MODESTO	CA
OXNARD	CA
PALMDALE	CA
PARAMOUNT	CA
PASADENA	CA
POMONA	CA
RANCHO CUCAMONGA	CA
REDDING	CA
RIALTO	CA
SAN FERNANDO	CA
SANTA ANA	CA
SANTA MARIA	CA
SOUTH SAN FRANCISCO	CA
STOCKTON	CA
TORRANCE	CA
COLORADO SPRINGS	CO
FORT COLLINS	CO
PUEBLO	CO
AURORA	CO
THORNTON	CO
LITTLETON	CO
TWIN FALLS	ID
COEUR D'ALENE	ID
POCATELLO	ID
BOISE	ID
FOREST CITY	NC
HENDERSON	NC
MOREHEAD CITY	NC
MOUNT AIRY	NC
KINSTON	NC
WILKESBORO	NC
SHELBY	NC
WILSON	NC
CHARLOTTE	NC
DURHAM	NC
CLINTON	NC
KERNERSVILLE	NC
WILLIAMSTON	NC
REIDSVILLE	NC
ALBEMARLE	NC
MORGANTON	NC
MARION	NC
ASHTABULA	OH
ATHENS	OH
CAMBRIDGE	OH
GARFIELD HEIGHTS	OH
REYNOLDSBURG	OH
FAIRBORN	OH
DOVER	OH
GALLIPOLIS	OH
LIMA	OH
ONTARIO	OH
SANDUSKY	OH
TOLEDO	OH
CHILLICOTHE	OH
ELYRIA	OH
FAIRLAWN	OH
LANCASTER	OH
MARION	OH
WOOSTER	OH
CHELTENHAM	PA
LANCASTER	PA
JOHNSTOWN	PA
MONACA	PA
E NORRITON TWP	PA
SHAMOKIN DAM	PA
STATE COLLEGE	PA
TANNERSVILLE	PA
UPPER DARBY	PA
WASHINGTON	PA
BURLESON	TX
AMARILLO	TX
BEAUMONT	TX
BRYAN	TX
DEL RIO	TX
DENTON	TX
LAKE JACKSON	TX
LUFKIN	TX
ODESSA	TX
SAN ANGELO	TX
CHRISTIANSBURG	VA
ALTAVISTA	VA
COLLINSVILLE	VA
DANVILLE	VA
FARMVILLE	VA
FRONT ROYAL	VA
GALAX	VA
LEESBURG	VA
PETERSBURG	VA
RICHMOND	VA
SOUTH HILL	VA
STAUNTON	VA
SUFFOLK	VA
TAPPAHANNOCK	VA
WOODBRIDGE	VA
BREMERTON	WA
EVERETT	WA
KENNEWICK	WA
MOUNT VERNON	WA
OLYMPIA	WA
RENTON	WA
SPOKANE	WA
UNION GAP	WA
LOGAN	WV
PRINCETON	WV
LEWISBURG	WV
BARBOURSVILLE	WV
OAK HILL	WV
SOUTH CHARLESTON	WV

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,
STATE OF COLORADO,
STATE OF IDAHO,
COMMONWEALTH OF PENNSYLVANIA,
STATE OF TEXAS,
COMMONWEALTH OF VIRGINIA,
STATE OF WASHINGTON,
and
STATE OF WEST VIRGINIA,
Plaintiffs,
v.
SPRINGLEAF HOLDINGS, INC.,
ONEMAIN FINANCIAL HOLDINGS, LLC,
and
CITIFINANCIAL CREDIT COMPANY,
Defendants.

CASE NO.: 1:15–cv–01992
JUDGE: Rosemary M. Collyer
FILED: 11/13/2015

Competitive Impact Statement

Plaintiff United States of America (''United States''), pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act (''APPA'' or ''Tunney Act''), 15 U.S.C. 16(b)–(h), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I. Nature and Purpose of the Proceeding

Pursuant to a Stock Purchase Agreement dated March 2, 2015, Springleaf Holdings, Inc. proposes to acquire OneMain Financial Holdings, LLC from CitiFinancial Credit Company, a wholly owned subsidiary of Citigroup, Inc., for approximately $4.25 billion. The proposed merger would combine the two largest providers of personal installment loans to subprime borrowers in the United States.

The United States filed a civil antitrust Complaint on November 13, 2015, seeking to enjoin the proposed acquisition. The Complaint alleges that the acquisition likely would substantially lessen competition for personal installment loans to subprime borrowers in numerous local markets across eleven states, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18. That loss of competition likely would result in a reduction of consumer choice that may drive financially struggling borrowers to much more expensive forms of credit or, worse, leave them with no reasonable alternative.

At the same time the Complaint was filed, the United States filed an Asset Preservation Stipulation and Order and a proposed Final Judgment designed to

eliminate the anticompetitive effects of the acquisition. Under the proposed Final Judgment, which is explained more fully below, Springleaf is required to divest 127 branches in eleven states to Lendmark Financial Services, or to one or more other Acquirers acceptable to the United States. Under the terms of the Asset Preservation Stipulation and Order, Springleaf will take certain steps to ensure that the divestiture branches are operated as competitively independent, economically viable, and ongoing business concerns; that they remain independent and uninfluenced by the consummation of the acquisition; and that competition is maintained during the pendency of the ordered divestiture.

The United States and Defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment would terminate this action, except that the Court would retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof.

II. Description of the Events Giving Rise to the Alleged Violation

A. The Defendants and the Proposed Transaction

Defendant Springleaf Holdings, Inc. (''Springleaf'') is a Delaware corporation with its headquarters in Evansville, Indiana. Springleaf is the second-largest provider of personal installment loans to subprime borrowers in the United States. Springleaf operates approximately 830 branches in 27 states and has a consumer loan portfolio of about $4.0 billion.

Defendant OneMain Financial Holdings, LLC (''OneMain'') is a Delaware limited liability company, headquartered in Baltimore, Maryland. OneMain is the largest provider of personal installment loans to subprime borrowers in the United States. OneMain operates 1,139 branches in 43 states and has a consumer loan portfolio that totals $8.4 billion. OneMain is a subsidiary of CitiFinancial Credit Company, a holding company that is a wholly owned subsidiary of Citigroup, Inc.

B. Background on Personal Installment Loans to Subprime Borrowers

Personal installment loans to subprime borrowers are closed-end, fixed-rate, fixed-term, and fully amortized loan products that typically range from $3,000 to $6,000. Both the principal and interest are paid fully through scheduled installments by the end of the loan term, which typically is between 18 and 60 months in duration. Each monthly payment is the same amount and the schedule of payments is clear.

Personal installment lenders target a unique segment of borrowers who may not be able to obtain cheaper sources of credit from other financial institutions but have enough cash flow to afford the monthly payments of personal installment loans. Borrowers of personal installment loans are considered ''subprime'' because of blemishes in their credit histories, such as serious delinquencies or defaults. These borrowers likely have been denied credit by a bank in the past and turn to personal installment lenders for the speed, ease, and likelihood of success in obtaining credit. Their borrowing needs vary, for example, from paying for unexpected expenses, such as car repairs or medical bills, to consolidating debts. A typical subprime borrower's annual income is in the range of $35,000 to $45,000.

The blemished credit histories of subprime borrowers suggest a higher propensity for default on future loans relative to so-called ''prime'' borrowers. Personal installment lenders mitigate this credit risk by closely analyzing a borrower's characteristics and ability to repay the loan, including the borrower's credit history, income and outstanding debts, stability of employment, and availability or value of collateral. Lenders typically require borrowers to meet face-to-face at a branch location to close the loan, even if the application begins online. This face-to-face meeting allows the lender to efficiently collect information used in underwriting and verify key documents (reducing the risk of fraud). Subprime borrowers seeking installment loans also value having a branch office close to where they live or work; a nearby branch reduces the borrower's travel cost to close the loan and allows convenient and timely access to loan proceeds. If approved, borrowers immediately obtain the funds at the branch.

Local branch presence also helps lenders and borrowers establish close customer relationships during the life of the loan. Local branch employees monitor delinquent payments of existing customers and assist borrowers in meeting their payment obligations to minimize loan loss. Borrowers also benefit from knowing the local branch employees. Borrowers may visit a branch to make payments, refinance their loans, or speak with a branch employee at times of financial difficulties. Lenders place branches where their target borrowers live or work so that it is convenient for their borrowers to come in to a branch.

The interest rate on a personal installment loan is the largest component of the total cost of a loan, but other fees increase the effective interest rate that a borrower will pay. The Annual Percentage Rate (''APR'') combines the interest rates and fees to indicate the annual charges associated with the loan. Although the maximum interest rates and fees charged on personal installment loans vary by state, Springleaf and OneMain have a self-imposed interest rate cap of 36 percent on their respective loans.

While subprime borrowers consider APR in selecting a loan, they typically focus most on the monthly payment and on the ease and speed of obtaining approval. For these reasons, negotiations between borrowers and lenders tend to focus more on the amount of the loan, the repayment terms, and collateral requirements than on the rates and fees.

Every state requires personal installment lenders to obtain licenses to offer loans to subprime borrowers. Many states also have regulations governing the interest rates and fees on personal installment loans, with some states imposing maximum rates and fees and others utilizing a tiered-rate system that establishes different interest rates and fees for different loan amounts. The nature of state regulations significantly affects the number of personal installment lenders operating in a state.

C. Relevant Product Market

Subprime borrowers turn to personal installment loans when they need cash but have limited access to credit from banks, credit card companies, and other lenders. As explained in the Complaint, the products offered by these lenders are not meaningful substitutes for personal installment loans for a substantial number of subprime borrowers.

For example, banks and credit unions offer personal installment loans at rates and terms much better than those offered by personal installment lenders, but subprime borrowers typically do not meet the underwriting criteria of those institutions and are unlikely to be approved. Further, the loan application and underwriting process at banks and credit unions typically take much longer than that of personal installment lenders.

Payday and title lenders provide short-term cash, but charge much higher rates and fees, usually lend in amounts well below $1,000, and require far quicker repayment than personal installment lenders. Rates and fees for

these types of short-term cash advances can exceed 250 percent APR with repayment generally due in less than 30 days.

Credit cards are also not a viable alternative for most subprime borrowers. Subprime borrowers may have difficulty obtaining credit cards, and those who have credit cards have often reached their credit limits and have limited access to additional credit extensions. Although subprime borrowers may use credit cards for everyday purchases, they typically have insufficient remaining credit to pay for larger expenses such as major car repairs or significant medical bills.

Finally, although online lenders have been successful in making loans to prime borrowers, they face challenges in meeting the needs of and mitigating the credit risk posed by subprime borrowers. Without a local branch presence, online lenders do not maintain close customer relationships, nor can they conduct face-to-face meetings to verify key documents, measures which reduce the risk of fraud and borrower default. Online lenders are also unable to process applications and distribute loan proceeds as quickly as local personal installment lenders.

For all of these reasons, as explained in the Complaint, subprime borrowers generally would not turn to banks and credit unions, payday and title lenders, credit cards, or online lenders in the event lenders offering personal installment loans to subprime borrowers were to increase the interest rate or otherwise make their loan terms less appealing by a small but significant amount. Accordingly, the Complaint alleges that the provision of personal installment loans to subprime borrowers is a line of commerce and a relevant product market within the meaning of Section 7 of the Clayton Act.

D. Relevant Geographic Market

As explained in the Complaint, subprime borrowers seeking personal installment loans value convenience, including quick access to borrowed funds and minimal travel time, and look for a branch near where they live or work. While the distance a borrower is willing to travel may vary by geography, the vast majority of subprime borrowers travel less than twenty miles to a branch for a personal installment loan.

Personal installment lenders have established local trade areas for their branches. Lenders usually rely on direct mail solicitations as the primary means of marketing and solicit customers who live within close proximity to their branches. Lenders who place branches in the same areas compete to serve the same target borrower base. Borrowers view lenders with branches in close proximity to each other as close substitutes.

For these reasons, the overlapping trade areas of competing personal installment lenders form geographic markets where the lenders located within the trade areas compete for subprime borrowers who live or work near the branches. The size and shape of the overlapping trade areas of these branches may vary as the distance borrowers are willing to travel depends on factors specific to each local area. Even so, typically more than three-quarters of the personal installment loans to subprime borrowers made by a given branch are made to borrowers residing within twenty miles of the branch. Personal installment lenders with branches located outside these trade areas usually are not convenient alternatives for borrowers.

Springleaf and OneMain have a high degree of geographic overlap between their branch networks. In local areas within and around 126 towns and municipalities in eleven states—Arizona, California, Colorado, Idaho, North Carolina, Ohio, Pennsylvania, Texas, Virginia, Washington, and West Virginia—Springleaf and OneMain have branches located within close proximity of one another, often within five miles. In these overlapping trade areas of Springleaf's and OneMain's branches, few, if any, other lenders have branches offering personal installment loans to subprime borrowers.

According to the Complaint, in local areas within and around the 126 towns and municipalities in Arizona, California, Colorado, Idaho, North Carolina, Ohio, Pennsylvania, Texas, Virginia, Washington, and West Virginia, subprime borrowers of personal installment loans would not seek such loans outside the local areas in the event lenders offering personal installment loans to subprime borrowers were to increase the interest rate or otherwise make their loans less appealing by a small but significant amount. Accordingly, the overlapping trade areas located in the 126 towns and municipalities identified in the Appendix attached to the Complaint constitute relevant geographic markets within the meaning of Section 7 of the Clayton Act.

E. Anticompetitive Effects

As alleged in the Complaint, Springleaf and OneMain are the two largest providers of personal installment loans to subprime borrowers in the United States. Both companies have a long history in the business, an extensive branch network, and close ties to the local communities in which they operate. Both companies have used their years of experience and large customer base to develop sophisticated risk analytics that allow them to minimize expected credit losses. Other lenders that offer personal installment loans to subprime borrowers have much smaller branch footprints and are present in fewer states and local markets than Springleaf and OneMain.

In local markets within and around the 126 towns and municipalities in Arizona, California, Colorado, Idaho, North Carolina, Ohio, Pennsylvania, Texas, Virginia, Washington, and West Virginia identified in the Appendix to the Complaint, the market for the provision of personal installment loans to subprime borrowers is highly concentrated. In these local markets, Springleaf and OneMain are the largest providers of personal installment loans to subprime borrowers, and face little, if any, competition from other personal installment lenders. The Complaint alleges that the proposed acquisition would substantially increase concentration in these local markets and likely would result in subprime borrowers facing higher interest rates or fees, greater limits on the amount they can borrow and restraints on their ability to obtain loans, and more onerous loan terms. The proposed acquisition therefore likely will substantially lessen competition in the provision of personal installment loans to subprime borrowers.

F. Difficulty of Entry

According to the Complaint, entry of additional competitors into the provision of personal installment loans to subprime borrowers in the 126 local markets in Arizona, California, Colorado, Idaho, North Carolina, Ohio, Pennsylvania, Texas, Virginia, Washington, and West Virginia identified in the Complaint is unlikely to be timely or sufficient to defeat the likely anticompetitive effects of the proposed acquisition. In some states, the state regulatory rate caps create unattractive markets for entry. In others, lenders face entry barriers in terms of cost and time to establish a local branch presence. Personal installment lenders need experienced branch employees with knowledge of the local market to build a base of customer relationships. A new lender in a local market faces more risks as it does not have knowledge of local market conditions. A lender also must obtain funding and devote resources to building a successful local presence. As a result of these barriers, entry is unlikely to

remedy the anticompetitive effects of the proposed acquisition.

III. Explanation of the Proposed Final Judgment

The divestiture required by the proposed Final Judgment will eliminate the anticompetitive effects of the acquisition by establishing an independent and economically viable competitor in the provision of personal installment loans to subprime borrowers in each of the local markets of concern.

Specifically, Paragraphs IV(A) and IV(B) of the proposed Final Judgment requires Defendants to divest 127 Springleaf branches, which are identified in the Attachment to the proposed Final Judgment, to Lendmark Financial Services or to one or more alternative Acquirers acceptable to the United States. The branches to be divested are located in the local markets within and around the 126 towns and municipalities identified in the Appendix to the Complaint. The divestiture will establish Lendmark or an alternative Acquirer as a new, independent and economically viable competitor in some states and will allow Lendmark or an alternative Acquirer to compete in new local areas and to enhance its competitive presence in others.

The divestiture of the 127 Springleaf branches includes all active loans originated or serviced at those branches, including all historical performance information (including account-level payment histories) and all customers' credit scores and other credit metrics with respect to loans that are active, closed, paid-off, or defaulted that have been originated or serviced at the Divestiture Branches at any point since January 1, 2010. The historical performance information will allow a lender to gain an understanding of local market conditions and to perform risk analytics essential to making personal installment loans to subprime borrowers. In the event that Lendmark is not the Acquirer, Paragraph II(G)(3) provides that Springleaf will further divest, at the Acquirer's option, assets related to back office and technical support that would provide the Acquirer with additional capability and know-how.

Paragraph IV(A) of the proposed Final Judgment requires Springleaf to divest the Divestiture Assets within 120 calendar days after the filing of the Complaint or within five (5) calendar days after satisfaction of all state licensing requirements, whichever is sooner. The United States, in its sole discretion, after consultation with the Plaintiff States, may agree to one or more extensions of the time period, not to exceed sixty (60) calendar days in total. In addition, in the event that Lendmark has initiated the state licensing process in a particular state but has not satisfied the state's licensing requirements before the end of the period specified in Paragraph IV(A), the period to divest the Divestiture Assets of that particular state shall be extended to five (5) calendar days after satisfaction of the state licensing requirements. Paragraph IV(A) also requires Springleaf to use its best efforts to divest the Divestiture Assets as expeditiously as possible.

In the event that Lendmark is unable to acquire the Divestiture Assets in one or more states, Paragraphs IV(B) provides that Springleaf shall divest the remaining Divestiture Assets to an alternative Acquirer(s) acceptable to the United States, in its sole discretion, after consultation with the relevant Plaintiff States. Springleaf shall divest the remaining Divestiture Assets within thirty (30) days after the United States receives notice that Lendmark is not the Acquirer of such Divestiture Assets, or within five (5) days of satisfaction of all state licensing requirements, whichever is sooner. The United States, in its sole discretion, after consultation with the relevant Plaintiff States, may agree to one or more extensions of the time period, not to exceed sixty (60) calendar days in total. Pursuant to Paragraph V(I), Springleaf must divest to a single Acquirer all of the Divestiture Branches located in a particular state.

Paragraph IV(G) prohibits Defendants from entering into non-compete agreements with any employee at any of Defendants' branches or with any regional manager with responsibility for managing any of Defendants' branches for a period of two (2) years from the date of the filing of the Complaint. Defendants also must waive any existing non-compete agreements with such employees. Paragraph IV(G) ensures that competing providers of personal installment loans, including the Acquirer, may hire Defendants' branch employees and regional managers who are experienced in making personal installment loans to subprime borrowers.

Paragraph IV(H) provides for the possibility of a transition services agreement between Springleaf and the Acquirer(s) for a period of up to six (6) months. This provision is necessary because the transfer of loan records and customer information from Springleaf's data system to the Acquirer's data system will require system testing, and the transition may take a period of months after the divestiture. The transition services provided pursuant to such an agreement shall include providing the Acquirer(s) access to a separate information technology environment within Springleaf's information system for loan origination, administration and services. During the term of the transition services agreement, Springleaf shall implement and maintain procedures to preclude the sharing of data between Springleaf and the Acquirer(s). The United States, in its sole discretion, may approve one or more extensions of this agreement for a total of up to an additional six (6) months.

Section X of the proposed Final Judgment provides that the United States may appoint a Monitoring Trustee with the power and authority to investigate and report on Defendants' compliance with the terms of the proposed Final Judgment and the Asset Preservation Stipulation and Order during the pendency of the divestiture. Because satisfaction of the state licensing requirements may take 120 calendar days or longer, a Monitoring Trustee will assist Plaintiffs in monitoring the divestiture process and ensuring Defendants' compliance with the Asset Preservation Stipulation and Order. The Monitoring Trustee shall file monthly reports with the United States and shall serve until the completion of the divestiture and the expiration of any transition services agreement.

In the event that Springleaf does not accomplish the divestiture to either Lendmark or an alternative Acquirer(s) within the periods prescribed in the proposed Final Judgment, pursuant to Section V, the Court shall appoint a Divestiture Trustee selected by the United States and approved by the Court to effect the divestiture. If a Divestiture Trustee is appointed, the proposed Final Judgment provides that Springleaf will pay all costs and expenses of the trustee. After its appointment becomes effective, the Divestiture Trustee will file monthly reports with the Court and the United States setting forth its efforts to accomplish the divestiture. At the end of six (6) months, if the divestiture has not been accomplished, the Divestiture Trustee and the United States will make recommendations to the Court, which shall enter such orders as appropriate, in order to carry out the purpose of the Final Judgment, including extending the trust or the term of the Divestiture Trustee's appointment.

IV. Remedies Available to Potential Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who

has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the proposed Final Judgment has no prima facie effect in any subsequent private lawsuit that may be brought against Defendants.

V. Procedures Available for Modification of the Proposed Final Judgment

The United States and Defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least sixty (60) days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty (60) days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the United States Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time prior to the Court's entry of judgment. The comments and the response of the United States will be filed with the Court. In addition, comments will be posted on the U.S. Department of Justice, Antitrust Division's Internet Web site and, under certain circumstances, published in the **Federal Register**.

Written comments should be submitted to:

Maribeth Petrizzi, Chief, Litigation II Section, Antitrust Division, United States Department of Justice, 450 Fifth Street NW., Suite 8700, Washington, DC 20530.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. Alternatives to the Proposed Final Judgment

The United States considered, as an alternative to the proposed Final Judgment, a full trial on the merits against Defendants. The United States could have continued the litigation and sought preliminary and permanent injunctions against Springleaf's acquisition of OneMain. The United States is satisfied, however, that the divestiture of assets described in the proposed Final Judgment will preserve competition for personal installment loans to subprime borrowers. Thus, the proposed Final Judgment would achieve all or substantially all of the relief the United States would have obtained through litigation, but avoids the time, expense, and uncertainty of a full trial on the merits of the Complaint.

VII. Standard of Review Under the APPA for the Proposed Final Judgment

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a sixty-day comment period, after which the Court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. 16(e)(1). In making that determination, the Court, in accordance with the statute as amended in 2004, is required to consider:

> (A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and
>
> (B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A) & (B). In considering these statutory factors, the Court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1461 (D.C. Cir. 1995); *see generally United States* v. *SBC Commc'ns, Inc.,* 489 F. Supp. 2d 1 (D.D.C. 2007) (assessing public interest standard under the Tunney Act); *United States v, U.S. Airways Group, Inc.,* 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the ''court's inquiry is limited'' in Tunney Act settlements); *United States* v. *InBev N.V./S.A.,* No. 08–1965 (JR), 2009–2 Trade Cas. (CCH) ¶ 76,736, 2009 U.S. Dist. LEXIS 84787, at *3, (D.D.C. Aug. 11, 2009) (noting that the court's review of a consent judgment is limited and only inquires ''into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanism to enforce the final judgment are clear and manageable.'').[1]

As the United States Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations set forth in the government's complaint, whether the decree is sufficiently clear, whether enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See Microsoft,* 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the decree, a court may not ''engage in an unrestricted evaluation of what relief would best serve the public.'' *United States* v. *BNS, Inc.,* 858 F.2d 456, 462 (9th Cir. 1988) (quoting *United States* v. *Bechtel Corp.,* 648 F.2d 660, 666 (9th Cir. 1981)); *see also Microsoft,* 56 F.3d at 1460–62; *United States* v. *Alcoa, Inc.,* 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *3. Courts have held that:

> [t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is ''*within the reaches of the public interest.''* More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).[2] In

[1] The 2004 amendments substituted ''shall'' for ''may'' in directing relevant factors for courts to consider and amended the list of factors to focus on competitive considerations and to address potentially ambiguous judgment terms. *Compare* 15 U.S.C. 16(e) (2004), *with* 15 U.S.C. 16(e)(1) (2006); *see also SBC Commc'ns,* 489 F. Supp. 2d at 11 (concluding that the 2004 amendments ''effected minimal changes'' to Tunney Act review).

[2] *Cf. BNS,* 858 F.2d at 464 (holding that the court's ''ultimate authority under the [APPA] is

Continued

determining whether a proposed settlement is in the public interest, a district court ''must accord deference to the government's predictions about the efficacy of its remedies, and may not require that the remedies perfectly match the alleged violations.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that a court should not reject the proposed remedies because it believes others are preferable); *Microsoft,* 56 F.3d at 1461 (noting the need for courts to be ''deferential to the government's predictions as to the effect of the proposed remedies''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant due respect to the United States's prediction as to the effect of proposed remedies, its perception of the market structure, and its views of the nature of the case).

Courts have greater flexibility in approving proposed consent decrees than in crafting their own decrees following a finding of liability in a litigated matter. ''[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is 'within the reaches of public interest.' '' *United States* v. *Am. Tel. & Tel. Co.,* 552 F. Supp. 131, 151 (D.D.C. 1982) (citations omitted) (quoting *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975)), *aff'd sub nom. Maryland* v. *United States,* 460 U.S. 1001 (1983); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (noting that room must be made for the government to grant concessions in the negotiation process for settlements) (citing *Microsoft,* 56 F.3d at 1461); *United States* v. *Alcan Aluminum Ltd.,* 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving the consent decree even though the court would have imposed a greater remedy). To meet this standard, the United States ''need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17.

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint, and does not authorize the Court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *20 (''the 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged''). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60. As this Court confirmed in *SBC Communications,* courts ''cannot look beyond the complaint in making the public interest determination unless the complaint is drafted so narrowly as to make a mockery of judicial power.'' *SBC Commc'ns,* 489 F. Supp. 2d at 15.

In its 2004 amendments, Congress made clear its intent to preserve the practical benefits of utilizing consent decrees in antitrust enforcement, adding the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). The language wrote into the statute what Congress intended when it enacted the Tunney Act in 1974, as Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). Rather, the procedure for the public interest determination is left to the discretion of the Court, with the recognition that the Court's ''scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.'' *SBC Commc'ns,* 489 F. Supp. 2d at 11.[3] A court can make its public interest determination based on the competitive impact statement and response to public comments alone. *U.S. Airways,* 38 F. Supp. 3d at 76.

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: November 13, 2015

Respectfully submitted,

_____/s/_____

Angela Ting (DC Bar #449576)
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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,
STATE OF COLORADO,
STATE OF IDAHO,
COMMONWEALTH OF PENNSYLVNIA,
STATE OF TEXAS,
COMMONWEALTH OF VIRGINIA,
STATE OF WASHINGTON,
and
STATE OF WEST VIRGINIA,
Plaintiffs,
v.
SPRINGLEAF HOLDINGS, INC.,
ONEMAIN FINANCIAL HOLDINGS, LLC,
and
CITIFINANCIAL CREDIT COMPANY,
Defendants.
CASE NO.: 1:15–cv–01992
JUDGE: Rosemary M. Collyer
FILED: 11/13/2015

Proposed Final Judgment

Whereas, Plaintiffs United States of America, and the States of Colorado, Idaho, Texas, Washington and West Virginia, and the Commonwealths of Pennsylvania and Virginia (collectively, ''Plaintiff States''), filed their Complaint on November 13, 2015, Plaintiffs and Defendants Springleaf Holdings, Inc., OneMain Financial Holdings, LLC, and CitiFinancial Credit Company, by their respective attorneys, have consented to the entry of this Final Judgment without

limited to approving or disapproving the consent decree''); *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to ''look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass''). *See generally Microsoft,* 56 F.3d at 1461 (discussing whether ''the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest' '').

[3] *See United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the ''Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone''); *United States* v. *Mid-Am. Dairymen, Inc.,* No. 73–CV–681–W–1, 1977–1 Trade Cas. (CCH) ¶ 61,508, at 71,980, *22 (W.D. Mo. 1977) (''Absent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should . . . carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.''); S. Rep. No. 93–298, at 6 (1973) (''Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.'').

trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against or admission by any party regarding any issue of fact or law;

And whereas, Defendants agree to be bound by the provisions of this Final Judgment pending its approval by the Court;

And whereas, the essence of this Final Judgment is the prompt and certain divestiture of certain rights or assets by the Defendants to assure that competition is not substantially lessened;

And whereas, Plaintiffs require Defendants to make certain divestitures for the purpose of remedying the loss of competition alleged in the Complaint;

And whereas, Defendants have represented to Plaintiffs that the divestitures required below can and will be made and that Defendants will later raise no claim of hardship or difficulty as grounds for asking the Court to modify any of the divestiture provisions contained below;

Now therefore, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is *ordered, adjudged and decreed:*

I. Jurisdiction

This Court has jurisdiction over the subject matter of and each of the parties to this action. The Complaint states a claim upon which relief may be granted against Defendants under Section 7 of the Clayton Act, as amended (15 U.S.C. 18).

II. Definitions

As used in this Final Judgment:

A. ''Acquirer'' means Lendmark or another entity to which Defendants divest the Divestiture Assets.

B. ''Springleaf'' means Defendant Springleaf Holdings, Inc., a Delaware corporation with its headquarters in Evansville, Indiana, and its *successors, assigns, subsidiaries, divisions, groups, affiliates, partnerships and joint ventures, and their directors, officers, managers, agents, and employees.*

C. ''OneMain'' means Defendant OneMain Financial Holdings, LLC, a Delaware limited liability company with its headquarters in Baltimore, Maryland, and its *successors, assigns, subsidiaries, divisions, groups, affiliates, partnerships and joint ventures, and their directors, officers, managers, agents, and employees.*

D. ''CitiFinancial'' means Defendant CitiFinancial Credit Company, a Delaware corporation, with its headquarters in Dallas, Texas, that is a wholly owned subsidiary of Citigroup and the holding company of OneMain.

E. ''Lendmark'' means Lendmark Financial Services, LLC, a Georgia limited liability company with its headquarters in Covington, Georgia, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships and joint ventures, and their directors, officers, managers, agents, and employees.

F. ''Divestiture Branches'' means the Springleaf branches identified in the Attachment to this Final Judgment.

G. ''Divestiture Assets'' means the Divestiture Branches, including, but not limited to:

(1) All real property and improvements, equipment, fixed assets, personal property, office furniture, materials, and supplies; all licenses, permits and authorizations issued by any governmental organization to the extent permitted by such governmental organization; and all contracts, leases and agreements related to the Divestiture Branches.

(2) All active loans originated or serviced at the Divestiture Branches; all insurance and other ancillary products sold in conjunction with such loans; all loan documents, records, files, current and past customer information, accounts, and agreements related to such loans and ancillary products; all historical performance information (including account-level payment histories) and all customers' credit scores and other credit metrics with respect to loans that are active, closed, paid-off, or defaulted that have been originated or serviced at the Divestiture Branches at any point since January 1, 2010.

(3) In the event that Lendmark is not the Acquirer, at the Acquirer's option, all tangible and intangible assets related to Springleaf's back office and technical support for loan origination, underwriting, and servicing at the Divestiture Branches, including, but not limited to, all equipment and fixed assets; all patents, licenses and sublicenses, intellectual property, technical information, computer software and related documentation, know-how, and trade secrets; and all manuals and technical information Springleaf provides to its own employees.

III. Applicability

A. This Final Judgment applies to Springleaf, OneMain and CitiFinancial, as defined above, and all other persons in active concert or participation with any of them who receive actual notice of this Final Judgment by personal service or otherwise.

B. If, prior to complying with Section IV and V of this Final Judgment, Springleaf sells or otherwise disposes of all or substantially all of its assets or of lesser business units that include the Divestiture Assets, it shall require the purchaser to be bound by the provisions of this Final Judgment. Springleaf need not obtain such an agreement from the Acquirer(s) of the assets divested pursuant to this Final Judgment.

IV. Divestitures

A. Springleaf is ordered and directed within 120 calendar days after the filing of the Complaint in this matter, or within five (5) calendar days after satisfaction of all state licensing requirements, whichever is sooner, to divest the Divestiture Assets in a manner consistent with this Final Judgment to Lendmark. The United States, in its sole discretion, after consultation with the Plaintiff States, may agree to one or more extensions of this time period not to exceed sixty (60) calendar days in total, and shall notify the Court in such circumstances. In the event that Lendmark has initiated the state licensing process in a particular state but has not satisfied the state's licensing requirements before the end of the period specified in this Paragraph IV(A), the period shall be extended until five (5) calendar days after satisfaction of the state licensing requirements with respect to those Divestiture Assets. Springleaf agrees to use its best efforts to divest the Divestiture Assets as expeditiously as possible.

B. In the event Lendmark is not the Acquirer of the Divestiture Assets in one or more states, Springleaf or the Monitoring Trustee shall promptly notify the United States of that fact in writing. In such circumstance, within thirty (30) calendar days after the United States receives such notice, or within five (5) days of satisfaction of all state licensing requirements, whichever is sooner, Springleaf shall divest the remaining Divestiture Assets in a manner consistent with this Final Judgment to an alternative Acquirer(s) acceptable to the United States, in its sole discretion, after consultation with the relevant Plaintiff States. The United States, in its sole discretion, after consultation with the relevant Plaintiff States, may agree to one or more extensions of either time period in this Paragraph IV(B), provided that the extension of either time period shall not exceed sixty (60) calendar days in total. The United States shall notify the Court of any such extension of time.

C. In the event that Lendmark is not the Acquirer of the Divestiture Assets in one or more states, Springleaf shall

make known, by usual and customary means, the availability of the remaining Divestiture Assets. Springleaf shall inform any person making an inquiry regarding a possible purchase of the Divestiture Assets that they are being divested pursuant to this Final Judgment and provide that person with a copy of this Final Judgment. Springleaf shall offer to furnish to all prospective acquirers, subject to customary confidentiality assurances, all information and documents relating to the Divestiture Assets customarily provided in a due diligence process except such information or documents subject to the attorney-client privilege or work-product doctrine. Springleaf shall make available such information to Plaintiffs at the same time that such information is made available to any other person.

D. Springleaf shall provide the Acquirer(s) and the United States information relating to the personnel employed at each Divestiture Branch to enable the Acquirer(s) to make offers of employment. Springleaf shall not interfere with any negotiations by the Acquirer(s) to employ any Springleaf employee who works at any Divestiture Branch.

E. Springleaf shall permit prospective acquirers of the Divestiture Assets to have reasonable access to personnel and to make inspections of the Divestiture Branches; access to any and all environmental, zoning, and other permit documents and information; and access to any and all financial, operational, or other documents and information customarily provided as part of a due diligence process.

F. Defendants shall not take any action that would impede in any way the permitting, operation, or divestiture of the Divestiture Assets. Springleaf shall use its best efforts to assist the Acquirer(s) in satisfying any state licensing requirements or obtaining any other needed governmental approvals relating to the acquisition of the Divestiture Assets.

G. For a period of two (2) years from the date of the filing of the Complaint in this matter, Defendants shall not enter into any non-compete agreement with any employee at any of Defendants' branches or with any regional manager with responsibility for managing any of Defendants' branches. Defendants shall waive all obligations under any existing non-compete agreement with any such employee.

H. At the option of the Acquirer(s), Springleaf shall enter into a transition services agreement with the Acquirer(s) for back office and technical support sufficient to meet all or part of the needs of the Acquirer(s) for a period of up to six (6) months. The United States, in its sole discretion, may approve one or more extensions of this agreement for a total of up to an additional six (6) months. The transition services provided pursuant to such an agreement shall include, but are not limited to, providing the Acquirer(s) access to a separate information technology environment within Springleaf's information systems for loan origination, administration and servicing. During the term of the transition services agreement, Springleaf shall implement and maintain procedures to preclude the sharing of data between Springleaf and the Acquirer(s). The terms and conditions of any contractual arrangement intended to satisfy this provision must be reasonably related to market conditions.

I. Unless the United States otherwise consents in writing, the divestiture pursuant to Section IV, or by a Divestiture Trustee appointed pursuant to Section V, of this Final Judgment, shall include the entire Divestiture Assets, and shall be accomplished in such a way as to satisfy the United States, in its sole discretion, after consultation with the relevant Plaintiff States, that the Divestiture Assets can and will be used by the Acquirer(s) as part of a viable, ongoing business involving the provision of personal installment loans to subprime borrowers in the United States. Divestiture of the Divestiture Branches may be made to one or more Acquirer(s), provided that Springleaf must divest to a single Acquirer all of the Divestiture Branches located in a particular state and that, in each instance, it is demonstrated to the sole satisfaction of the United States that the Divestiture Branches will remain viable and the divestiture of such assets will remedy the competitive harm alleged in the Complaint. The divestiture, whether pursuant to Section IV or Section V of this Final Judgment,

(1) shall be made to an Acquirer or Acquirers that, in the United States's sole judgment, after consultation with the Plaintiff States, has the intent and capability (including the necessary managerial, operational, technical and financial capability) of competing effectively in the provision of personal installment loans to subprime borrowers in the United States; and

(2) shall be accomplished so as to satisfy the United States, in its sole discretion, after consultation with the Plaintiff States, that none of the terms of any agreement between the Acquirer(s) and Springleaf gives Springleaf the ability unreasonably to raise the Acquirer's costs, to lower the Acquirer's efficiency, or otherwise to interfere in the ability of the Acquirer(s) to compete effectively.

V. Appointment of Divestiture Trustee

A. If Springleaf has not divested the Divestiture Assets within the time period specified in Paragraph IV(A) or Paragraph IV(B), Springleaf shall notify Plaintiffs of that fact in writing. Upon application of the United States, the Court shall appoint a Divestiture Trustee selected by the United States and approved by the Court to effect the divestiture of the Divestiture Assets.

B. After the appointment of a Divestiture Trustee becomes effective, only the Divestiture Trustee shall have the right to sell the Divestiture Assets. The Divestiture Trustee shall have the power and authority to accomplish the divestiture to an Acquirer or Acquirers acceptable to the United States, after consultation with the Plaintiff States, at such price and on such terms as are then obtainable upon reasonable effort by the Divestiture Trustee, subject to the provisions of Sections IV, V, and VI of this Final Judgment, and shall have such other powers as this Court deems appropriate. Subject to Paragraph V(D) of this Final Judgment, the Divestiture Trustee may hire at the cost and expense of Springleaf any investment bankers, attorneys, or other agents, who shall be solely accountable to the Divestiture Trustee, reasonably necessary in the Divestiture Trustee's judgment to assist in the divestiture. Any such investment bankers, attorneys, or other agents shall serve on such terms and conditions as the United States approves including confidentiality requirements and conflict of interest certifications.

C. Defendants shall not object to a sale by the Divestiture Trustee on any ground other than the Divestiture Trustee's malfeasance. Any such objections by Defendants must be conveyed in writing to the United States and the Divestiture Trustee within ten (10) calendar days after the Divestiture Trustee has provided the notice required under Section VI.

D. The Divestiture Trustee shall serve at the cost and expense of Springleaf pursuant to a written agreement, on such terms and conditions as the United States approves including confidentiality requirements and conflict of interest certifications. The Divestiture Trustee shall account for all monies derived from the sale of the assets sold by the Divestiture Trustee and all costs and expenses so incurred. After approval by the Court of the Divestiture Trustee's accounting, including fees for its services yet unpaid

and those of any professionals and agents retained by the Divestiture Trustee, all remaining money shall be paid to Springleaf and the trust shall then be terminated. The compensation of the Divestiture Trustee and any professionals and agents retained by the Divestiture Trustee shall be reasonable in light of the value of the Divestiture Assets and based on a fee arrangement providing the Divestiture Trustee with an incentive based on the price and terms of the divestiture and the speed with which it is accomplished, but timeliness is paramount. If the Divestiture Trustee and Springleaf are unable to reach agreement on the Divestiture Trustee's or any agents' or consultants' compensation or other terms and conditions of engagement within fourteen (14) calendar days of appointment of the Divestiture Trustee, the United States may, in its sole discretion, take appropriate action, including making a recommendation to the Court. The Divestiture Trustee shall, within three (3) business days of hiring any other professionals or agents, provide written notice of such hiring and the rate of compensation to Springleaf and the United States.

E. Springleaf shall use its best efforts to assist the Divestiture Trustee in accomplishing the required divestiture. The Divestiture Trustee and any consultants, accountants, attorneys, and other agents retained by the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities of the business to be divested, and Springleaf shall develop financial and other information relevant to such business as the Divestiture Trustee may reasonably request, subject to reasonable protection for trade secret or other confidential research, development, or commercial information or any applicable privileges. Defendants shall take no action to interfere with or to impede the Divestiture Trustee's accomplishment of the divestiture.

F. After its appointment, the Divestiture Trustee shall file monthly reports with the United States and, as appropriate, the Court setting forth the Divestiture Trustee's efforts to accomplish the divestiture ordered under this Final Judgment. To the extent such reports contain information that the Divestiture Trustee deems confidential, such reports shall not be filed in the public docket of the Court. Such reports shall include the name, address, and telephone number of each person who, during the preceding month, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, any interest in the Divestiture Assets, and shall describe in detail each contact with any such person. The Divestiture Trustee shall maintain full records of all efforts made to divest the Divestiture Assets.

G. If the Divestiture Trustee has not accomplished the divestiture ordered under this Final Judgment within six (6) months after its appointment, the Divestiture Trustee shall promptly file with the Court a report setting forth (1) the Divestiture Trustee's efforts to accomplish the required divestiture, (2) the reasons, in the Divestiture Trustee's judgment, why the required divestiture has not been accomplished, and (3) the Divestiture Trustee's recommendations. To the extent such report contains information that the Divestiture Trustee deems confidential, such reports shall not be filed in the public docket of the Court. The Divestiture Trustee shall at the same time furnish such report to the United States which shall have the right to make additional recommendations consistent with the purpose of the trust. The Court thereafter shall enter such orders as it shall deem appropriate to carry out the purpose of the Final Judgment, which may, if necessary, include extending the trust and the term of the Divestiture Trustee's appointment by a period requested by the United States.

H. If the United States determines that the Divestiture Trustee has ceased to act or failed to act diligently or in a reasonably cost-effective manner, it may recommend the Court appoint a substitute Divestiture Trustee.

VI. Notice of Proposed Divestiture

A. Within two (2) business days following execution of a definitive divestiture agreement, Springleaf or the Divestiture Trustee, whichever is then responsible for effecting the divestiture required herein, shall notify Plaintiffs of any proposed divestiture required by Section IV or V of this Final Judgment. If the Divestiture Trustee is responsible, it shall similarly notify Springleaf. The notice shall set forth the details of the proposed divestiture and list the name, address, and telephone number of each person not previously identified who offered or expressed an interest in or desire to acquire any ownership interest in the Divestiture Assets, together with full details of the same.

B. Within fifteen (15) calendar days of receipt by the United States of such notice, the United States, after consultation with the Plaintiff States, may request from Springleaf, the proposed Acquirer(s), any other third party, or the Divestiture Trustee, if applicable, additional information concerning the proposed divestiture, the proposed Acquirer(s), and any other potential Acquirer(s). Springleaf and the Divestiture Trustee shall furnish any additional information requested within fifteen (15) calendar days of the receipt of the request, unless the parties shall otherwise agree.

C. Within thirty (30) calendar days after receipt of the notice or within twenty (20) calendar days after the United States has been provided the additional information requested from Springleaf, the proposed Acquirer(s), any third party, and the Divestiture Trustee, whichever is later, the United States shall provide written notice to Springleaf and the Divestiture Trustee, if there is one, stating whether or not it objects to the proposed divestiture. If the United States provides written notice that it does not object, the divestiture may be consummated, subject only to Springleaf's limited right to object to the sale under Paragraph V(C) of this Final Judgment. Absent written notice that the United States does not object to the proposed Acquirer(s) or upon objection by the United States, a divestiture proposed under Section IV or Section V shall not be consummated. Upon objection by Springleaf under Paragraph V(C), a divestiture proposed under Section V shall not be consummated unless approved by the Court.

VII. Financing

Defendants shall not finance all or any part of any purchase made pursuant to Section IV or V of this Final Judgment.

VIII. Asset Preservation

Until the divestiture required by this Final Judgment has been accomplished, Defendants shall take all steps necessary to comply with the Asset Preservation Stipulation and Order entered by this Court. Defendants shall take no action that would jeopardize the divestiture ordered by this Court.

IX. Affidavits

A. Within twenty (20) calendar days of the filing of the Complaint in this matter, and every thirty (30) calendar days thereafter until the divestiture has been completed under Section IV or V, Springleaf shall deliver to the United States an affidavit as to the fact and manner of its compliance with Section IV or V of this Final Judgment. Each such affidavit shall include the name, address, and telephone number of each person who, during the preceding thirty (30) calendar days, made an offer to acquire, expressed an interest in

acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, any interest in the Divestiture Assets, and shall describe in detail each contact with any such person during that period. Each such affidavit shall also include a description of the efforts Springleaf has taken to solicit buyers for the Divestiture Assets, and to provide required information to prospective acquirers, including the limitations, if any, on such information. Assuming the information set forth in the affidavit is true and complete, any objection by the United States to information provided by Springleaf, including limitation on information, shall be made within fourteen (14) calendar days of receipt of such affidavit.

B. Within twenty (20) calendar days of the filing of the Complaint in this matter, Defendants shall deliver to the United States an affidavit that describes in reasonable detail all actions Defendants have taken and all steps Defendants have implemented on an ongoing basis to comply with Section VIII of this Final Judgment. Defendants shall deliver to the United States an affidavit describing any changes to the efforts and actions outlined in Defendants' earlier affidavits filed pursuant to this section within fifteen (15) calendar days after the change is implemented.

C. Springleaf shall keep all records of all efforts made to preserve and divest the Divestiture Assets until one year after such divestiture has been completed.

X. Appointment of Monitoring Trustee

A. Upon application of the United States, the Court shall appoint a Monitoring Trustee selected by the United States and approved by the Court.

B. The Monitoring Trustee shall have the power and authority to monitor Defendants' compliance with the terms of this Final Judgment and the Asset Preservation Stipulation and Order entered by this Court, and shall have such other powers as this Court deems appropriate. The Monitoring Trustee shall be required to investigate and report on the Defendants' compliance with this Final Judgment and the Asset Preservation Stipulation and Order and the Defendants' progress toward effectuating the purposes of this Final Judgment.

C. Subject to Paragraph X(E) of this Final Judgment, the Monitoring Trustee may hire at the cost and expense of Springleaf any consultants, accountants, attorneys, or other agents, who shall be solely accountable to the Monitoring Trustee, reasonably necessary in the Monitoring Trustee's judgment. Any such consultants, accountants, attorneys, or other agents shall serve on such terms and conditions as the United States approves including confidentiality requirements and conflict of interest certifications.

D. Springleaf shall not object to actions taken by the Monitoring Trustee in fulfillment of the Monitoring Trustee's responsibilities under any Order of this Court on any ground other than the Monitoring Trustee's malfeasance. Any such objections by Springleaf must be conveyed in writing to the United States and the Monitoring Trustee within ten (10) calendar days after the action taken by the Monitoring Trustee giving rise to Springleaf's objection.

E. The Monitoring Trustee shall serve at the cost and expense of Springleaf pursuant to a written agreement with Springleaf and on such terms and conditions as the United States approves, including confidentiality requirements and conflict of interest certifications. The compensation of the Monitoring Trustee and any consultants, accountants, attorneys, and other agents retained by the Monitoring Trustee shall be on reasonable and customary terms commensurate with the individual's experience and responsibilities. If the Monitoring Trustee and Springleaf are unable to reach agreement on the Monitoring Trustee's or any agent's or consultant's compensation or other terms and conditions of engagement within fourteen (14) calendar days of appointment of the Monitoring Trustee, the United States may, in its sole discretion, take appropriate action, including making a recommendation to the Court. The Monitoring Trustee shall, within three (3) business days of hiring any consultants, accountants, attorneys, or other agents, provide written notice of such hiring and the rate of compensation to Springleaf and the United States.

F. The Monitoring Trustee shall have no responsibility or obligation for the operation of Springleaf's business.

G. Defendants shall use their best efforts to assist the Monitoring Trustee in monitoring Defendants' compliance with their individual obligations under this Final Judgment and under the Asset Preservation Stipulation and Order. The Monitoring Trustee and any consultants, accountants, attorneys, and other agents retained by the Monitoring Trustee shall have full and complete access to the personnel, books, records, and facilities relating to compliance with this Final Judgment, subject to reasonable protection for trade secret or other confidential research, development, or commercial information or any applicable privileges. Defendants shall take no action to interfere with or to impede the Monitoring Trustee's accomplishment of its responsibilities.

H. After its appointment, the Monitoring Trustee shall file reports monthly, or more frequently as needed, with the United States and, as appropriate, the Court, setting forth Defendants' efforts to comply with their obligations under this Final Judgment and under the Asset Preservation Stipulation and Order. To the extent such reports contain information that the Monitoring Trustee deems confidential, such reports shall not be filed in the public docket of the Court.

I. The Monitoring Trustee shall serve until the divestiture of all the Divestiture Assets is finalized pursuant to either Section IV or Section V of this Final Judgment and the expiration of any continuing transition services agreement.

J. If the United States determines that the Monitoring Trustee has ceased to act or failed to act diligently or in a reasonably cost-effective manner, it may recommend the Court appoint a substitute Monitoring Trustee.

XI. Compliance Inspection

A. For the purposes of determining or securing compliance with this Final Judgment, or of any related orders such as any Asset Preservation Order, or of determining whether the Final Judgment should be modified or vacated, and subject to any legally recognized privilege, from time to time authorized representatives of the United States Department of Justice, including consultants and other persons retained by the United States, shall, upon written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to Defendants, be permitted:

(1) Access during Defendants' office hours to inspect and copy, or at the option of the United States, to require Defendants to provide hard copy or electronic copies of, all books, ledgers, accounts, records, data, and documents in the possession, custody, or control of Defendants, relating to any matters contained in this Final Judgment; and

(2) to interview, either informally or on the record, Defendants' officers, employees, or agents, who may have their individual counsel present, regarding such matters. The interviews shall be subject to the reasonable convenience of the interviewee and without restraint or interference by Defendants.

B. Upon the written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, Defendants shall submit written reports or response to written interrogatories, under oath if requested, relating to any of the matters contained in this Final Judgment as may be requested.

C. No information or documents obtained by the means provided in this section shall be divulged by the United States to any person other than an authorized representative of the executive branch of the United States, or the Plaintiff States, except in the course of legal proceedings to which the United States is a party (including grand jury proceedings), or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. If at the time information or documents are furnished by Defendants to the United States, Defendants represent and identify in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and Defendants mark each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure,'' then the United States shall give Defendants ten (10) calendar days notice prior to divulging such material in any legal proceeding (other than a grand jury proceeding).

XII. No Reacquisition

Defendants may not reacquire any part of the Divestiture Assets during the term of this Final Judgment.

XIII. Retention of Jurisdiction

This Court retains jurisdiction to enable any party to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

XIV. Expiration of Final Judgment

Unless this Court grants an extension, this Final Judgment shall expire ten (10) years from the date of its entry.

XV. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon and the United States's responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Date: _____

Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. 16

_____

United States District Judge

ATTACHMENT

Branch name	Address	City	State	Zip code
PHOENIX-SW	9130 W THOMAS RD STE A–103	PHOENIX	AZ	85037
TEMPE	744 W ELLIOT RD STE 104	TEMPE	AZ	85284
TUCSON MIDSTAR	4528 E BROADWAY BLVD	TUCSON	AZ	85711
TUCSON WEST	680 W PRINCE RD STE 100	TUCSON	AZ	85705
ANAHEIM	691 N EUCLID ST	ANAHEIM	CA	92801
ANTIOCH	4049 LONE TREE WAY STE B	ANTIOCH	CA	94531
BAKERSFIELD	4905 STOCKDALE HWY	BAKERSFIELD	CA	93309
CHICO	2499 FOREST AVE STE 100	CHICO	CA	95928
CHULA VISTA	565 TELEGRAPH CANYON RD	CHULA VISTA	CA	91910
SACRAMENTO-ELK GROVE	8250 CALVINE RD STE B	SACRAMENTO	CA	95828
ESCONDIDO	306 W EL NORTE PKWY STE A	ESCONDIDO	CA	92026
FREMONT	39146 FREMONT HUB	FREMONT	CA	94538
FRESNO	3140 W SHAW AVE STE 109	FRESNO	CA	93711
HANFORD	1560 W LACEY BLVD STE 105	HANFORD	CA	93230
LEMON GROVE	6957 BROADWAY	LEMON GROVE	CA	91945
LONG BEACH	2296 E CARSON ST	LONG BEACH	CA	90807
MADERA	2185 W CLEVELAND AVE STE B,	MADERA	CA	93637
MERCED	510 W MAIN ST STE D	MERCED	CA	95340
MODESTO/SYLVAN	2101 SYLVAN AVE	MODESTO	CA	95355
OXNARD	1991 E VENTURA BLVD STE C,	OXNARD	CA	93036
PALMDALE	40008 10TH ST W STE E	PALMDALE	CA	93551
PARAMOUNT	7902 ALONDRA BLVD	PARAMOUNT	CA	90723
PASADENA	1272 E COLORADO BLVD	PASADENA	CA	91106
POMONA	355 E FOOTHILL BLVD STE A	POMONA	CA	91767
RANCHO CUCAMONGA	11553 FOOTHILL BLVD STE 104	RANCHO CUCAMONGA	CA	91730
REDDING	107 LAKE BLVD	REDDING	CA	96003
RIALTO	1270 W FOOTHILL BLVD STE C	RIALTO	CA	92376
SAN FERNANDO	1129 SAN FERNANDO RD	SAN FERNANDO	CA	91340
SANTA ANA	3853 S BRISTOL ST	SANTA ANA	CA	92704
SANTA MARIA	2125 S BROADWAY STE 107	SANTA MARIA	CA	93454
SOUTH SAN FRANCISCO	949 EL CAMINO REAL	SOUTH SAN FRANCISCO	CA	94080
STOCKTON	3421 BROOKSIDE RD STE C	STOCKTON	CA	95219
TORRANCE	20036 HAWTHORNE BLVD	TORRANCE	CA	90503
COLORADO SPRINGS	5689 N ACADEMY BLVD	COLORADO SPRINGS	CO	80918
FORT COLLINS	4032 S COLLEGE AVE UNIT 6	FORT COLLINS	CO	80525
PUEBLO	204 W 29TH ST	PUEBLO	CO	81008
AURORA	15025 E MISSISSIPPI AVE	AURORA	CO	80012
THORNTON	550 THORNTON PKWY UNIT 182B	THORNTON	CO	80229
LITTLETON	8500 W CRESTLINE AVE UNIT G8	LITTLETON	CO	80123
TWIN FALLS	1563 FILLMORE ST STE 2F	TWIN FALLS	ID	83301

Branch name	Address	City	State	Zip code
COEUR D'ALENE	503 W APPLEWAY STE G	COEUR D'ALENE	ID	83814
POCATELLO	345 YELLOWSTONE AVE STE C1	POCATELLO	ID	83201
BOISE EAST	2140 BROADWAY AVE	BOISE	ID	83706
FOREST CITY	181 COMMERCIAL ST	FOREST CITY	NC	28043
HENDERSON	891 S BECKFORD DR STE B	HENDERSON	NC	27536
MOREHEAD CITY	5000 HWY 70 W STE 105	MOREHEAD CITY	NC	28557
MOUNT AIRY	2133 ROCKFORD ST STE 700	MOUNT AIRY	NC	27030
KINSTON	4167 W VERNON AVE	KINSTON	NC	28504
NORTH WILKESBORO	1724 WINKLER ST	WILKESBORO	NC	28697
SHELBY	711 E DIXON BLVD	SHELBY	NC	28152
WILSON	2835 RALEIGH ROAD W STE 105	WILSON	NC	27896
CHARLOTTE	3220 WILKINSON BLVD UNIT A4	CHARLOTTE	NC	28208
DURHAM-CHAPEL HILL	4711 HOPE VALLEY RD STE 5C	DURHAM	NC	27707
CLINTON	1351 SUNSET AVE STE B	CLINTON	NC	28328
KERNERSVILLE	960 S MAIN ST STE B	KERNERSVILLE	NC	27284
WILLIAMSTON	1127 WALMART DR	WILLIAMSTON	NC	27892
REIDSVILLE	1560 FREEWAY DR STE J	REIDSVILLE	NC	27320
ALBEMARLE	720 NC 24 27 BYP E STE 3	ALBEMARLE	NC	28001
MORGANTON	126 FIDDLERS RUN BLVD	MORGANTON	NC	28655
MARION	500 N MAIN ST STE 12	MARION	NC	28752
ASHTABULA	2902 N RIDGE E	ASHTABULA	OH	44004
ATHENS	1013 E STATE ST	ATHENS	OH	45701
CAMBRIDGE	1225 WOODLAWN AVE STE 1	CAMBRIDGE	OH	43725
GARFIELD HEIGHTS	9531 VISTA WAY UNIT 3C	GARFIELD HEIGHTS	OH	44125
REYNOLDSBURG	6156 E MAIN ST	REYNOLDSBURG	OH	43068
FAIRBORN	2628 COLONEL GLENN HWY STE B	FAIRBORN	OH	45324
DOVER	329 W 3RD ST	DOVER	OH	44622
GALLIPOLIS	444 SILVER BRIDGE PLZ	GALLIPOLIS	OH	45631
LIMA	1092 N CABLE RD	LIMA	OH	45805
ONTARIO	2020 AUGUST DR	ONTARIO	OH	44906
SANDUSKY	5500 MILAN RD STE 338	SANDUSKY	OH	44870
TOLEDO-MONROE	5305 MONROE ST STE 1	TOLEDO	OH	43623
CHILLICOTHE	1534 N BRIDGE ST STE 1	CHILLICOTHE	OH	45601
ELYRIA	5222 DETROIT RD	ELYRIA	OH	44035
FAIRLAWN	55 GHENT RD STE 300	FAIRLAWN	OH	44333
LANCASTER	1617 VICTOR RD NW	LANCASTER	OH	43130
MARION	1330 MOUNT VERNON AVE	MARION	OH	43302
WOOSTER	2827 CLEVELAND RD	WOOSTER	OH	44691
CHELTENHAM	7400 FRONT ST	CHELTENHAM	PA	19012
LANCASTER	2054 FRUITVILLE PIKE	LANCASTER	PA	17601
JOHNSTOWN	1397 EISENHOWER BLVD STE 100	JOHNSTOWN	PA	15904
MONACA	3944 BRODHEAD RD STE 8	MONACA	PA	15061
E. NORRITON TWP	42 E GERMANTOWN PIKE	E. NORRITON TWP	PA	19401
SHAMOKIN DAM	30 BALDWIN BLVD STE 90	SHAMOKIN DAM	PA	17876
STATE COLLEGE	2264 E COLLEGE AVE	STATE COLLEGE	PA	16801
TANNERSVILLE	2959 ROUTE 611 STE 105	TANNERSVILLE	PA	18372
UPPER DARBY	1500 GARRETT RD STE F	UPPER DARBY	PA	19082
WASHINGTON	198 W CHESTNUT ST	WASHINGTON	PA	15301
BURLESON	621 SW JOHNSON AVE STE B	BURLESON	TX	76028
AMARILLO	2818 S SONCY RD	AMARILLO	TX	79124
BEAUMONT	196 S DOWLEN RD	BEAUMONT	TX	77707
BRYAN-COLLEGE STATION	725 E VILLA MARIA RD STE 2100	BRYAN	TX	77802
DEL RIO	2400 VETERANS BLVD STE 27	DEL RIO	TX	78840
DENTON	2215 S LOOP 288 STE 327	DENTON	TX	76205
LAKE JACKSON	145 OYSTER CREEK DR STE 5	LAKE JACKSON	TX	77566
LUFKIN	3009 S JOHN REDDITT DR STE C	LUFKIN	TX	75904
ODESSA	2237 E 52ND ST	ODESSA	TX	79762
SAN ANGELO	3224 SHERWOOD WAY	SAN ANGELO	TX	76901
CHRISTIANSBURG	438 PEPPERS FERRY RD NW	CHRISTIANSBURG	VA	24073
ALTAVISTA	105 CLARION RD STE K	ALTAVISTA	VA	24517
COLLINSVILLE	3404 VIRGINIA AVE	COLLINSVILLE	VA	24078
DANVILLE	625 PINEY FOREST RD STE 201	DANVILLE	VA	24540
FARMVILLE	907 S MAIN ST STE 9	FARMVILLE	VA	23901
FRONT ROYAL	290 REMOUNT RD	FRONT ROYAL	VA	22630
GALAX	544 E STUART DR STE B	GALAX	VA	24333
LEESBURG	534 E MARKET ST	LEESBURG	VA	20176
PETERSBURG-BATTLEFIELD	3323 S CRATER RD STE A	PETERSBURG	VA	23805
RICHMOND-E	5211 S LABURNUM AVE	RICHMOND	VA	23231
SOUTH HILL	1167 E ATLANTIC ST	SOUTH HILL	VA	23970
STAUNTON	729 RICHMOND AVE STE 103	STAUNTON	VA	24401
SUFFOLK	2815 GODWIN BLVD STE K	SUFFOLK	VA	23434
TAPPAHANNOCK	1830 TAPPAHANNOCK BLVD	TAPPAHANNOCK	VA	22560
WOODBRIDGE	3109 GOLANSKY BLVD	WOODBRIDGE	VA	22192
BREMERTON	4203 WHEATON WAY STE F6	BREMERTON	WA	98310

Branch name	Address	City	State	Zip code
EVERETT	5920 EVERGREEN WAY STE F	EVERETT	WA	98203
KENNEWICK	3107 W KENNEWICK AVE STE B	KENNEWICK	WA	99336
MOUNT VERNON	1616 N 18TH ST STE 120	MOUNT VERNON	WA	98273
OLYMPIA	1600 COOPER POINT RD SW	OLYMPIA	WA	98502
RENTON	101 SW 41ST ST STE A	RENTON	WA	98057
SPOKANE NS	515 W FRANCIS AVE STE 4	SPOKANE	WA	99205
UNION GAP	1601 E WASHINGTON AVE STE 106	UNION GAP	WA	98903
LOGAN	105 LB AND T WAY	LOGAN	WV	25601
PRINCETON	1257 STAFFORD DR	PRINCETON	WV	24740
LEWISBURG	518 N JEFFERSON ST	LEWISBURG	WV	24901
BARBOURSVILLE	6006 US ROUTE 60 E	BARBOURSVILLE	WV	25504
OAK HILL	329 MALL RD	OAK HILL	WV	25901
SOUTH CHARLESTON	10 RIVER WALK MALL	SOUTH CHARLESTON	WV	25303

[FR Doc. 2015–29895 Filed 11–23–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2015–0005]

Federal Advisory Council on Occupational Safety and Health (FACOSH)

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Announcement of the renewal of the FACOSH charter and appointment of new members to FACOSH.

SUMMARY: The Secretary of Labor has renewed the FACOSH charter and appointed six individuals to serve on FACOSH.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Mr. Frank Meilinger, Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1999; email *meilinger.francis2@dol.gov.*

For general information: Mr. Francis Yebesi, Director, OSHA Office of Federal Agency Programs, N–3622, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2233; email *yebesi.francis@dol.gov.*

SUPPLEMENTARY INFORMATION:

Renewal of FACOSH Charter

On September 30, 2015, President Barack Obama signed Executive Order (E.O.) 13708 continuing certain federal advisory committees, including FACOSH, until September 30, 2017 (80 FR 60271 (10/15/2015)). In response, the Secretary of Labor (Secretary) renewed and filed the FACOSH charter on October 14, 2015. FACOSH will terminate on September 30, 2017, unless the President continues the committee. (The FACOSH charter is available to read or download on the FACOSH page on OSHA's Web page at *http://www.osha.gov.*)

FACOSH is authorized by 5 U.S.C. 7902, section 19 of the Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 668), and E.O. 11612, as amended, to advise the Secretary on all matters relating to the occupational safety and health of federal employees. This includes providing advice on how to reduce and keep to a minimum the number of injuries and illnesses in the federal workforce and how to encourage each federal Executive Branch department and agency to establish and maintain effective occupational safety and health programs.

Appointment of FACOSH Members

FACOSH is comprised of 16 members; eight who represent federal agency management and eight from labor organizations that represent federal employees. The Secretary has appointed or re-appointed the following individuals to serve on FACOSH:

Federal employee representatives:

- Mr. William Dougan, National Federation of Federal Employees (Reappointment). Term expires December 31, 2018;
- Ms. Nan Thompson Ernst, American Federation of State, County and Municipal Employees. Term expires December 31, 2016;
- Ms. Deborah Kleinberg, Seafarers International Union (Reappointment). Term expires December 31, 2018; and
- Ms. Irma Westmoreland, National Nurses United (Reappointment). Term expires December 31, 2018.

Federal agency management representatives:

- Mr. Gregory Parham, U.S. Department of Agriculture (Reappointment). Term expires December 31, 2018; and
- Mr. Charles Rosenfarb, U.S Department of State. Term expires December 31, 2018.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice pursuant to 5 U.S.C. 7902; 5 U.S.C. App. 2; 29 U.S.C. 668; E.O. 13708 (80 FR 60271 (10/5/2015) and 12196 (45 CFR 12629 (2/27/1980)); 41 CFR part 102–3; and Secretary of Labor's Order No. 1–2012 (77 FR 3912 (1/25/2012)).

Signed at Washington, DC, on November 19, 2015.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2015–29905 Filed 11–23–15; 8:45 am]

BILLING CODE 4510–26–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Notice of Meeting

In accordance with the purposes of Sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards (ACRS) will hold a meeting on December 3–5, 2015, 11545 Rockville Pike, Rockville, Maryland.

Thursday, December 3, 2015, Conference Room T–2B1, 11545 Rockville Pike, Rockville, Maryland

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–11:00 a.m.: 10 CFR 50.46c Rulemaking Activities (Open)—The Committee will hear presentations by and hold discussions with representatives of the staff regarding 10 CFR 50.46c rulemaking activities.

11:15 a.m.–12:00 p.m.: Discussion of Potential Commission Meeting Topics (Open)—The Committee will discuss potential topics for its anticipated March 2016 meeting with the Commission.

1:00 p.m.–3:00 p.m.: LEE Combined License Application (COLA) Review (Open)—The Committee will hear presentations by and hold discussions with representatives of the staff and Duke Energy regarding the draft safety evaluation report associated with the COLA for William States Lee III Nuclear Station, Units 1 and 2.

3:15 p.m.–6:00 p.m.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports on matters discussed during this meeting.

Friday, December 4, 2015, Conference Room T2–B1, 11545 Rockville Pike, Rockville, Maryland

8:30 a.m.–10:00 a.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee (Open/Closed)—The Committee will discuss the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS Meetings, and matters related to the conduct of ACRS business, including anticipated workload and member assignments. [**Note:** A portion of this meeting may be closed pursuant to 5 U.S.C. 552b(c)(2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.]

10:00 a.m.–10:15 a.m.: Reconciliation of ACRS Comments and Recommendations (Open)—The Committee will discuss the responses from the NRC Executive Director for Operations to comments and recommendations included in recent ACRS reports and letters.

10:30 a.m.–6:00 p.m.: Preparation of ACRS Reports (Open)—The Committee will continue its discussion of proposed ACRS reports on matters discussed during this meeting.

Saturday, December 5, 2015, Conference Room T2–B1, 11545 Rockville Pike, Rockville, Maryland

8:30 a.m.–11:30 a.m.: Preparation of ACRS Reports (Open)—The Committee will continue its discussion of proposed ACRS reports.

11:30 a.m.–12:00 p.m.: Miscellaneous (Open)—The Committee will continue its discussion related to the conduct of Committee activities and specific issues that were not completed during previous meetings.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 21, 2015 (80 FR 63846). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements should notify Quynh Nguyen, Cognizant ACRS Staff (Telephone: 301–415–5844, Email: *Quynh.Nguyen@nrc.gov*), five days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Cognizant ACRS staff if such rescheduling would result in major inconvenience.

Thirty-five hard copies of each presentation or handout should be provided 30 minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the Cognizant ACRS Staff one day before meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the Cognizant ACRS Staff with a CD containing each presentation at least 30 minutes before the meeting.

In accordance with Subsection 10(d) of Public Law 92–463 and 5 U.S.C. 552b(c), certain portions of the December 4th meeting may be closed, as specifically noted above. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agendas, meeting transcripts, and letter reports are available through the NRC Public Document Room at *pdr.resource@nrc.gov,* or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System (PARS) component of NRC's document system (ADAMS) which is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html* or *http://www.nrc.gov/reading-rm/doc-collections/ACRS/.*

Video teleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service should contact Mr. Theron Brown, ACRS Audio Visual Technician (301–415–8066), between 7:30 a.m. and 3:45 p.m. (ET), at least 10 days before the meeting to ensure the availability of this service. Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the video teleconferencing link. The availability of video teleconferencing services is not guaranteed.

Dated at Rockville, Maryland, this 18th day of November, 2015.

For the Nuclear Regulatory Commission.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 2015–29880 Filed 11–23–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–295 and 50–304; NRC–2015–0265]

ZionSolutions, LLC, Zion Nuclear Power Station, Units 1 and 2; Partial Site Release

AGENCY: Nuclear Regulatory Commission.

ACTION: Request for comment and public meeting.

SUMMARY: On August 27, 2015, the U.S. Nuclear Regulatory Commission (NRC) received from Zion*Solutions,* LLC, (ZS), a request for approval to remove a portion of the site from the operating licenses for Zion Nuclear Power Station (ZNPS), Units 1 and 2. Specifically, ZS intends to remove and release the radiologically non-impacted portions of the site from its license. The NRC is requesting public comments on ZS's partial site release and will hold a public meeting to discuss the request.

DATES: Submit comments by December 24, 2015. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0265. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: John Hickman, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001, telephone: 301–415–3017, email: *John.Hickman@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0265 when contacting the NRC about the availability of information for 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–2015–0265.

• *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 ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.

• *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–2015–0265 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

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 entering 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. Discussion

Zion*Solutions,* LLC, (ZS) is the holder of Facility Operating License Nos. DPR–39 and DPR–48. The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the NRC now or hereafter in effect. The facility consists of two pressurized-water reactors located in Lake County, Illinois.

In September 1996, ZNPS Unit 2 was permanently shut-down after approximately 23 years of operation. In February 1997, ZNPS Unit 1 was permanently shut-down after approximately 24 years of operation. In early 1998, in accordance with section 50.82(a)(1)(i) and (ii) of title 10 of the *Code of Federal Regulations* (10 CFR), Exelon Generating Company LLC (Exelon) notified the NRC of the permanent cessation of operations at the ZNPS and the permanent removal of all spent fuel assemblies from the reactor vessels to the spent fuel pool (ADAMS Legacy Accession Nos. 9902200407 and 9803110251). On February 14, 2000, Exelon submitted a Post-Shutdown Decommissioning Activities Report (PSDAR) for the Zion units, pursuant to 10 CFR 50.82(a)(4)(i) (ADAMS Accession No. ML003685889). The PSDAR was updated on March 18, 2008 (ADAMS Accession No. ML080840398). On September 1, 2010, the NRC transferred Facility Operating License Numbers DPR–39 and DPR–48 from Exelon to ZS (ADAMS Accession No. ML102290437). Zion*Solutions,* LLC, acquired ZNPS to conduct the decommissioning of the facility and then return the decommissioned site back to Exelon. The spent fuel has been moved from the spent fuel pool to the Independent Spent Fuel Storage Installation. Decommissioning of ZNPS is scheduled to be completed in 2018.

By letter dated December 19, 2014 (ADAMS Accession No. ML15005A336), and supplemented on February 26, 2015 (ADAMS Accession No. ML15061A281), ZS submitted the License Termination Plan (LTP) for ZNPS in accordance with 10 CFR 50.82(a)(9). The LTP includes a site characterization to ensure that final radiation surveys (FRS) cover all areas where contamination existed, remains, or has the potential to exist or remain; identification of remaining dismantlement activities; plans for site remediation; a description of the FRS plan to confirm that ZNPS will meet the release criteria in 10 CFR part 20, subpart E; dose-modeling scenarios that ensure compliance with the radiological criteria for license termination; an estimate of the remaining site-specific decommissioning costs; and a supplement to the Defueled Safety Analysis Report and the Environmental Report describing any new information or significant environmental change associated with proposed license termination activities. The Zion LTP is currently being reviewed by the NRC.

By letter dated August 27, 2015 (ADAMS Accession No. ML15243A029), ZS submitted a request for approval to remove a portion of the site from the part 50 License Nos. DPR–39 and DPR–48. Specifically, ZS intends to remove and release the radiologically non-impacted portions of the site from its part 50 licenses in accordance with 10 CFR 50.83(b), ''Release of part of a power reactor facility or site for unrestricted use.'' This request is the subject of this notice.

III. Request for Comment and Public Meeting

The NRC is requesting public comments on the ZNPS partial site release. The NRC will conduct a public meeting to discuss the partial site release and receive comments on Tuesday, December 1, 2015, from 7:00 p.m. until 8:30 p.m., Central Time, at the Courtyard Chicago Waukegan/Gurnee, located at 3800 Northpoint Boulevard, Waukegan, IL 60085. For additional information regarding the meeting, see the NRC's Public Meeting Schedule Web site at *http://meetings.nrc.gov/pmns/mtg.* The agenda will be posted no later than 10 days prior to the meeting.

Dated at Rockville, Maryland, this 17th day of November, 2015.

For the Nuclear Regulatory Commission.

John Clements,

Acting Chief, Reactor Decommissioning Branch, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2015–29881 Filed 11–23–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0001]

Sunshine Act Meeting Notice

DATE: November 23, 30, December 7, 14, 21, 28, 2015.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of November 23, 2015

There are no meetings scheduled for the week of November 23, 2015.

Week of November 30, 2015—Tentative

Thursday, December 3, 2015

9:30 a.m. Briefing on Equal Employment Opportunity and Civil Rights Outreach (Public Meeting) (Contact: Larniece McKoy Moore: 301–415–1942).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of December 7, 2015—Tentative

There are no meetings scheduled for the week of December 7, 2015.

Week of December 14, 2015—Tentative

Tuesday, December 15, 2015

9:00 a.m. Hearing on Construction Permit for SHINE Medical Isotope Production Facility: Section 189a. of the Atomic Energy Act Proceeding (Public Meeting) (Contact: Steven Lynch: 301–415–1524).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Thursday, December 17, 2015

9:30 a.m. Briefing on Project AIM 2020 (Public Meeting) (Contact: John Jolicoeur 301–415–1642).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of December 21, 2015—Tentative

There are no meetings scheduled for the week of December 21, 2015.

Week of December 28, 2015—Tentative

There are no meetings scheduled for the week of December 28, 2015.

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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.*

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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: November 20, 2015.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2015–30004 Filed 11–20–15; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0261]

Biweekly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Biweekly notice.

SUMMARY: Pursuant to Section 189a. (2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from October 27, 2015, to November 9, 2015. The last biweekly notice was published on November 10, 2015.

DATES: Comments must be filed by December 24, 2015. A request for a hearing must be filed January 25, 2016.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0261. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.*
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Lynn M. Ronewicz, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1927, email: *Lynn.Ronewicz@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0261 when contacting the NRC about the availability of information for 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–2015–0261.
- *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 ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section

• *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–2015–0261, facility name, unit number(s), application date, and subject 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 entering 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. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in § 50.92 of Title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the

hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC's regulations, policies and procedures.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)-(iii).

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, federally-recognized Indian tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by December 28, 2015. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document, and should meet the requirements for petitions for leave to intervene set forth in this section, except that under § 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. A State, local governmental body, Federally-recognized Indian tribe, or agency thereof may also have the opportunity to participate under 10 CFR 2.315(c).

If a hearing is granted, any person who does not wish, or is not qualified, to become a party to the proceeding may, in the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by January 25, 2016.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they

can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)–(iii).

For further details with respect to these license amendment applications, see the application for amendment which is available for public inspection in ADAMS and at the NRC's PDR. For additional direction on accessing information related to this document, see the ''Obtaining Information and Submitting Comments'' section of this document.

Dominion Nuclear Connecticut, Inc., Docket No. 50–423, Millstone Power Station, Unit No. 3 (MPS3), New London County, Connecticut

Date of amendment request: August 31, 2015. A publicly-available version is in ADAMS under Accession No. ML15246A118.

Description of amendment request: The amendment would modify the MPS3 Technical Specification (TS) 5.6.3, to specify the spent fuel pool storage (SFP) capacity limit in terms of the total number of fuel assemblies. Specifically, the description of the MPS3 SFP storage capacity would be revised to remove the word ''available'' from TS 5.6.3 and specify a storage capacity limit of 1860 fuel assemblies.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed amendment does not represent any physical change to plant systems, structures, or components (SSC), or to procedures established for plant operation. The proposed amendment would not increase the likelihood of a malfunction of any plant SSC. Therefore, initial conditions associated with, and systems credited for mitigating the consequences of accidents previously evaluated remain unchanged.

Therefore, the proposed amendment does not involve a significant increase in the probability or the consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any previously evaluated?

Response: No.

The proposed amendment does not involve a physical alteration of the plant. No new or different types of equipment will be installed and there are no physical modifications to existing equipment associated with the proposed amendment. Similarly, the proposed amendment would not physically change any plant systems, structures, or components involved in the mitigation or any postulated accidents. Thus, no new initiators or precursors of a new or different kind of accident are created. Furthermore, the proposed amendment does not create the possibility of a new failure mode associated with any equipment or personnel failures.

Therefore, the proposed amendment would not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed amendment does not represent any physical change to plant systems, structures, or components, or to procedures established for plant operation. The proposed amendment does not affect the inputs or assumptions of any of the design basis analyses and current design limits will continue to be met. The proposed amendment does not alter or create a new mode of plant operation or configuration. Margins of safety are not significantly reduced.

Therefore, operation of the facility in accordance with the proposed change to TS 5.6.3 does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lillian M. Cuoco, Senior Counsel, Dominion Resources Services, Inc., 120 Tredegar Street, RS–2, Richmond, VA 23219.

NRC Branch Chief: Travis L. Tate.

DTE Electric Company, Docket No. 50–341, Fermi 2, Monroe County, Michigan

Date of amendment request: September 24, 2015. A publicly-available version is in ADAMS under Accession No. ML15268A422.

Description of amendment request: The amendment would delete the note associated with Surveillance Requirement (SR) 3.5.1.4 to reflect the Residual Heat Removal (RHR) system

design and ensure the RHR system operation is consistent with technical specification (TS) 3.5.1 Limiting Condition for Operation requirements.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

No physical changes to the facility will occur as a result of this proposed amendment. The proposed change will not alter the physical design. The current TS SR note could make Fermi 2 susceptible to potential water hammer in the RHR system if a subsystem is operating in the shutdown cooling mode of RHR in Mode 3 and is required to swap from the shutdown cooling to LPCI [low pressure coolant injection] mode of RHR. The proposed LAR will eliminate the risk for cavitation of the pump and voiding in the suction piping, thereby avoiding potential to damage the RHR system, including water hammer.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not alter the physical design, safety limits, or safety analysis assumptions associated with the operation of the plant. Accordingly, the change does not introduce any new accident initiators, nor does it reduce or adversely affect the capabilities of any plant structure, system, or component to perform their safety function. Deletion of the TS SR note is appropriate because current TS could put the plant at risk for potential cavitation of the pump and voiding in the suction piping, resulting in potential occurrence of water hammer and damage the RHR system.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change conforms to NRC regulatory guidance regarding the content of plant technical specifications. The proposed change does not alter the physical design, safety limits, or safety analysis assumptions associated with the operation of the plant.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jon P. Christinidis, DTE Energy, Expert Attorney—Regulatory, 688 WCB, One Energy Plaza, Detroit, MI 48226.

NRC Branch Chief: David L. Pelton.

Duke Energy Carolinas, LLC, Docket Nos. 50–413 and 50–414, Catawba Nuclear Station (CNS), Units 1 and 2, York County, South Carolina; and Docket Nos. 50–369 and 50–370, McGuire Nuclear Station (MNS), Units 1 and 2, Mecklenburg County, North Carolina

Date of amendment request: August 20, 2015. A publicly-available version is available at ADAMS Accession No. ML15295A016.

Description of amendment request: The proposed amendments would revise the Technical Specifications (TSs) to allow the use of Optimized Zirlo™. Specifically, the proposed change would modify TS 4.2.1 to add Optimized Zirlo™ as an allowable cladding and TS 5.6.5.b to add associated methodologies for determining the core operating limits report.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed TS changes add flexibility in the selection of fuel rod cladding materials for use at CNS and MNS. The proposed change of adding a cladding material does not result in an increase to the probability or consequences of an accident previously evaluated. TS 4.2.1 addresses the fuel assembly design, and currently specifies that ''Each assembly shall consist of a matrix of either ZIRLO® or Zircaloy fuel rods . . .''. The proposed change will add Optimized ZIRLO™ to the approved fuel rod cladding materials listed in this TS. In addition, a reference to the Westinghouse VANTAGE+ fuel assembly core reference report, WCAP–12610–P–A, and the topical report for Optimized ZIRLO™, WCAP–12610–P–A and CENPD–404–P–A, Addendum 1–A, will be included in the listing of approved methods used to determine the core operating limits for CNS and MNS given in TS 5.6.5.b. Westinghouse topical report WCAP–12610–P–A and CENPD–404–P–A, Addendum 1–A, Optimized ZIRLO™, provides the details and results of material testing of Optimized ZIRLO™ compared to standard ZIRLO®, as well as the material properties to be used in various models and methodologies when analyzing Optimized ZIRLO™. As the nuclear industry pursues longer operating cycles with increased fuel discharge burnup and fuel duty, the corrosion performance requirements for the nuclear fuel cladding become more demanding. Optimized ZIRLO™ was developed to meet these industry needs by providing a reduced corrosion rate while maintaining the composition and physical properties, such as mechanical strength, similar to standard ZIRLO®. Fuel rod internal pressure has also become more limiting due to changes such as increased fuel duty and use of integral fuel burnable absorbers. Reducing the associated corrosion buildup by using Optimized ZIRLO™ in turn reduces temperature feedback effects, providing additional margin to the fuel rod internal pressure design criterion. Fuel with Optimized ZIRLO™ cladding will continue to satisfy the pertinent design basis operating limits, so cladding integrity is maintained. There are no changes that will adversely affect the ability of existing components and systems to mitigate the consequences of any accident. Therefore, addition of Optimized ZIRLO™ to the allowable cladding materials for CNS and MNS does not result in an increase in the probability or consequences of an accident previously evaluated.

The NRC has previously approved use of Optimized ZIRLO™ fuel cladding material in Westinghouse fueled reactors provided that licensees ensure compliance with the Conditions and Limitations set forth in the NRC Safety Evaluation for the topical report. Confirmation that these Conditions are satisfied is performed as part of the normal core reload process.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed TS changes add flexibility in the selection of fuel rod cladding materials for use at CNS and MNS. Optimized ZIRLO™ was developed to provide a reduced cladding corrosion rate while maintaining the benefits of mechanical strength and resistance to accelerated corrosion from potential abnormal chemistry conditions. The fuel rod design bases are established to satisfy the general and specific safety criteria addressed in the CNS and MNS [Updated Final Safety Analysis Report] UFSAR, Chapter 15 (Accident Analyses). The fuel rods are designed to prevent excessive fuel temperatures, excessive fuel rod internal gas pressures due to fission gas releases, and excessive cladding stresses and strains. Westinghouse topical report WCAP–12610–P–A and CENPD–404–P–A, Addendum 1–A, Optimized ZIRLO™, provides the details and results of material testing of Optimized ZIRLO™ compared to standard ZIRLO®, as well as the material properties to be used in various models and methodologies when analyzing Optimized ZIRLO™. The original

fuel design basis requirements have been maintained. No new single failure mechanisms will be created, and there are no alterations to plant equipment or procedures that would introduce any new or unique operational modes or accident precursors. Therefore, addition of another approved cladding material of similar composition and properties as the current approved cladding materials to the CNS and MNS TS does not create the possibility of a new or different kind of accident or malfunction from those previously evaluated within the UFSAR.

3. Does the proposed change involve a significant reduction in the margin of safety?

Response: No.

The proposed change will not involve a significant reduction in the margin of safety because it has been demonstrated that the material properties of the Optimized ZIRLO™ are not significantly different from those of standard ZIRLO®. Optimized ZIRLO™ is expected to perform similarly to standard ZIRLO® for all normal operating and accident scenarios, including both loss of coolant accident (LOCA) and non-LOCA scenarios. For LOCA scenarios, where the slight difference in Optimized ZIRLO™ material properties relative to standard ZIRLO® could have some impact on the overall accident scenario, plant-specific LOCA analyses using Optimized ZIRLO™ properties demonstrates that the acceptance criteria of 10 CFR 50.46 has been satisfied, therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lara S. Nichols, Associate General Counsel, Duke Energy Corporation, 526 South Church Street—EC07H, Charlotte, NC 28202.

NRC Branch Chief: Robert J. Pascarelli.

Florida Power & Light Company, et al., Docket Nos. 50–335 and 50–389, St. Lucie Plant, Units Nos. 1 and 2, St. Lucie County, Florida

Date of amendment request: July 15, 2015. A publicly-available version is in ADAMS under Accession No. ML15198A028.

Description of amendment request: The amendments would revise Technical Specifications required actions for inoperability of auxiliary feedwater pumps.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

The proposed change will not result in any significant increase in the probability or consequences of an accident previously evaluated. The auxiliary feedwater system mitigates the consequences of any event with a loss of normal feedwater. By prohibiting a plant maneuver when there are no operable auxiliary feedwater pumps, the plant will not be placed into a less safe condition where the probability could be increased, consequences could be exacerbated, or different consequences could result for an accident previously evaluated.

The proposed enhancements and administrative changes are modifications to existing actions that have no potential to impact the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

The proposed change does not involve physical modification of the plant. No new or different type of equipment will be installed. The proposed change will require prompt action to restore at least one auxiliary feedwater pump to operable status when all three are inoperable. Restricting a power maneuver until at least one auxiliary feedwater pump has been restored to operable status will preclude entry into a less safe condition with no auxiliary feedwater available for accident mitigation. This change will not have an adverse effect on equipment required for accident mitigation.

The proposed enhancements and administrative changes are modifications to existing actions that have no potential to impact equipment required for accident mitigation.

3. Does the proposed change involve a significant reduction in a margin of safety?

The proposed change does not involve a significant reduction in a margin of safety. No plant equipment or accident analyses will be affected. Additionally, the proposed change will not relax any criteria used to establish safety limits, safety system settings, or the bases for any limiting conditions for operation. Safety analysis acceptance criteria are not affected. Plant operation will continue within the design basis.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: William S. Blair, Managing Attorney—Nuclear, Florida Power & Light, 700 Universe Blvd., MS LAW/JB, Juno Beach, FL 33408–0420.

NRC Branch Chief: Shana R. Helton.

Florida Power & Light Company, et al., Docket Nos. 50–335 and 50–389, St. Lucie Plant, Unit Nos. 1 and 2, St. Lucie County, Florida

Date of amendment request: August 31, 2015. A publicly-available version is in ADAMS under Accession No. ML15254A180.

Description of amendment request: The amendments would modify Technical Specifications to risk-inform requirements regarding selected Required Action End States. Minor variations or deviations are included in the request, but the proposed amendments are otherwise consistent with NRC-approved Technical Specification Task Force (TSTF) Traveler TSTF–422, Revision 2, ''Change in Technical Specifications End States (CE NPSD–1186),'' dated December 22, 2009 (ADAMS Accession No. ML093570241) (76 FR 19510, April 7, 2011).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change allows a change to certain required end states when the Technical Specification (TS) Completion Times (CTs) for remaining in power operation are exceeded. Most of the requested TS changes are to permit an end state of hot shutdown (Mode 4) rather than an end state of cold shutdown (Mode 5) contained in the current TS. The request was limited to: (1) Those end states where entry into the shutdown mode is for a short interval, (2) entry is initiated by inoperability of a single train of equipment or a restriction on a plant operational parameter, unless otherwise stated in the applicable TS, and (3) the primary purpose is to correct the initiating condition and return to power operation a [as] soon as is practical. Risk insights from both the qualitative and quantitative risk assessments were used in specific TS assessments. Such assessments are documented in Section 5.5 of CE NIPSD–1186, Rev 0, ''Technical Justification for the Risk-Informed Modification to Selected Required Action End States for CEOG [Combustion Engineering Owners Group] Member PWRs [Pressurized Water Reactors].'' They provide an integrated discussion of deterministic and probabilistic issues, focusing on specific TSs, which are used to support the proposed TS end state and associated restrictions. Therefore, the probability of an accident previously evaluated is not significantly increased, if at all. The consequences of an accident after adopting proposed TSTF–422 are no different

than the consequences of an accident prior to adopting TSTF–422. Therefore, the consequences of an accident previously evaluated are not significantly affected by this change. The addition of a requirement to assess and manage the risk introduced by this change will further minimize possible concerns.

Therefore, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not involve a physical alteration of the plant (no new or different type of equipment will be installed). Allowing a change to certain required end states when the TS CTs for remaining in power operation are exceeded, *i.e.,* entry into hot shutdown rather than cold shutdown to repair equipment, if risk is assessed and managed, will not introduce new failure modes or effects and will not, in the absence of other unrelated failures, lead to an accident whose consequences exceed the consequences of accidents previously evaluated. The addition of a requirement to assess and manage the risk introduced by this change and the commitment by the licensee to adhere to the guidance in WCAP–16364–NP, Revision 2, ''Implementation Guidance for Risk Informed Modification to Selected Required Action End States at combustion Engineering NSSS [Nuclear Steam Supply System] Plants (TSTF–422),'' will further minimize possible concerns.

Therefore, this change does not create the possibility of a new or different kind of accident from an accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change allows, for some systems, entry into hot shutdown rather than cold shutdown to repair equipment, if risk is assessed and managed. The CEOG's [Combustion Engineering Owners Group] risk assessment approach is comprehensive and follows NRC staff guidance as documented in Regulatory Guides (RGs) 1.174 and 1.177. In addition, the analyses show that the criteria of the three-tiered approach for allowing TS changes are met. The risk impact of the proposed TS changes was assessed following the three-tiered approach recommended in RG 1.177. A risk assessment was performed to justify the proposed TS changes. The net change to the margin of safety is insignificant.

Therefore, this change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: William S. Blair, Managing Attorney—Nuclear, Florida Power & Light Company, 700 Universe Boulevard, MS LAW/JB, Juno Beach, FL 33408–0420.

NRC Branch Chief: Benjamin G. Beasley.

Omaha Public Power District, Docket No. 50–285, Fort Calhoun Station (FCS), Unit No. 1, Washington County, Nebraska

Date of amendment request: September 10, 2015. A publicly-available version is in ADAMS under Accession No. ML15258A680.

Description of amendment request: The amendment would revise the Updated Safety Analysis Report (USAR) to allow the use of the equipment classification methodology in industry standard American National Standards Institute/American Nuclear Society (ANSI/ANS)–58.14–2011, ''Safety and Pressure Integrity Classification Criteria for Light Water Reactors.''

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change to the Updated Safety Analysis Report (USAR) allows the use of the methodology from ANSI/ANS–58.14–2011, *Safety and Pressure Integrity Classification Criteria for Light Water Reactors,* for the classification of structures, systems and components (SSCs) in accordance with the Current Licensing Basis (CLB). These changes are applicable only to the classification of equipment and have no impact on the accidents and transients as defined in the Current Licensing Basis. The methodology of the standard requires that the plant design basis be reviewed and applied to the classification process which assures that there is no significant change in the probability or consequences of accidents.

The USAR accident analyses assume the proper functioning of systems in demonstrating the adequacy of the plant's design. The methodology of ANSI/ANS–58.14–2011 is intended to assure equipment is classified correctly and in accordance with the CLB. This change, therefore, does not change the intended function of any plant equipment nor does this change affect or increase the probability of equipment malfunction which could increase the probability or consequences of an accident previously evaluated in the USAR.

The proposed change does not degrade the performance of a system assumed to function in the accident analyses. Also, this change does not increase the challenges to safety systems assumed to function in the accident analysis such that safety system performance is degraded below the design basis without compensating effects.

FCS is licensed to the requirements of 10 CFR 50.67 and 10 CFR 20. These licensed limits are maintained by radiological barrier performance which is unaffected by this change. Hence, there will be no change in radiological barrier performance that would increase the dose to on-site personnel (10 CFR 20) or the public at the site boundary (10 CFR 100.11/10 CFR 50.67).

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated in the USAR.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed amendment allows the use of the NRC approved methodology of ANSI/ANS–58.14–2011 to facilitate proper equipment classification. This standard will be used to confirm that equipment has been properly classified in accordance with the FCS Current Licensing Basis. This approach will not introduce any methods or analytical techniques that could create the possibility of a new or different kind of accident. Application of a classification methodology does not create an accident.

No new unanalyzed interactions between systems or components will be created by the application of ANSI/ANS–58.14–2011. The proposed change does not create a new failure mechanism or new accident initiator. The proposed amendment does not involve a change in methods governing the operation of the plant systems or components.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated in the USAR.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

This proposed amendment revises the CLB to allow the use of ANSI/ANS–58.14–2011 for equipment classification. The proposed change will not modify, change, revise or otherwise affect any current calculations concerning the plant accident analysis or supporting basis for which the Technical Specifications, Technical Specification Bases or USAR safety margins were established. The proposed amendment is consistent with regulatory guidance.

Therefore, the proposed amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David A. Repka, Esq., Winston & Strawn, 1700 K Street NW., Washington, DC 20006–3817.

NRC Branch Chief: Michael T. Markley.

Omaha Public Power District, Docket No. 50–285, Fort Calhoun Station, Unit No. 1, Washington County, Nebraska

Date of amendment request: September 11, 2015. A publicly-available version is in ADAMS under Accession No. ML15254A464.

Description of amendment request: The amendment would revise Technical Specification (TS) 2.7, ''Electrical Systems,'' to replace the numerical volume requirements for stored diesel fuel and lubricating oil inventory with requirements that state that volumes equivalent to 7 days and 6 days of fuel oil are available. The licensee proposes to remove the numerical fuel oil volume requirements from TS 2.7(1)m and TS 2.7(3)a and substitute an equivalent requirement for 7 days and 6 days of fuel; revise the value of the required fuel inventory in storage tank FO–10; remove the numerical lubricating oil volume requirements from TS 2.7(1)n and TS 2.7(3)b and replace them with equivalent 7-day and 6-day requirements; and add a minimum inventory for fuel and lubricating oil to TS 3.2, Table 3–5, Surveillance Requirements 9a and 9b, respectively. The licensee proposes to move the numerical volumes equivalent to 7-day and 6-day supplies to the TS Bases. The proposal removes the current numerical volume requirements for stored fuel from the TS and places the corrected value in the TS Bases and moves the associated current 7-day basis from the TS Bases to the TS. The proposed changes are generally consistent with Technical Specification Task Force (TSTF) Traveler TSTF–501, Revision 1, ''Relocate Stored Fuel Oil and Lube Oil Volume Values to Licensee Control,'' but include plant-specific variances.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change places the numerical volume of diesel fuel oil and lube oil required to support seven-day operation of the onsite DGs [diesel generators], and the numerical volume equivalent to a six-day supply, in the TS Bases under licensee control. The required volumes of fuel oil equivalent to a seven-day and six-day supply is calculated considering the DG manufacturer's fuel oil consumption rates and worst DG loading resulting from a loss of offsite power coincident with a design basis accident. The numerical volume of lube oil equivalent to a seven-day and six-day supply is based on the DG manufacturer's consumption values for the run time of the DG. The requirement to meet Updated Safety Analysis Report (USAR) diesel loading assumptions, maintain a seven-day supply, and the actions taken when the volume of fuel oil available is less than a seven-day or a six-day supply have not changed. These requirements remain consistent with the assumptions in the accident analyses, and neither the probability nor the consequences of any accident previously evaluated will be affected by the proposed change.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The change does not involve a physical alteration of the plant (*i.e.,* no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. The change does not alter assumptions made in the safety analysis but ensures that diesel generator loads operate as assumed in the accident analysis. The proposed change is consistent with the safety analysis assumptions.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change places the numerical volume of diesel fuel oil and lubricating oil required to support 7-day operation of an onsite diesel generator, and the numerical volume equivalent to a 6-day supply, in the TS Bases under licensee control. As the basis for the existing limits on diesel fuel oil, and lubricating oil are unchanged, no change is made to the accident analysis assumptions and no margin of safety is reduced as a result of this change.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David A. Repka, Esq., Winston & Strawn, 1700 K Street NW., Washington, DC 20006–3817.

NRC Branch Chief: Michael T. Markley.

Omaha Public Power District, Docket No. 50–285, Fort Calhoun Station, Unit No. 1, Washington County, Nebraska

Date of amendment request: September 11, 2015. A publicly-available version is in ADAMS under Accession No. ML15254A445.

Description of amendment request: The amendment would revise Technical Specification requirements to adopt the changes described in Technical Specification Task Force (TSTF) Traveler–TSTF–426, Revision 5, ''Revise or Add Actions to Preclude Entry into LCO [Limiting Condition for Operation] 3.0.3—RITSTF [Risk-Informed TSTF] Initiatives 6b & 6c.''

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change provides a short Completion Time to restore an inoperable system for conditions under which the existing Technical Specifications require a plant shutdown to begin within one hour in accordance with Limiting Condition for Operation (LCO) 2.0.1. Entering into Technical Specification Actions is not an initiator of any accident previously evaluated. As a result, the probability of an accident previously evaluated is not significantly increased. The consequences of any accident previously evaluated that may occur during the proposed Completion Times are no different from the consequences of the same accident during the existing one hour allowance. As a result, the consequences of any accident previously evaluated are not significantly increased.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

No new or different accidents result from utilizing the proposed change. The changes do not involve a physical alteration of the plant (*i.e.,* no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. In addition, the changes do not impose any new or different requirements. The changes do not alter assumptions made in the safety analysis.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change increase[s] the time the plant may operate without the ability to perform an assumed safety function. The analyses in [Westinghouse Electric Company LLC technical report] WCAP–16125–NP–A, ''Justification for Risk-Informed Modifications to Selected Technical Specifications for Conditions Leading to Exigent [P]lant Shutdown,'' Revision 2, August 2010 [(ADAMS Accession No. ML110070500)], demonstrated that there is an acceptably small increase in risk due to a limited period of continued operation in these conditions and that this risk is balanced by avoiding the risks associated with a plant shutdown. As a result, the change to the margin of safety provided by requiring a plant shutdown within one hour is not significant.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David A. Repka, Esq., Winston & Strawn, 1700 K Street NW., Washington, DC 20006–3817.

NRC Branch Chief: Michael T. Markley.

Southern Nuclear Operating Company, Inc., Docket Nos. 50–321 and 50–366, Hatch Nuclear Plant, Units 1 and 2, Appling County, Georgia

Date of amendment request: October 15, 2015. A publicly-available version is in ADAMS under Accession No. ML15288A528.

Description of amendment request: The proposed amendment would revise Technical Specification (TS) Surveillance Requirements (SR) to increase the allowable time for the Standby Gas Treatment System to draw down the secondary containment to negative pressure from 2 minutes to 10 minutes.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), Southern Nuclear Operating Company has provided its analysis of the issue of no significant hazards consideration as stated below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of any accident previously evaluated?

Response: No.

This amendment proposes to increase the post-accident drawdown time for the secondary containment from its current value of 120 seconds, to 10 minutes. No physical modifications are proposed for any system, structure, or component (SSC) designed for the prevention of previously analyzed events. Neither does this amendment request change the operation or maintenance of any of those SSCs; accordingly the amendment does not involve a significant increase in the probability of occurrence of a previously evaluated event.

The increase in the drawdown time does not result in a significant increase in the consequences of a previously analyzed accident because the offsite doses, the main control room dose, and the technical support center dose do not significantly increase. As described in the Technical Evaluation section of this amendment request, the off-site doses for the Low Population Zone (LPZ) and the Exclusion Area Boundary (EAB) increase from 0.75 and 0.34 Rem [Total Effective Dose Equivalent (TEDE)] to 1.10 and 0.61 Rem TEDE, respectively. However, this is still well within the 10 CFR 50.67 limits of 25 Rem for the LPZ and EAB. Regarding the [main control room (MCR)], the increase in drawdown time has very little effect on dose to the MCR operators. Since the HNP MCR is located within the turbine building, MCR doses are due primarily to [main steam isolation valve (MSIV)] leakage which goes to the main condenser and subsequently leaks into the turbine building. Finally, the dose to the [Technical Support Center (TSC)] decreased from 3.9 Rem TEDE to 3.1 Rem TEDE. This is due to the reduction in the assumed unfiltered in-leakage to the TSC. Currently, 10,000 cfm is assumed for the TSC leakage. The new calculation assumed a more realistic value of 1000 cfm.

Therefore, the change in the drawdown time does not represent a significant increase in the consequences of a previously analyzed event.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any previously evaluated?

Response: No.

This Technical Specifications revision request increases the allowed time given the [Standby Gas Treatment System (SGTS)] to drawdown the secondary containment to 0.20 inches of water vacuum from 120 seconds to 10 minutes. No physical modifications are being made to the secondary containment system or to the SGTS as a result of this Tech Spec amendment request. Additionally, other than the increase in the allowed drawdown time to 10 minutes, no changes are being made to the function or operation of the secondary containment. Therefore, its design function of containing fission products released after design basis accidents, such as [loss of coolant accident] LOCA, remains unchanged. Likewise, no changes are being proposed to the function or operation of the SGTS. It remains capable of adequately accomplishing its design function of processing the post accident atmosphere in the secondary containment.

Since no new modes of operation are created, no new accident initiators are created by this amendment request.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

Margins are applied at several levels with respect to the secondary containment safety function and to other functions intended to reduce off-site and on-site dose consequences. One is the control room unfiltered in-leakage rate, which is reduced from 115 cfm to 39 cfm for this analysis. However, results for the last MCR in-leakage test were actually far below 39 cfm. In fact, the in-leakage rate tests for the pressurization mode of the Main Control Room Environmental Control system, performed in April of 2015, indicated rates between 8 and 12 scfm, roughly one third of the assumed in-leakage value. Therefore, although the margin was reduced, a significant amount of margin remains. In-leakage to the Technical Support Center was assumed at 1000 cfm for this calculation. Currently, 10,000 cfm is the assumed in-leakage. Therefore margin is reduced with respect to this parameter. However, 10,000 cfm is an extremely high, unrealistic value. The 1000 cfm in-leakage assumed for this calculation is a reasonable and justifiable value, in fact equal to twice the filtered intake rate. The MSIV leakage rate is assumed at the TS value of 100 scfh, unchanged from the current analysis. As mentioned in the Technical Evaluation section of this submittal, the Volume Correction Factor (VCF) which is a parameter representing control room dose immersion, is assumed at 0.47 as opposed to the current evaluation which assumes a VCF of 0.50. The actual number is, in fact, 0.47, but was previously rounded up conservatively. Therefore, this margin is being eliminated in the current calculation. However, this does not represent a significant reduction in the margin of safety because margin exists in other areas, namely the Control Room in-leakage, TSC in-leakage, and Main Steam Isolation Valve leakage, as discussed above. As described in the Technical Evaluation portion of this submittal, the margins to the 10 CFR 50.67 main control room and offsite dose limits are not significantly reduced. The total MCR doses are virtually unchanged. The off-site doses do increase, but the resultant doses are still a small fraction (< 5%) of the regulatory limit of 25 Rem to the Low Population Zone and 25 Rem to the Exclusion Area Boundary. The doses to the TSC actually decrease from those of the current analysis; the decrease is due to the reduced in-leakage assumption, as previously mentioned.

For all the reasons provided above, this amendment does not represent a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jennifer M. Buettner, Associate General Counsel, Southern Nuclear Operating Company, 40 Inverness Center Parkway, Birmingham, AL 35201.

NRC Branch Chief: Robert J. Pascarelli.

South Carolina Electric and Gas Company, Docket Nos. 52–027 and 52–028, Virgil C. Summer Nuclear Station (VCSNS), Units 2 and 3, Fairfield County, South Carolina

Date of amendment request: October 1, 2015. A publicly-available version is in ADAMS under Accession No. ML15274A540.

Description of amendment request: The amendment request proposes to revise the VCSNS Units 2 and 3 plant-specific emergency planning inspections, tests, analyses, and acceptance criteria (ITAAC) in Appendix C of the VCSNS Units 2 and 3 COLs. Changes to the plant-specific emergency planning ITAAC are proposed to remove the copies of Design Control Document (DCD) Table 7.5–1, ''Post-Accident Monitoring System,'' and Final Safety Analysis Report (FSAR) Table 7.5–201, ''Post-Accident Monitoring System,'' and to replace the references to DCD Table 7.5–1 and FSAR Table 7.5–201 with Updated Final Safety Analysis Report (UFSAR) Table 7.5–1 in Table C.3.8–1 for ITAAC Numbers C.3.8.01.01.01, C.3.8.01.05.01.05, and C.3.8.01.05.02.04.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The [Virgil C. Summer Nuclear Station] VCSNS Units 2 and 3 emergency planning inspections, tests, analyses, and acceptance criteria (ITAAC) provide assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's rules and regulations. The proposed changes to remove the copies of [Design Control Document] DCD Table 7.5–1 and [Final Safety Analysis Report] FSAR Table 7.5–201 from Appendix C of the VCSNS Units 2 and 3 [combined license] COLs do not affect the design of a system, structure, or component (SSC) used to meet the design bases of the nuclear plant. Nor do the changes affect the construction or operation of the nuclear plant itself, so there is no change to the probability or consequences of an accident previously evaluated. Removing the copies of the tables from Appendix C of the COLs does not affect prevention and mitigation of abnormal events (*e.g.,* accidents, anticipated operational occurrences, earthquakes, floods and turbine missiles) or their safety or design analyses. No safety-related SSC or function is adversely affected. The changes do not involve nor interface with any SSC accident initiator or initiating sequence of events, and thus, the probabilities of the accidents evaluated in the [Updated Final Safety Analysis Report] UFSAR are not affected. Because the changes do not involve any safety-related SSC or function used to mitigate an accident, the consequences of the accidents evaluated in the UFSAR are not affected.

Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The VCSNS Units 2 and 3 emergency planning ITAAC provide assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's rules and regulations. The changes do not affect the design of an SSC used to meet the design bases of the nuclear plant, nor do the changes affect the construction or operation of the nuclear plant. Consequently, there is no new or different kind of accident from any accident previously evaluated. The changes do not affect safety-related equipment, nor do they affect equipment which, if it failed, could initiate an accident or a failure of a fission product barrier. In addition, the changes do not result in a new failure mode, malfunction or sequence of events that could affect safety or safety-related equipment.

No analysis is adversely affected. No system or design function or equipment qualification is adversely affected by the changes. This activity will not allow for a new fission product release path, result in a new fission product barrier failure mode, nor create a new sequence of events that would result in significant fuel cladding failures.

Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The VCSNS Units 2 and 3 emergency planning ITAAC provide assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's rules and regulations. The changes do not affect the assessments or the plant itself. The changes do not adversely interface with safety-related equipment or fission product barriers. No safety analysis, design basis limit or acceptance criterion are challenged or exceeded by the proposed change.

Therefore, the proposed amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Ms. Kathryn M. Sutton, Morgan, Lewis & Bockius LLC, 1111 Pennsylvania Avenue NW., Washington, DC 20004–2514.

NRC Branch Chief: Lawrence J. Burkhart.

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50–395, Virgil C. Summer Nuclear Station, Unit 1, Fairfield County, South Carolina

Date of amendment request: September 29, 2015. A publicly-available version is in ADAMS Accession No. ML15275A089.

Description of amendment request: The licensee proposes to revise the Technical Specifications to adopt Technical Specifications Task Force (TSTF)–523. ''Generic Letter 2008–01, Managing Gas Accumulation.''

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change revises or adds Surveillance Requirement(s) (SRs) that require verification that the Emergency Core Cooling System (ECCS), the Reactor Cooling System (RCS), Residual Heat Removal (RHR) and Reactor Building (RB) Spray System are not rendered inoperable due to accumulated gas and to provide allowances which permit performance of the revised verification. Gas accumulation in the subject systems is not an initiator of any accident previously evaluated. As a result, the probability of any accident previously evaluated is not significantly increased. The proposed SRs ensure that the subject systems continue to be capable to perform their assumed safety function and are not rendered inoperable due to gas accumulation. Thus, the consequences of any accident previously evaluated are not significantly increased.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change revises or adds SRs that require verification that the ECCS, RCS, RHR and RB Spray System are not rendered inoperable due to accumulated gas and to provide allowances which permit performance of the revised verification. The proposed change does not involve a physical alteration of the plant (*i.e.,* no new or different type of equipment will be installed) or a change in the methods governing normal

plant operation. In addition, the proposed change does not impose any new or different requirements that could initiate an accident. The proposed change does not alter assumptions made in the safety analysis and is consistent with the safety analysis assumptions.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change revises or adds SRs that require verification that the ECCS, RCS, RHR and RB Spray System are not rendered inoperable due to accumulated gas and to provide allowances which permit performance of the revised verification. The proposed change adds new requirements to manage gas accumulation in order to ensure the subject systems are capable of performing their assumed safety functions. The proposed SRs are more comprehensive than the current SRs and will ensure that the assumptions of the safety analysis are protected. The proposed change does not adversely affect any current plant safety margins or the reliability of the equipment assumed in the safety analysis. Therefore, there are no changes being made to any safety analysis assumptions, safety limits or limiting safety system settings that would adversely affect plant safety as a result of the proposed change.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: J. Hagood Hamilton, Jr., South Carolina Electric & Gas Company, Post Office Box 764, Columbia, SC 29218.

NRC Branch Chief: Michael T. Markley.

South Carolina Electric and Gas Company, Docket Nos. 52–027 and 52–028, Virgil C. Summer Nuclear Station (VCSNS), Units 2 and 3, Fairfield County, South Carolina

Date of amendment request: October 22, 2015. A publicly-available version is in ADAMS under Accession No. ML15295A091.

Description of amendment request: The amendment request proposes to revise Section 5.0, ''Administrative Controls,'' of the VCSNS Units 2 and 3 COL, Appendix A, Technical Specifications, to change the title of ''Shift Supervisor,'' to ''Shift Manager.''

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes to the Technical Specifications regarding the Shift Supervisor to Shift Manager title are administrative changes. It has no impact on accident initiators or plant equipment and thus does not affect the probability or consequences of an accident.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not involve a change to the design of the physical plant or operations. This is an administrative title change that does not contribute to accident initiation. Therefore, it does not produce a new accident scenario or produce a new type of equipment malfunction.

2. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

Since the change is administrative and changes no previously evaluated accidents or creates no possibility for any new unevaluated accidents to occur, there is no reduction in the margin of safety. This change also does not affect plant equipment or operation and therefore does not affect safety limits or limiting safety systems settings.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Ms. Kathryn M. Sutton, Morgan, Lewis & Bockius LLC, 1111 Pennsylvania Avenue NW., Washington, DC 20004–2514.

NRC Branch Chief: Lawrence J. Burkhart.

Wolf Creek Nuclear Operating Corporation, Docket No. 50–482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: September 23, 2015. A publicly-available version is in ADAMS under Accession No. ML15273A156.

Description of amendment request: The amendment would revise the diesel generator (DG) full load rejection test and endurance and margin test specified by Technical Specification 3.8.1, ''AC [Alternating Current] Sources—Operating,'' Surveillance Requirements (SR) 3.8.1.10 and 3.8.1.14, respectively. The proposed change would add a new Note to SR 3.8.1.10 and SR 3.8.1.14, consistent with Technical Specification Task Force (TSTF) Traveler TSTF–276–A, Revision 2, ''Revise DG full load rejection test.'' The Note allows the full load rejection test and endurance and margin test be performed at the specified power factor (PF) with clarifications addressing situations when the power factor cannot be achieved.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

Performing [an] SR that tests the DG is not a precursor of any accident previously evaluated. These changes only affect surveillance testing of mitigative equipment and, therefore, do not have an impact on the probability of an accident previously evaluated.

Relaxing the requirement to maintain PF when paralleled to offsite power does not affect performance of the DG under accident conditions. The performance of the surveillances ensures that mitigative equipment is capable of performing its intended function.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

No new accident scenarios, failure mechanisms, or limiting single failures are introduced as a result of the proposed changes. The systems, structures, and components previously required for the mitigation of a transient remain capable of fulfilling their intended design functions. The proposed changes have no adverse effects on a safety-related system or component and do not challenge the performance or integrity of safety related systems. As such, it does not introduce a mechanism for initiating a new or different accident than those described in the Updated Safety Analysis Report.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed changes do not involve a significant reduction in a margin of safety. The margin of safety is related to the ability of the fission product barriers to perform their design safety functions during and

following an accident situation. These barriers include the fuel cladding, the reactor coolant system, and containment. The proposed changes to the testing requirements for the plant DGs do not affect the OPERABILITY requirements for the DGs, as verification of such OPERABILITY will continue to be performed as required. Continued verification of OPERABILITY supports the capability of the DGs to perform their required function of providing emergency power to plant equipment that supports or constitutes the fission product barriers. Only one DG is tested at a time and the remaining DG will be available to safely shut down the plant or respond to a design basis accident, if required. Consequently, the performance of these fission product barriers will not be impacted by implementation of the proposed amendment.

In addition, the proposed changes involve no changes to safety setpoints or limits established or assumed by the accident analysis. On this and the above basis, no safety margins will be impacted.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jay Silberg, Esq., Pillsbury Winthrop Shaw Pittman LLP, 2300 N Street NW., Washington, DC 20037.

NRC Branch Chief: Michael T. Markley.

III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commissions related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items can be accessed as described in the ''Obtaining Information and Submitting Comments'' section of this document.

Dominion Nuclear Connecticut, Inc., Docket No. 50–336, Millstone Power Station, Unit No. 2, New London County, Connecticut

Date of amendment request: October 22, 2014, as supplemented by letters dated June 5, July 20, and August 27, 2015.

Brief description of amendment: The amendment revised the Technical Specifications (TSs) by relocating specific surveillance frequencies to a licensee controlled program with the adoption of Technical Specification Task Force (TSTF)–425, Revision 3, ''Relocate Surveillance Frequencies to Licensee Control-[Risk-Informed Technical Specification Task Force (RITSTF)] Initiative 5b.'' Additionally, the amendment added a new program, the Surveillance Frequency Control Program, to TS Section 6, Administrative Controls.

Date of issuance: October 29, 2015.

Effective date: As of the date of issuance and shall be implemented within 90 days from the date of issuance.

Amendment No.: 324. A publicly-available version is in ADAMS under Accession No. ML15280A242; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–65: Amendment revised the Renewed Operating License and TSs.

Date of initial notice in ***Federal Register****:* April 28, 2015 (80 FR 23601). The supplemental letters dated June 5, July 20, and August 27, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 29, 2015.

No significant hazards consideration comments received: No.

Duke Energy Florida, Inc. (DEF), et al., Docket No. 50–302, Crystal River Unit 3 Nuclear Generating Plant (CR–3), Citrus County, Florida

Date of amendment request: November 7, 2014, as supplemented by letters dated April 30, 2015, and October 5, 2015.

Brief description of amendment: By Order dated May 29, 2015, as published in the **Federal Register** on June 8, 2015 (80 FR 32416), the NRC approved a direct license transfer for Facility Operating License No. DPR–72 for the CR–3. This amendment reflects the direct transfer of the ownership held by eight minority co-owners in CR–3 to DEF. The transfer of ownership will take place pursuant to the Settlement, Release and Acquisition Agreement, dated September 26, 2014, wherein DEF will purchase the 6.52 percent combined ownership share in CR–3 held by these minority co-owners, leaving DEF and Seminole Electric Cooperative, Inc. as the remaining licensees for CR–3.

Date of issuance: October 30, 2015

Effective date: As of the date of its issuance and shall be implemented within 60 days of issuance.

Amendment No.: 248. A publicly-available version of the amendment and the Order are in ADAMS under Accession Nos. ML15191A179 and ML15121A570, respectively; documents related to this amendment are listed in the Safety Evaluation enclosed with the Order dated May 29, 2015. Subsequent to the issuance of the order, the licensee submitted a letter dated October 5, 2015 (ADAMS Accession No. ML15280A474). This letter provided insurance documentation and the closing transaction date, as was required by the Order.

Facility Operating License No. DPR–72: Amendment revised the Facility Operating License.

Date of initial notice in ***Federal Register****:* April 28, 2015 (80 FR 23612). The supplements dated April 30, 2015, and October 5, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 29, 2015.

No significant hazards consideration comments received: No.

Exelon Generation Company, LLC, Docket Nos. STN 50–456 and STN 50–457, Braidwood Station, Units 1 and 2, Will County, Illinois Docket Nos. STN 50–454 and STN 50–455, Byron Station, Unit Nos. 1 and 2, Ogle County, Illinois

Date of amendment request: October 16, 2014, as supplemented by letter dated May 27, 2015.

Brief description of amendments: The amendments permit utilization of WCAP–16143–P, Revision 1, ''Reactor Vessel Closure Head/Vessel Flange Requirements Evaluation for Byron/Braidwood Units 1 and 2,'' dated October 2014, as an analytical method to determine the reactor coolant system pressure and temperature limits.

Date of issuance: October 28, 2015.

Effective date: As of the date of issuance and shall be implemented within 60 days from the date of issuance.

Amendment Nos.: 186, 186, 192, and 192. A publicly-available version is in ADAMS under Accession No. ML15232A441; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. NPF–72. NPF–77, NPF–37, and NPF–66: The amendments revised the Facility Operating License and Technical Specifications.

Date of initial notice in ***Federal Register****:* March 3, 2015 (80 FR 11494). The supplemental letter dated May 27, 2015, contained clarifying information and did not change the scope of the proposed action or affect the NRC staff's initial no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 28, 2015.

No significant hazards consideration comments received: No.

NextEra Energy Seabrook, LLC, Docket No. 50–443, Seabrook Station, Unit No. 1, Rockingham County, New Hampshire

Date of amendment request: July 24, 2014, as supplemented by letters dated March 9, April 23, June 24, July 9, July 20, and September 8, 2015.

Brief description of amendment: The amendment incorporated revised reactor coolant system (RCS) pressure-temperature limits in the technical specifications (TS) applicable to 55 effective full power years. The change will also provide new overpressure protection setpoints and lower the RCS temperature at which the TS is applicable.

Date of issuance: November 2, 2015.

Effective date: As of the date of issuance and shall be implemented by March 2, 2017.

Amendment No.: 151. A publicly-available version is in ADAMS under Accession No. ML15096A255; documents related to this amendment are listed in the safety evaluation enclosed with the amendment.

Facility Operating License No. NPF–86: Amendment revised the Facility Operating License and TSs.

Date of initial notice in ***Federal Register****:* September 30, 2014 (79 FR 58822). The supplemental letters dated March 9, April 23, June 24, July 9, July 20, and September 8, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a safety evaluation dated November 2, 2015.

No significant hazards consideration comments received: No.

South Carolina Electric and Gas Company, Docket Nos. 52–027 and 52–028, Virgil C. Summer Nuclear Station, Units 2 and 3 (VCSNS), Fairfield County, South Carolina

Date of amendment request: October 23, 2014.

Brief description of amendment: The amendment is to Combined License Nos. NPF–93 and NPF–94 for VCSNS, Units 2 and 3. The amendment consists of changes to Tier 2 information in the Updated Final Safety Analysis Report (UFSAR) for VCSNS, Units 2 and 3 due to administrative changes in the description and scope of the Initial Test Program in the UFSAR to the Facility Combined Licenses. Because the amendment changes Tier 2 information to conform to the associated amendment requested Tier 1 changes that constitute a departure from the AP1000 certified design, South Carolina Electric and Gas Company requested a permanent exemption pursuant to 10 CFR, Part 52, Appendix D, Section III.B, ''Design Certification Rule for the AP1000 Design, Scope and Contents.'' The exemption allows a departure from certain Tier 1 information in the generic AP1000 Design Control Document (DCD). Specifically, the exemption changes the plant-specific AP1000 DCD Tier 1 information, as specified in LAR 14–08, which are the administrative description and scope of the plant-specific UFSAR, Tier 1, Section 3.4, ''Initial Test Program.''

Date of issuance: September 9, 2015.

Effective date: As of the date of issuance and shall be implemented within 30 days of issuance.

Amendment No.: 32. A publicly-available version is in ADAMS under Accession No. ML15195A518 documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Facility Combined Licenses No. NPF–93 and NPF–94: Amendment revised the Facility Combined Licenses.

Date of initial notice in ***Federal Register****:* December 9, 2014 (79 FR 73112).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 9, 2015.

No significant hazards consideration comments received: No.

Susquehanna Nuclear, LLC, Docket Nos. 50–387 and 50–388, Susquehanna Steam Electric Station (SSES), Units 1 and 2, Luzerne County, Pennsylvania

Date of amendment request: December 2, 2014, as supplemented by letters dated February 12, 2015; May 4, 2015; and August 28, 2015.

Brief description of amendments: The amendments revised the SSES, Units 1 and 2, Cyber Security Plan (CSP) Milestone 8 full implementation date as set forth in the SSES CSP Implementation Schedule. The amendments also modified the existing Renewed Facility Operating License Condition 2.D related to implementing and maintaining in effect all provisions of a Commission-approved CSP.

This license amendment request was submitted by PPL Susquehanna, LLC; however, on June 1, 2015, the NRC staff issued an amendment changing the name on the SSES license from PPL Susquehanna, LLC to Susquehanna Nuclear, LLC (ADAMS Accession No. ML15054A066). These amendments were issued subsequent to an order issued on April 10, 2015, to SSES, approving an indirect license transfer of the SSES license to Talen Energy Corporation (ADAMS Accession No. ML15058A073).

Date of issuance: November 2, 2015.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment Nos.: 264 (Unit 1) and 245 (Unit 2). A publicly-available version is in ADAMS under Accession

No. ML15267A381; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. NPF–14 and NPF–22: Amendments revised the Renewed Facility Operating Licenses.

Date of initial notice in ***Federal Register****:* July 7, 2015 (80 FR 38776). The supplemental letter dated August 28, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 2, 2015.

No significant hazards consideration comments received: No.

Tennessee Valley Authority, Docket Nos. 50–259, 50–260, and 50–296, Browns Ferry Nuclear Plant, Units 1, 2, and 3, Limestone County, Alabama

Date of amendment request: March 27, 2013, as supplemented by letters dated May 16, November 22, and December 20, 2013; January 10, January 14, February 13, March 14, May 30, June 13, July 10, August 14, August 26, August 29, September 16, October 6, and December 17, 2014; March 26, April 9, June 19, August 18, September 8, and October 20, 2015.

Brief description of amendment: The amendments modified the Renewed Facility Operating Licenses (RFOLs) and Technical Specifications (TSs) to each unit to incorporate a new fire protection licensing basis in accordance with 10 CFR Section 50.48(c). The amendments authorize the transition of each unit's fire protection program to a risk-informed and performance-based program based on the 2001 Edition of National Fire Protection Association Standard 805, ''Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants.'' This standard describes how to use performance-based methods, such as fire modeling and risk-informed methods, to demonstrate compliance with nuclear safety performance criteria.

Date of issuance: October 28, 2015.

Effective date: As of the date of issuance, to be implemented in accordance with the schedule incorporated in the new fire protection license condition of each unit.

Amendment Nos.: 290 (Unit 1), 315 (Unit 2), and 273 (Unit 3). A publicly-available version is in ADAMS under Accession No. ML15212A796; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

RFOL Nos. DPR–33, DPR–52, and DPR–68: Amendments revised the RFOLs and TSs.

Date of initial notice in ***Federal Register****:* August 13, 2013 (78 FR 49302). The supplemental letters dated May 16, November 22, and December 20, 2013; January 10, January 14, February 13, March 14, May 30, June 13, July 10, August 14, August 26, August 29, September 16, October 6, and December 17, 2014; March 26, April 9, June 19, August 18, September 8, and October 20, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 28, 2015.

No significant hazards consideration comments received: No.

Union Electric Company, Docket No. 50–483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of amendment request: March 12, 2015.

Brief description of amendment: The amendment revised the Technical Specification requirements to address NRC Generic Letter 2008–01, ''Managing Gas Accumulation in Emergency Core Cooling, Decay Heat Removal, and Containment Spray Systems,'' as described in Technical Specification Task Force (TSTF) Traveler TSTF–523, Revision 2, ''Generic Letter 2008–01, Managing Gas Accumulation.''

Date of issuance: October 28, 2015.

Effective date: As of the date of issuance and shall be implemented within 90 days of issuance.

Amendment No.: 213. A publicly-available version is in ADAMS under Accession No. ML15258A510; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. NPF–30: The amendment revised the Operating License and TS.

Date of initial notice in ***Federal Register****:* June 9, 2015 (80 FR 32630).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 28, 2015.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 12th day of November 2015.

For the Nuclear Regulatory Commission.

Anne T. Boland,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2015–29696 Filed 11–23–15; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. R2016–2; Order No. 2824]

Market Dominant Price Adjustment

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recently-filed Postal Service notice announcing plans to implement five temporary promotions and associated classification changes. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 7, 2015.

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:

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I. Introduction

On November 16, 2015, the Postal Service filed a notice, pursuant to 39 U.S.C. 3622 and 39 CFR part 3010, of plans to implement five temporary promotions and associated classification changes.[1] The effective dates of the promotions vary, the first two of which are scheduled to take effect on March 1, 2016. Notice at 1.

II. Overview

A. Filing Details

The Postal Service's filing consists of a Notice, which the Postal Service

[1] United States Postal Service Notice of Market-Dominant Price Adjustment, November 16, 2015 (Notice).

represents provides the data and information required under 39 CFR 3010.12; three attachments to the Notice; and two sets of workpapers filed as library references. Attachment A presents the proposed Mail Classification Schedule changes (in legislative format) related to the five promotions. Attachment B provides a 2016 promotions calendar with detailed descriptions of the five promotions. Attachment C outlines the Postal Service's price cap calculation. The Postal Service also provides library references in support of its assertion that the temporary promotions comply with the price cap.[2]

B. Planned Temporary Promotions

The Postal Service seeks approval for the following five promotions for the periods indicated:

- Emerging and Advanced Technology/Video in Print Promotion (March–August 2016);
- Tactile, Sensory, and Interactive Mailpiece Engagement Promotion (March–August 2016);
- Earned Value Reply Mail Promotion (April–June 2016);
- Mobile Shopping Promotion (July–December 2016); and
- Personalized Color Transpromo Promotion (July–December 2016).

Notice at 3–6. The Postal Service asserts that these five promotions are continuations of the calendar year (CY) 2015 technology promotions and the Earned Value Reply Mail promotion approved by the Commission in Docket No. R2015–4.[3] Three promotions apply to First-Class Mail products: Emerging and Advanced Technology/Video in Print Promotion; Earned Value Reply Mail Promotion; and Personalized Color Transpromo Promotion. Four promotions apply to Standard Mail products: Emerging and Advanced Technology/Video in Print Promotion; Tactile, Sensory, and Interactive Mailpiece Engagement Promotion; Earned Value Reply Mail Promotion; and Mobile Shopping Promotion.

The Postal Service states that its price cap calculation reflects the expiration of the CY 2015 First-Class Mail and Standard Mail promotions and the renewal of those promotions in CY 2016. Notice at 6. The Postal Service asserts that there is no change in the unused price adjustment authority because the Notice is limited to continuing the promotions offered in 2015. *Id.*

In its Notice, the Postal Service provides a calculation of its new overall price adjustment authority for First-Class Mail and Standard Mail. Combining the unused price adjustment authority with the inflation-based price adjustment authority, the Postal Service calculates that there will be 0.074 percent in unused pricing authority available for First-Class Mail and 0.104 percent available for Standard Mail. *Id.* at 9, Table 1.

The Postal Service asserts the five temporary promotions do not affect workshare discounts. *Id.* at 12. Since the program does not exclude any mailers, the Postal Service also asserts the promotions do not affect compliance with any preferred price requirement. *Id.*

III. Initial Administrative Actions

Public notice. The Commission hereby provides public notice of the Postal Service's filing pursuant to rule 3010.11(a) and establishes Docket No. R2016–2 to consider the planned promotions for market dominant postal products and related classification changes identified in the Postal Service's Notice filed November 16, 2015. The Commission invites comments from interested persons on whether the Notice is consistent with 39 U.S.C. 3622, and the requirements of 39 CFR part 3010. Comments are due no later than December 7, 2015. Pursuant to 39 U.S.C. 505, the Commission appoints Elisabeth S. Shellan to represent the interests of the general public (Public Representative) in this proceeding.

Availability of documents. The Commission has posted the Postal Service's Notice and associated library references on its Web site at *http://www.prc.gov.* The Commission will post documents the Postal Service submits in this docket on its Web site, along with related Commission documents, comments, or other submissions.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. R2016–2 to consider the planned temporary promotions for market dominant postal products and related classification changes identified in the Postal Service's Notice filed November 16, 2015.

2. Comments on the planned temporary promotions and related classification changes are due no later than December 7, 2015.

3. Pursuant to 39 U.S.C. 505, Elisabeth S. Shellan is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

4. The Commission directs the Secretary to arrange for prompt publication of this notice in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

Commissioner Goldway, abstaining.

[FR Doc. 2015–29833 Filed 11–23–15; 8:45 am]

BILLING CODE 7710–FW–P

[2] Library Reference USPS–LR–R2016–2/1, November 16, 2015. Library Reference USPS–LR–R2016–2/2, November 16, 2015.

[3] *Id.* at 2. *See also* Docket No. R2015–4, Order No. 2365, Order on Price Adjustments for First-Class Mail Products and Related Mail Classification Changes, February 24, 2015; Docket No. R2015–4, Order No. 2472, Order on Revised Price Adjustments for Standard Mail, Periodicals, and Package Services Products and Related Mail Classification Changes, May 7, 2015.

PRESIDIO TRUST

Notice of Public Meeting of Presidio Institute Advisory Council

AGENCY: The Presidio Trust.

ACTION: Notice of public meeting of Presidio Institute Advisory Council.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given that a public meeting of the Presidio Institute Advisory Council (Council) will be held from 3:00 p.m. to 4:30 p.m. on Monday, December 14, 2015. The meeting is open to the public, and oral public comment will be received at the meeting. The Council was formed to advise the Executive Director of the Presidio Trust (Trust) on matters pertaining to the rehabilitation and reuse of Fort Winfield Scott as a new national center focused on service and leadership development.

SUPPLEMENTARY INFORMATION: The Trust's Executive Director, in consultation with the Chair of the Board of Directors, has determined that the Council is in the public interest and supports the Trust in performing its duties and responsibilities under the Presidio Trust Act, 16 U.S.C. 460bb appendix.

The Council advises on the establishment of a new national center (Presidio Institute) focused on service and leadership development, with specific emphasis on: (a) Assessing the role and key opportunities of a national center dedicated to service and leadership at Fort Scott in the Presidio of San Francisco; (b) providing recommendations related to the Presidio Institute's programmatic goals, target audiences, content, implementation and evaluation; (c) providing guidance on a phased development approach that leverages a combination of funding sources including philanthropy; and (d)

making recommendations on how to structure the Presidio Institute's business model to best achieve the Presidio Institute's mission and ensure long-term financial self-sufficiency.

Meeting Agenda: This meeting of the Council will include an update on Presidio Institute programs. The period from 4:00 p.m. to 4:30 p.m. will be reserved for public comments.

Public Comment: Individuals who would like to offer comments are invited to sign-up at the meeting and speaking times will be assigned on a first-come, first-served basis. Written comments may be submitted on cards that will be provided at the meeting, via mail to Amanda Marconi, Presidio Institute, 1201 Ralston Avenue, San Francisco, CA 94129–0052, or via email to *amarconi@presidiotrust.gov.* If individuals submitting written comments request that their address or other contact information be withheld from public disclosure, it will be honored to the extent allowable by law. Such requests must be stated prominently at the beginning of the comments. The Trust will make available for public inspection all submissions from organizations or businesses and from persons identifying themselves as representatives or officials of organizations and businesses.

Time: The meeting will be held from 3:00 p.m. to 4:30 p.m. on Monday, December 14, 2015.

Location: The meeting will be held at the Presidio Institute, Building 1202 Ralston Avenue, San Francisco, CA 94129.

For Further Information: Additional information is available online at *http://www.presidio.gov/explore/Pages/fort-scott-council.aspx.*

Dated: November 13, 2015.

Andrea Andersen,

Acting General Counsel.

[FR Doc. 2015–29873 Filed 11–23–15; 8:45 am]

BILLING CODE 4310–4R–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76470; File No. SR–BATS–2015–101]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing of a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, To Adopt Rule 8.17 To Provide a Process for an Expedited Suspension Proceeding and Rule 12.15 To Prohibit Disruptive Quoting and Trading Activity

November 18, 2015.

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 November 6, 2015, BATS Exchange, Inc. (''Exchange'' or ''BATS'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. On November 17, 2015, the Exchange filed Amendment No. 1 to the proposal.[3] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to adopt a new rule to clearly prohibit disruptive quoting and trading activity on the Exchange, as further described below. Further, the Exchange proposes to amend Exchange Rules to permit the Exchange to take prompt action to suspend Members or their clients that violate such rule. This Amendment No. 1 to SR–BATS–2015–101 amends and replaces the original proposal in its entirety.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Introduction

The Exchange is filing this proposal to adopt a new rule to clearly prohibit disruptive quoting and trading activity on the Exchange and to amend Exchange Rules to permit the Exchange to take prompt action to suspend Members or their clients that violate such rule. The Exchange notes, as further described below, that it previously filed this proposal as File No. SR–BATS–2015–57 and Amendment No. 1 thereto (the ''Initial Proposal''). The Exchange received comments on the Initial Proposal and simultaneously with this filing both responded to such comments[4] and withdrew such Initial Proposal. The Exchange submits this proposal, as revised, in order to solicit additional comment. The Exchange believes that the revisions it has made to the Initial Proposal satisfactorily address comments received and that there is good cause to approve the proposal, as revised.

Background

As a national securities exchange registered pursuant to Section 6 of the Act, the Exchange is required to be organized and to have the capacity to enforce compliance by its members and persons associated with its members, with the Act, the rules and regulations thereunder, and the Exchange's Rules.[5] Further, the Exchange's Rules are required to be ''designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade . . . and, in general, to protect investors and the public interest.''[6] In fulfilling these requirements, the Exchange has developed a comprehensive regulatory program that includes automated surveillance of trading activity that is both operated directly by Exchange staff and by staff of the Financial Industry

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] As the Exchange states in Item I, Amendment No. 1 amended and replaced the original proposal in its entirety.

[4] *See* letter to Brent J. Fields, Secretary, Commission, from Anders Franzon, VP, Associate General Counsel, BATS, dated November 6, 2015 (''BATS Comment Response Letter'').

[5] 15 U.S.C. 78f(b)(1).

[6] 15 U.S.C. 78f(b)(5).

Regulatory Authority (''FINRA'') pursuant to a Regulatory Services Agreement (''RSA''). When disruptive and potentially manipulative or improper quoting and trading activity is identified, the Exchange or FINRA (acting as an agent of the Exchange) conducts an investigation into the activity, requesting additional information from the Member or Members involved. To the extent violations of the Act, the rules and regulations thereunder, or Exchange Rules have been identified and confirmed, the Exchange or FINRA as its agent will commence the enforcement process, which might result in, among other things, a censure, a requirement to take certain remedial actions, one or more restrictions on future business activities, a monetary fine, or even a temporary or permanent ban from the securities industry.

The process described above, from the identification of disruptive and potentially manipulative or improper quoting and trading activity to a final resolution of the matter, can often take several years. The Exchange believes that this time period is generally necessary and appropriate to afford the subject Member adequate due process, particularly in complex cases. However, as described below, the Exchange believes that there are certain obvious and uncomplicated cases of disruptive and manipulative behavior or cases where the potential harm to investors is so large that the Exchange should have the authority to initiate an expedited suspension proceeding in order to stop the behavior from continuing on the Exchange.

In recent years, several cases have been brought and resolved by the Exchange and other SROs that involved allegations of wide-spread market manipulation, much of which was ultimately being conducted by foreign persons and entities using relatively rudimentary technology to access the markets and over which the Exchange and other SROs had no direct jurisdiction. In each case, the conduct involved a pattern of disruptive quoting and trading activity indicative of manipulative layering [7] or spoofing.[8] The Exchange and other SROs were able to identify the disruptive quoting and trading activity in real-time or near real-time; nonetheless, in accordance with Exchange Rules and the Act, the Members responsible for such conduct or responsible for their customers' conduct were allowed to continue the disruptive quoting and trading activity on the Exchange and other exchanges during the entirety of the subsequent lengthy investigation and enforcement process. The Exchange believes that it should have the authority to initiate an expedited suspension proceeding in order to stop the behavior from continuing on the Exchange if a Member is engaging in or facilitating disruptive quoting and trading activity and the Member has received sufficient notice with an opportunity to respond, but such activity has not ceased.

The following two examples are instructive on the Exchange's rationale for the proposed rule change.

In July 2012, Biremis Corp. (formerly Swift Trade Securities USA, Inc.) (the ''Firm'') and its CEO were barred from the industry for, among other things, supervisory violations related to a failure by the Firm to detect and prevent disruptive and allegedly manipulative trading activities, including layering, short sale violations, and anti-money laundering violations.[9] The Firm's sole business was to provide trade execution services via a proprietary day trading platform and order management system to day traders located in foreign jurisdictions. Thus, the disruptive and allegedly manipulative trading activity introduced by the Firm to U.S. markets originated directly or indirectly from foreign clients of the Firm. The pattern of disruptive and allegedly manipulative quoting and trading activity was widespread across multiple exchanges, and the Exchange, FINRA, and other SROs identified clear patterns of the behavior in 2007 and 2008. Although the Firm and its principals were on notice of the disruptive and allegedly manipulative quoting and trading activity that was occurring, the Firm took little to no action to attempt to supervise or prevent such quoting and trading activity until at least 2009. Even when it put some controls in place, they were deficient and the pattern of disruptive and allegedly manipulative trading activity continued to occur. As noted above, the final resolution of the enforcement action to bar the Firm and its CEO from the industry was not concluded until 2012, four years after the disruptive and allegedly manipulative trading activity was first identified.

In September of 2012, Hold Brothers On-Line Investment Services, Inc. (the ''Firm'') settled a regulatory action in connection with the Firm's provision of a trading platform, trade software and trade execution, support and clearing services for day traders.[10] Many traders using the Firm's services were located in foreign jurisdictions. The Firm ultimately settled the action with FINRA and several exchanges, including the Exchange, for a total monetary fine of $3.4 million. In a separate action, the Firm settled with the Commission for a monetary fine of $2.5 million.[11] Among the alleged violations in the case were disruptive and allegedly manipulative quoting and trading activity, including spoofing, layering, wash trading, and pre-arranged trading. Through its conduct and insufficient procedures and controls, the Firm also allegedly committed anti-money laundering violations by failing to detect and report manipulative and suspicious trading activity. The Firm was alleged to have not only provided foreign traders with access to the U.S. markets to engage in such activities, but that its principals also owned and funded foreign subsidiaries that engaged in the disruptive and allegedly manipulative quoting and trading activity. Although the pattern of disruptive and allegedly manipulative quoting and trading activity was identified in 2009, as noted above, the enforcement action was not concluded until 2012. Thus, although disruptive and allegedly manipulative quoting and trading was promptly detected, it continued for several years.

The Exchange also notes the current criminal proceedings that have commenced against Navinder Singh Sarao. Mr. Sarao's allegedly manipulative trading activity, which included forms of layering and spoofing in the futures markets, has been linked as a contributing factor to the ''Flash Crash'' of 2010, and yet continued through 2015.

The Exchange believes that the activities described in the cases above provide justification for the proposed rule change, which is described below.

[7] ''Layering'' is a form of market manipulation in which multiple, non-bona fide limit orders are entered on one side of the market at various price levels in order to create the appearance of a change in the levels of supply and demand, thereby artificially moving the price of the security. An order is then executed on the opposite side of the market at the artificially created price, and the non-bona fide orders are cancelled.

[8] ''Spoofing'' is a form of market manipulation that involves the market manipulator placing non-bona fide orders that are intended to trigger some type of market movement and/or response from other market participants, from which the market manipulator might benefit by trading bona fide orders.

[9] *See Biremis Corp. and Peter Beck,* FINRA Letter of Acceptance, Waiver and Consent No. 2010021162202, July 30, 2012.

[10] *See Hold Brothers On-Line Investment Services, LLC,* FINRA Letter of Acceptance, Waiver and Consent No. 20100237710001, September 25, 2012.

[11] *In the Matter of Hold Brothers On-Line Investment Services, LLC,* Exchange Act Release No. 67924, September 25, 2012.

Rule 8.17—Expedited Client Suspension Proceeding

The Exchange proposes to adopt new Rule 8.17 to set forth procedures for issuing suspension orders, immediately prohibiting a Member from conducting continued disruptive quoting and trading activity on the Exchange. Importantly, these procedures would also provide the Exchange the authority to order a Member to cease and desist from providing access to the Exchange to a client of the Member that is conducting disruptive quoting and trading activity in violation of proposed Rule 12.15.

Under proposed paragraph (a) of Rule 8.17, with the prior written authorization of the Chief Regulatory Officer (''CRO'') or such other senior officers as the CRO may designate, the Office of General Counsel or Regulatory Department of the Exchange (such departments generally referred to as the ''Exchange'' for purposes of proposed Rule 8.17) may initiate an expedited suspension proceeding with respect to alleged violations of Rule 12.15, which is proposed as part of this filing and described in detail below. Proposed paragraph (a) would also set forth the requirements for notice and service of such notice pursuant to the Rule, including the required method of service and the content of notice.

Proposed paragraph (b) of Rule 8.17 would govern the appointment of a Hearing Panel as well as potential disqualification or recusal of Hearing Officers. The proposed provision is consistent with existing Exchange Rule 8.6 and includes the requirement for a Hearing Officer to be recused in the event he or she has a conflict of interest or bias or other circumstances exist where his or her fairness might reasonably be questioned. In addition to recusal initiated by such a Hearing Officer, a party to the proceeding will be permitted to file a motion to disqualify a Hearing Officer. However, due to the compressed schedule pursuant to which the process would operate under Rule 8.17, the proposed rule would require such motion to be filed no later than 5 days after the announcement of the Hearing Panel and the Exchange's brief in opposition to such motion would be required to be filed no later than 5 days after service thereof. Pursuant to existing Rule 8.6(b), if the Hearing Panel believes the Respondent has provided satisfactory evidence in support of the motion to disqualify, the applicable Hearing Officer shall remove himself or herself and request the Chief Executive Officer to reassign the hearing to another Hearing Officer such that the Hearing Panel still meets the compositional requirements described in Rule 8.6(a). If the Hearing Panel determines that the Respondent's grounds for disqualification are insufficient, it shall deny the Respondent's motion for disqualification by setting forth the reasons for the denial in writing and the Hearing Panel will proceed with the hearing.

Under paragraph (c) of the proposed Rule, the hearing would be held not later than 15 days after service of the notice initiating the suspension proceeding, unless otherwise extended by the Chairman of the Hearing Panel with the consent of the Parties for good cause shown. In the event of a recusal or disqualification of a Hearing Officer, the hearing shall be held not later than five days after a replacement Hearing Officer is appointed. Proposed paragraph (c) would also govern how the hearing is conducted, including the authority of Hearing Officers, witnesses, additional information that may be required by the Hearing Panel, the requirement that a transcript of the proceeding be created and details related to such transcript, and details regarding the creation and maintenance of the record of the proceeding. Proposed paragraph (c) would also state that if a Respondent fails to appear at a hearing for which it has notice, the allegations in the notice and accompanying declaration may be deemed admitted, and the Hearing Panel may issue a suspension order without further proceedings. Finally, as proposed, if the Exchange fails to appear at a hearing for which it has notice, the Hearing Panel may order that the suspension proceeding be dismissed.

Under paragraph (d) of the proposed Rule, the Hearing Panel would be authorized to issue a written decision stating whether a suspension order would be imposed. The Hearing Panel would be required to issue the decision not later than 10 days after receipt of the hearing transcript, unless otherwise extended by the Chairman of the Hearing Panel with the consent of the Parties for good cause shown. The Rule would state that a suspension order shall be imposed if the Hearing Panel finds by a preponderance of the evidence that the alleged violation specified in the notice has occurred and that the violative conduct or continuation thereof is likely to result in significant market disruption or other significant harm to investors.

Proposed paragraph (d) would also describe the content, scope and form of a suspension order. As proposed, a suspension order shall be limited to ordering a Respondent to cease and desist from violating proposed Rule 12.15, and/or to ordering a Respondent to cease and desist from providing access to the Exchange to a client of Respondent that is causing violations of Rule 12.15. Under the proposed rule, a suspension order shall also set forth the alleged violation and the significant market disruption or other significant harm to investors that is likely to result without the issuance of an order. The order shall describe in reasonable detail the act or acts the Respondent is to take or refrain from taking, and suspend such Respondent unless and until such action is taken or refrained from. Finally, the order shall include the date and hour of its issuance. As proposed, a suspension order would remain effective and enforceable unless modified, set aside, limited, or revoked pursuant to proposed paragraph (e), as described below. Finally, paragraph (d) would require service of the Hearing Panel's decision and any suspension order consistent with other portions of the proposed rule related to service.

Proposed paragraph (e) of Rule 8.17 would state that at any time after the Office of Hearing Officers served the Respondent with a suspension order, a Party could apply to the Hearing Panel to have the order modified, set aside, limited, or revoked. If any part of a suspension order is modified, set aside, limited, or revoked, proposed paragraph (e) of Rule 8.17 provides the Hearing Panel discretion to leave the cease and desist part of the order in place. For example, if a suspension order suspends Respondent unless and until Respondent ceases and desists providing access to the Exchange to a client of Respondent, and after the order is entered the Respondent complies, the Hearing Panel is permitted to modify the order to lift the suspension portion of the order while keeping in place the cease and desist portion of the order. With its broad modification powers, the Hearing Panel also maintains the discretion to impose conditions upon the removal of a suspension—for example, the Hearing Panel could modify an order to lift the suspension portion of the order in the event a Respondent complies with the cease and desist portion of the order but additionally order that the suspension will be re-imposed if Respondent violates the cease and desist provisions modified order in the future. The Hearing Panel generally would be required to respond to the request in writing within 10 days after receipt of the request. An application to modify, set aside, limit or revoke a suspension

order would not stay the effectiveness of the suspension order.

Finally, proposed paragraph (f) would provide that sanctions issued under the proposed Rule 8.17 would constitute final and immediately effective disciplinary sanctions imposed by the Exchange, and that the right to have any action under the Rule reviewed by the Commission would be governed by Section 19 of the Act. The filing of an application for review would not stay the effectiveness of a suspension order unless the Commission otherwise ordered.

Rule 12.15—Disruptive Quoting and Trading Activity Prohibited

The Exchange currently has authority to prohibit and take action against manipulative trading activity, including disruptive quoting and trading activity, pursuant to its general market manipulation rules, including Rule 3.1. The Exchange proposes to adopt new Rule 12.15, which would more specifically define and prohibit disruptive quoting and trading activity on the Exchange. As noted above, the Exchange also proposes to apply the proposed suspension rules to proposed Rule 12.15.

Proposed Rule 12.15 would prohibit Members from engaging in or facilitating disruptive quoting and trading activity on the Exchange, as described in proposed Interpretation and Policies .01 and .02 of the Rule, including acting in concert with other persons to effect such activity. The Exchange believes that it is necessary to extend the prohibition to situations when persons are acting in concert to avoid a potential loophole where disruptive quoting and trading activity is simply split between several brokers or customers.

To provide proper context for the situations in which the Exchange proposes to utilize its proposed authority, the Exchange believes it is necessary to describe the types of disruptive quoting and trading activity that would cause the Exchange to use its authority. Accordingly, the Exchange proposes to adopt Interpretation and Policy .01 and .02, providing additional details regarding disruptive quoting and trading activity. Proposed Interpretation and Policy .01(a), which describes disruptive quoting and trading activity containing many of the elements indicative of layering, would describe disruptive quoting and trading activity as a frequent pattern in which the following facts are present: (a) A party enters multiple limit orders on one side of the market at various price levels (the ''Displayed Orders''); and (b) following the entry of the Displayed Orders, the level of supply and demand for the security changes; and (c) the party enters one or more orders on the opposite side of the market of the Displayed Orders (the ''Contra-Side Orders'') that are subsequently executed; and (d) following the execution of the Contra-Side Orders, the party cancels the Displayed Orders. Proposed Interpretation and Policy .01(b), which describes disruptive quoting and trading activity containing many of the elements indicative of spoofing, would describe disruptive quoting and trading activity as a frequent pattern in which the following facts are present: (a) A party narrows the spread for a security by placing an order inside the national best bid or offer; and (b) the party then submits an order on the opposite side of the market that executes against another market participant that joined the new inside market established by the order described in (a) that narrowed the spread. The Exchange believes that the proposed descriptions of disruptive quoting and trading activity articulated in the rule are consistent with the activities that have been identified and described in the client access cases described above. The Exchange further believes that the proposed descriptions will provide Members with clear descriptions of disruptive quoting and trading activity that will help them to avoid engaging in such activities or allowing their clients to engage in such activities.

The Exchange proposes to make clear in Interpretation and Policy .02 that, unless otherwise indicated, the descriptions of disruptive quoting and trading activity do not require the facts to occur in a specific order in order for the rule to apply. For instance, with respect to the pattern defined in proposed Interpretation and Policy .01(a) it is of no consequence whether a party first enters Displayed Orders and then Contra-side Orders or vice-versa. However, as proposed, it is required for supply and demand to change following the entry of the Displayed Orders. The Exchange also proposes to make clear that disruptive quoting and trading activity includes a pattern or practice in which some portion of the disruptive quoting and trading activity is conducted on the Exchange and the other portions of the disruptive quoting and trading activity are conducted on one or more other exchanges. The Exchange believes that this authority is necessary to address market participants who would otherwise seek to avoid the prohibitions of the proposed Rule by spreading their activity amongst various execution venues.

In sum, proposed Rule 12.15 coupled with proposed Rule 8.17 would provide the Exchange with authority to promptly act to prevent disruptive quoting and trading activity from continuing on the Exchange. Below is an example of how the proposed rule would operate.

Assume that through its surveillance program, Exchange staff identifies a pattern of potentially disruptive quoting and trading activity. After an initial investigation the Exchange would then contact the Member responsible for the orders that caused the activity to request an explanation of the activity as well as any additional relevant information, including the source of the activity. If the Exchange were to continue to see the same pattern from the same Member and the source of the activity is the same or has been previously identified as a frequent source of disruptive quoting and trading activity then the Exchange could initiate an expedited suspension proceeding by serving notice on the Member that would include details regarding the alleged violations as well as the proposed sanction. In such a case the proposed sanction would likely be to order the Member to cease and desist providing access to the Exchange to the client that is responsible for the disruptive quoting and trading activity and to suspend such Member unless and until such action is taken. The Member would have the opportunity to be heard in front of a Hearing Panel at a hearing to be conducted within 15 days of the notice. If the Hearing Panel determined that the violation alleged in the notice did not occur or that the conduct or its continuation would not have the potential to result in significant market disruption or other significant harm to investors, then the Hearing Panel would dismiss the suspension order proceeding. If the Hearing Panel determined that the violation alleged in the notice did occur and that the conduct or its continuation is likely to result in significant market disruption or other significant harm to investors, then the Hearing Panel would issue the order including the proposed sanction, ordering the Member to cease providing access to the client at issue and suspending such Member unless and until such action is taken. If such Member wished for the suspension to be lifted because the client ultimately responsible for the activity no longer would be provided access to the Exchange, then such Member could apply to the Hearing Panel to have the order modified, set aside, limited or

revoked. The Exchange notes that the issuance of a suspension order would not alter the Exchange's ability to further investigate the matter and/or later sanction the Member pursuant to the Exchange's standard disciplinary process for supervisory violations or other violations of Exchange rules or the Act.

The Exchange reiterates that it already has broad authority to take action against a Member in the event that such Member is engaging in or facilitating disruptive or manipulative trading activity on the Exchange. For the reasons described above, and in light of recent cases like the client access cases described above, as well as other cases currently under investigation, the Exchange believes that it is equally important for the Exchange to have the authority to promptly initiate expedited suspension proceedings against any Member who has demonstrated a clear pattern or practice of disruptive quoting and trading activity, as described above, and to take action including ordering such Member to terminate access to the Exchange to one or more of such Member's clients if such clients are responsible for the activity. The Exchange recognizes that its proposed authority to issue a suspension order is a powerful measure that should be used very cautiously. Consequently, the proposed rules have been designed to ensure that the proceedings are used to address only the most clear and serious types of disruptive quoting and trading activity and that the interests of Respondents are protected. For example, to ensure that proceedings are used appropriately and that the decision to initiate a proceeding is made only at the highest staff levels, the proposed rules require the CRO or another senior officer of the Exchange to issue written authorization before the Exchange can institute an expedited suspension proceeding. In addition, the Exchange believes that it would use this authority in limited circumstances, when necessary to protect investors, other Members and the Exchange. Further, the Exchange believes that the proposed expedited suspension provisions described above that provide the opportunity to respond as well as a Hearing Panel determination prior to taking action will ensure that the Exchange would not utilize its authority in the absence of a clear pattern or practice of disruptive quoting and trading activity.

2. Statutory Basis

The Exchange believes that the proposed rule changes are consistent with Section 6(b) of the Act [12] and further the objectives of Section 6(b)(5) of the Act [13] because they are 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 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. Pursuant to the proposal, the Exchange will have a mechanism to promptly initiate expedited suspension proceedings in the event the Exchange believes that it has sufficient proof that a violation of Rule 12.15 has occurred and is ongoing.

Further, the Exchange believes that the proposal is consistent with Sections 6(b)(1) and 6(b)(6) of the Act,[14] which require that the rules of an exchange enforce compliance with, and provide appropriate discipline for, violations of the Commission and Exchange rules. The Exchange also believes that the proposal is consistent with the public interest, the protection of investors, or otherwise in furtherance of the purposes of the Act because the proposal helps to strengthen the Exchange's ability to carry out its oversight and enforcement responsibilities as a self-regulatory organization in cases where awaiting the conclusion of a full disciplinary proceeding is unsuitable in view of the potential harm to other Members and their customers as well as the Exchange if conduct is allowed to continue on the Exchange. As explained above, the Exchange notes that it has defined the prohibited disruptive quoting and trading activity by modifying the traditional definitions of layering and spoofing [15] to eliminate an express intent element that would not be proven on an expedited basis and would instead require a thorough investigation into the activity. As noted throughout this filing, the Exchange believes it is necessary for the protection of investors to make such modifications in order to adopt an expedited process rather than allowing disruptive quoting and trading activity to occur for several years. Through this proposal, the Exchange does not intend to modify the definitions of spoofing and layering that have generally been used by the Exchange and other regulators in connection with actions like those cited above.

The Exchange further believes that the proposal is consistent with Section 6(b)(7) of the Act,[16] which requires that the rules of an exchange ''provide a fair procedure for the disciplining of members and persons associated with persons... and the prohibition or limitation by the exchange of any person with respect to access to services offered by the exchange or a member thereof.'' Finally, the Exchange also believes the proposal is consistent with Sections 6(d)(1) and 6(d)(2) of the Act,[17] which require that the rules of an exchange with respect to a disciplinary proceeding or proceeding that would limit or prohibit access to or membership in the exchange require the exchange to: provide adequate and specific notice of the charges brought against a member or person associated with a member, provide an opportunity to defend against such charges, keep a record, and provide details regarding the findings and applicable sanctions in the event a determination to impose a disciplinary sanction is made. The Exchange believes that each of these requirements is addressed by the notice and due process provisions included within proposed Rule 8.17. Importantly, as noted above, the Exchange anticipates using the authority proposed in this filing only in clear and egregious cases when necessary to protect investors, other Members and the Exchange, and even in such cases, the Respondent will be afforded due process in connection with the suspension proceedings.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes 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 Exchange believes that each self-regulatory organization should be empowered to regulate trading occurring on their market consistent with the Act and without regard to competitive issues. The Exchange is requesting authority to take appropriate action if necessary for the protection of investors, other Members and the Exchange.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] 15 U.S.C. 78f(b)(1) and 78f(b)(6).

[15] *See supra,* notes 7 and 8.

[16] 15 U.S.C. 78f(b)(7).

[17] 15 U.S.C. 78f(d)(1).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

As explained above, a similar proposal was filed by the Exchange as File No. SR–BATS–2015–57 and Amendment No. 1 thereto. The Exchange received five comments in response to the Initial Proposal and responded to such comments in the BATS Comment Response Letter.[18] The Exchange believes that the BATS Comment Response Letter as well as the changes to the Initial Proposal that are reflected in this proposal adequately address comments 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 will: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal, as modified by 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–BATS–2015–101 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–BATS–2015–101. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices 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–BATS–2015–101, and should be submitted on or before December 15, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Robert W. Errett,

Deputy Secretary.

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[18] *See supra* note 4.

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76467; SR–ISE–2015–36]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Withdrawal of a Proposed Rule Change Relating to a Corporate Transaction Involving Its Indirect Parent

November 18, 2015.

On October 30, 2015, the International Securities Exchange, LLC (the ''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 to amend and restate certain corporate governance documents in connection with a proposal to remove Eurex Frankfurt AG as an indirect, non-U.S. upstream owner of the Exchange. The proposed rule change was published for comment in the **Federal Register** on November 17, 2015.[3]

On November 13, 2015, the Exchange withdrew the proposed rule change (SR–ISE–2015–36).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[4]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–29840 Filed 11–23–15; 8:45 am]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

[3] *See* Securities Exchange Act Release No. 76415 (Nov. 10, 2015), 80 FR 71864.

[4] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76469; File No. SR–CBOE–2015–077]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Order Granting Approval of Proposed Rule Change Relating to Margin Requirements

November 18, 2015.

I. Introduction

On September 22, 2015, Chicago Board Options Exchange, Incorporated (''Exchange'' or ''CBOE'') 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 margin requirements. The proposed rule change was published for comment in the **Federal Register** on October 8, 2015.[3] The Commission received no comments on the proposed rule change. This order grants approval of the proposed rule change.

II. Description of the Proposed Rule Change

CBOE proposes to amend its rules related to margin requirements. Rule 12.3 sets forth margin requirements, and certain exceptions to those requirements, applicable to security positions of Trading Permit Holders' customers. Rule 12.3(c)(5)(C)(2) currently requires no margin for covered calls and puts. Specifically, that rule provides the following:

- No margin need be required in respect of an option contract, stock index warrant, currency index warrant or currency warrant carried in a short position which is covered by a long position in equivalent units of the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 76068 (October 2, 2015), 80 FR 60941 (''Notice'').

underlying security in the case of a call (covered call), or a short position in equivalent units of the underlying security in the case of a put (covered put).[4]

• An underlying stock basket [5] may serve as cover for an option contract or warrant on a market index carried short (subject to the same requirements for computing margin).

• No margin is required in respect of a call option on a Standard and Poor's 500 (S&P 500) market index carried in a short position where there is carried for the same account a long position in an underlying open-end index mutual fund (which will be specifically designated by the Exchange) having an aggregate market value at least equal to the underlying value of the S&P 500 contracts to be covered.

According to CBOE, the proposed rule change makes some nonsubstantive changes to Rule 12.3(c)(5)(C)(2). CBOE represents, the proposed rule change letters the provisions listed in the first two bulleted paragraphs above to become subparagraphs (2)(a) and (b) and moves part of the provision in the first bulleted paragraph to proposed subparagraph (2)(c) (as discussed below, the proposed rule change deletes the third bulleted paragraph above). CBOE further represents, the proposed rule change revises the language to be consistent throughout these provisions, including clarifying that the underlying security or one of the other permissible offsets must be carried in the same account as the option position. CBOE notes, the proposed rule change also makes the language more plain English, eliminates repetitive language, and inserts a missing space in proposed subparagraph (b).

CBOE states, the proposed rule change adds circumstances in which covered calls and puts require no margin. According to CBOE, the proposed rule change applies the provision in proposed subparagraph (b) to index mutual funds, index portfolio receipts (''IPRs''),[6] and index portfolio shares (''IPSs''),[7] in addition to underlying stock baskets, based on the same index underlying the index option and having a market value at least equal to the aggregate current index value.[8] IPRs and IPSs are commonly referred to as exchange-traded funds (''ETFs''). CBOE notes, the proposed rule change also deletes the provision that provides no margin is required in respect of options on a Standard and Poor's 500 (S&P 500) market index carried in a short position where there is carried for the same account a long position in the underlying open-end index mutual fund having an aggregate market value at least equal to the underlying value of the S&P 500 contracts to be covered.[9] CBOE further notes, proposed subparagraph (b) extends the same margin exception to any index option offset by a position in a mutual fund based on the same underlying index, making this current provision duplicative.

CBOE states that index ETFs and mutual funds function in a similar manner to underlying stock baskets, as they are intended to replicate the performance of their underlying market indexes. CBOE believes, the types and diversity of products available on the market that track indexes continues to increase and provide additional investment and hedging opportunities. CBOE also believes while an ETF or mutual fund may not meet the definition of an underlying stock basket (for example, some ETFs have a sampling of the securities that comprise the underlying index), it essentially has the same purpose as an underlying stock basket for investors. Therefore, CBOE represents, it closely tracks an underlying index, and thus can function as an offsetting position to an index option overlying the same index in the same way as an underlying stock basket.[10]

According to CBOE, the Board of Governors of the Federal Reserve System (''FRB'') previously indicated that no margin would be required if an index option (on a broad-based stock index with at least a 99% correlation with the S&P 500 index) is covered by an offsetting position in S&P Index Depositary Receipts (SPDRS), but rather such SPDR positions would be treated as cover in accordance with Section 220.5(c)(3) of Regulation T.[11] CBOE and another exchange later afforded the same margin treatment to options on the Dow Jones Industrial Average (DJIA)

[4] *See* Notice, *supra* note 3, at 60942. CBOE notes, in computing margin on such a position in the underlying security, (a) in the case of a call, the current market value to be used shall not be greater than the exercise price and (b) in the case of a put, margin will be the amount required by Rule 12.3(b)(2), plus the amount, if any, by which the exercise price of the put exceeds the current market value of the underlying.

[5] *See* Notice, *supra* note 3, at 60942. An ''underlying stock basket'' means a group of securities that includes each of the component securities of the applicable index and which meets the following conditions: (a) The quantity of each stock in the basket is proportional to its representation in the index, (b) the total market value of the basket is equal to the underlying index value of the index options or warrants to be covered, (c) the securities in the basket cannot be used to cover more than the number of index options or warrants represented by that value and (d) the securities in the basket shall be unavailable to support any other option or warrant transaction in the account. *See also* Rule 12.3(a)(7).

[6] *See* Notice, *supra* note 3, at 60942. The term ''index portfolio receipts'' or ''IPRs'' means securities that (a) represent an interest in a unit investment trust (''UIT'') which holds the securities that comprise an index on which a series of IPRs is based; (b) are issued by the UIT in a specified aggregate minimum number in return for a ''Portfolio Deposit'' consisting of specified numbers of shares of stock plus a cash amount; (c) when aggregated in the same specified minimum number, may be redeemed from the UIT which will pay to the redeeming holder the stock and cash then comprising the Portfolio Deposit; and (d) pay holders a periodic cash payment corresponding to the regular cash dividends or distributions declared and paid with respect to the component securities of the stock index on which the IPRs are based, less certain expenses and other charges as set forth in the UIT prospectus. IPRs are ''UIT interests'' within the meaning of the CBOE Rules. *See also* CBOE Rule 1.1, Interpretation and Policy .02.

[7] *See* Notice, *supra* note 3, at 60942. The term ''index portfolio shares'' or ''IPSs'' means securities that (a) are issued by an open-end management investment company based on a portfolio of stocks or fixed income securities designed to provide investment results that correspond generally to the price and yield performance of a specified foreign or domestic stock index or fixed income securities index; (b) are issued by such an open-end management investment company in a specified aggregate minimum number in return for a deposit of specified number of shares of stock and/or a cash amount, or a specified portfolio of fixed income securities and/or a cash amount, with a value equal to the next determined net asset value; and (c) when aggregated in the same specified minimum number, may be redeemed at a holder's request by such open-end management investment company which will pay to the redeeming holder stock and/or cash, or a specified portfolio of fixed income securities and/or cash with a value equal to the next determined net asset value. *See also* CBOE Rule 1.1, Interpretation and Policy .03.

[8] *See* Notice, *supra* note 3, at 60942. The term ''aggregate current index value'' means the current index value times the index multiplier. *See also* CBOE Rule 12.3, Interpretation and Policy .07.

[9] *See* Notice, *supra* note 3, at 60942. CBOE notes, the proposed rule change also deletes the requirement for CBOE to specifically designate funds, as it thinks this is no longer necessary due to the continued increase in availability of these types of products, as discussed below.

[10] *See* Notice, *supra* note 3, at 60943. The Exchange notes that current federal net capital rules that apply to options define a qualified stock basket to mean a set or basket of stock positions which represents no less than 50% of the capitalization for a high-capitalization or non-high-capitalization diversified market index or no less than 95% of the capitalization of a narrow-based index. Those rules require positions in index options be grouped with related instruments within the option's class and qualified stock baskets in the same index. *See also* 17 CFR 240.15c3–1a(b)(1)(i)(D) and (ii). Similar to a qualified stock basket, while an ETF or mutual fund may not hold every stock included in the underlying market index, its holdings are intended to track the index.

[11] *See* Notice, *supra* note 3, at 60943. *See* Letter dated February 1, 1993 from Michael J. Schoenfeld, FRB, to James McNeil, American Stock Exchange (''Amex''); *see also* Letter dated August 19, 1992 from James M. McNeil, Amex, to Sharon Lawson, Commission, and Letter dated January 14, 1993 from James M. McNeil, Amex, to Laura M. Homer, FRB. The section of Regulation T referenced in these letters currently corresponds to Section 220.4(b)(4), which provides margin requirements when stock is used as cover for short option positions.

covered by units of the DIAMONDS Trust held in the same account.[12] CBOE notes, based on this previous guidance from the FRB and the Commission, and in conjunction with the Exchange's current rules, CBOE has applied this margin treatment to short index option positions where there are offsetting positions in an ETF that tracks the same underlying index held in the same margin account (which treatment the Exchange has announced in Regulatory Circulars).[13] CBOE believes the proposed rule change is consistent with these previous findings and applies this margin treatment generally to all ETFs and mutual funds that overly market indexes, in the same manner that the rules currently apply to underlying stock baskets. Given that the Exchange regularly lists new products, including index options, the Exchange believes it is appropriate to have a more general rule related to margin on these index option products that applies in the same manner rather than identifying this margin treatment in Regulatory Circulars.

III. Discussion and Commission Findings

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[14] Specifically, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[15] 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. Specifically, the Commission believes that providing for a specific margin treatment related to covered puts and calls to apply to all index options in the same manner will promote just and equitable principles of trade because stock baskets, ETFs and mutual funds that trade a reference index can generally provide the same economic function as a security underlying an option.

Finally, the Commission believes the non-substantive technical changes will benefit investors by offering more clarity with respect to the margin rules by providing for more consistent and plain English language in the rule.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[16] that the proposed rule change (SR–CBOE–2015–077) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–29842 Filed 11–23–15; 8:45 am]

BILLING CODE 8011–01–P

[12] *See* Notice, *supra* note 3, at 60943. *See* Letter dated December 3, 1997 from James M. McNeil, Amex, to Scott Holz, FRB, and Letter dated January 8, 1998 from Scott Holz, FRB to James M. McNeil, Amex; *see also* Letter dated December 16, 1997 from Richard Lewandowski, CBOE, to Mr. Michael Walinskas, Commission. There was no objection from the FRB or the Commission to Amex's or CBOE's extension of the margin treatment previously provided to SPDRS to DIAMONDS.

[13] *See* Notice, *supra* note 3, at 60943. *See also* Regulatory Circulars RG99–09 (permitting SPDRS and DIAMONDS to cover short positions of options on the S&P 500 (''SPX options'') and on the DJIA (DJX), respectively); RG00–171 (permitting units of iShares S&P 100 Index Fund to cover short positions of options on the S&P 100 Index (OEX)); RG01–119 (permitting Nasdaq-100 Index Tracking Shares to cover short positions of options on the Nasdaq-100 Shares (QQQ), the Nasdaq 100 Index (NDX) or the Mini-Nasdaq 100 Index (MNX); RG02–110 (permitting units of the iShares S&P 500 Fund (IVV) to cover short SPX option positions); and RG07–126 (permitting units of the iShares Russell 200 Index Fund (IWM) to cover short positions of options on the Russell 2000 index (RUT)).

[14] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[15] 15 U.S.C. 78f(b)(5).

[16] 15 U.S.C. 78s(b)(2).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76468; SR–ISEGemini-2015–24]

Self-Regulatory Organizations; ISE Gemini, LLC; Notice of Withdrawal of a Proposed Rule Change Relating to a Corporate Transaction Involving Its Indirect Parent

November 18, 2015.

On October 30, 2015, ISE Gemini, LLC (the ''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 to amend and restate certain corporate governance documents in connection with a proposal to remove Eurex Frankfurt AG as an indirect, non-U.S. upstream owner of the Exchange. The proposed rule change was published for comment in the **Federal Register** on November 17, 2015.[3]

On November 13, 2015, the Exchange withdrew the proposed rule change (SR–ISEGemini–2015–24).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[4]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–29841 Filed 11–23–15; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 76416 (Nov. 10, 2015), 80 FR 71876.

[4] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76466; File No. SR–C2–2015–031]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Delivery of the Regulatory Element of C2's Continuing Education Program

November 18, 2015.

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 November 05, 2015, C2 Options Exchange, Incorporated (the ''Exchange'' or ''C2'') 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 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 the Substance of the Proposed Rule Change

The purpose of the proposed rule change is to expand on the Exchange's past representations made in SR–C2–2015–024 [3] with respect to Continuing Education (''CE'') Fees and Web-based delivery of the Regulatory Element of the Exchange's CE program. There are no proposed changes to the text of the Exchange's rules.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 76150 (October 14, 2015), 80 FR 63593 (October 20, 2015) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend the Fees Schedule) (SR–C2–2015–024).

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 correct certain statements in SR–C2–2015–024.[4] On October 2, 2015, the Exchange filed SR–C2–2015–024 to amend the Fees Schedule with respect to CE-related fees and, in particular, fees related to Web-based delivery of the Regulatory Element of the Exchange's CE program.[5] SR–C2–2015–024 was materially based upon changes to FINRA Rule 1250, which were approved by the Securities and Exchange Commission (''SEC'' or ''Commission'') in SR–FINRA–2015–015.[6]

Notably, within the Purpose section of SR–C2–2015–024, the Exchange incorrectly stated that ''[t]he Regulatory Element of these Continuing Education Programs [(*i.e.* the S106 for Investment Company and Variable Contracts Representatives, the S201 for Registered Principals and Supervisors, and the S901 for Operations Professionals)] will continue to be offered at testing centers through January 4, 2016'' and that ''[p]ursuant to the Approval Order to SR–FINRA–2015–015, the fee for test-center delivery of the Regulatory Element of the S106, S201, and S901 Continuing Education Programs will continue to be $100 per session through January 4, 2016 when the programs will no longer be offered at testing centers.'' According to SR–FINRA–2015–015, however, the Regulatory Element of the S106 for Investment Company and Variable Contracts Representatives, the S201 for Registered Principals and Supervisors, and the S901 for Operations Professionals will continue to be offered at testing centers *until no later than six months after* January 4, 2016.[7] The Exchange therefore is submitting this filing for the purpose of correcting SR–C2–2015–024 and in an effort to avoid any confusion among Permit Holders as to how long the Regulatory Element of the S106 for Investment Company and Variable Contracts Representatives, the S201 for Registered Principals and Supervisors, and the S901 for Operations Professionals will continue to be offered at testing centers.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[8] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[9] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[10] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. In particular, the Exchange believes that this filing will clarify its rules and help ensure that Permit Holders are not confused by discrepancies that existed between SR–C2–2015–024 and SR–FINRA–2015–015. The Exchange believes that clarity in the Rules is in the interests of Permit Holders and all investors and consistent with 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 of the purposes of the Act. This filing relates generally to CE requirements required of all Permit Holders. In addition, the filing is merely a clarification of a previous filing already submitted by the Exchange. Accordingly, the Exchange does not believe that the proposed rule change will impose any burden on competition in the marketplace.

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 written 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[11] and subparagraph (f)(6) of Rule 19b–4 thereunder.[12]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of filing.[13] Rule 19b–4(f)(6)(iii), however, permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest.[14] 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 has stated that waiver of the operative delay is necessary in order to correct statements in a previous filing[15] and to avoid any potential confusion to investors. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest as it will allow C2 to update without delay its fee schedule to accurately reflect the timing by which FINRA will phase out offering the regulatory element of certain continuing education programs

[4] *Id.*

[5] *See id.*

[6] *See* Securities Exchange Act Release No. 75581 (July 31, 2015), 80 FR 47018 (August 6, 2015) (Order Approving a Proposed Rule Change to Provide a Web-based Delivery Method for Completing the Regulatory Element of the Continuing Education Requirements) (SR–FINRA–2015–015).

[7] According to SR–FINRA–2015–015, test-center delivery of the Regulatory Element will be phased out *by no later than six months after* January 4, 2016. *See id.*

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] *Id.*

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] *Id.*

[15] *See* Securities Exchange Act Release No. 76150 (October 14, 2015), 80 FR 63593 (October 20, 2015) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend the Fees Schedule) (SR–C2–2015–024).

in person at testing centers. Since C2's proposed rule change is intended to correct an external reference that was the subject of a separate FINRA proposed rule change, the Commission believes it is in the public interest to correct and update the C2 fee schedule without delay. Accordingly, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–C2–2015–031 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–C2–2015–031. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices 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–C2–2015–031, and should be submitted on or before December 15, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–29839 Filed 11–23–15; 8:45 am]

BILLING CODE 8011–01–P

[16] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76471; File No. SR–CBOE–2015–102]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Administration of Livevol X License Agreements

November 18, 2015.

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 November 13, 2015, 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, 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

CBOE proposes to update the status of CBOE's administration of license agreements for Livevol X (''LVX'').

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

On August 7, 2015, CBOE Livevol, LLC (formerly CBOE IV, LLC) (''CBOE Livevol'') completed its acquisition of certain technology assets from the entity formerly known as Livevol, Inc. (''Livevol''), including LVX, a front-end order entry and management tool. CBOE had previously submitted a rule filing that, among other things, described the functionality of LVX and proposed applicable fees, which would become operative upon closing of the acquisition of assets from Livevol.[3] In that filing, CBOE stated that it expected CBOE Livevol to assume agreements between Livevol and its then-current LVX customers at the closing of the acquisitions. CBOE further stated that CBOE Livevol intended to prepare a form license agreement for LVX and, no later than three months following the closing of the acquisition,[4] ensure each customer executed the form agreement so that all LVX customers used the product pursuant to the same terms and conditions.[5]

CBOE has made significant progress over the last three months in the complicated process of integrating the acquired Livevol business into CBOE's business and is in the process of distributing its form license agreement to LVX users. However, as LVX has

[3] *See* Securities Exchange Act Release No. 34–75302 (June 25, 2015), 80 FR 37685 (July 1, 2015) (SR–CBOE–2015–062).

[4] November 6, 2015 was the date three months following the closing of the acquisition.

[5] *See supra* note 3, at note 16.

hundreds of users, CBOE believes it needs additional time to collect executed versions of this agreement from all these LVX users. At this time, CBOE expects to complete this process and ensure all LVX users have executed the form (and will thus be using LVX pursuant to the same contractual terms and conditions) by January 31, 2016. CBOE notes that all LVX users currently pay the same fees for LVX as set forth in the CBOE Fees Schedule.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with 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 to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed rule change does not discriminate among market participants, as CBOE continues to make LVX available to all market participants in the same manner, and use of LVX continues to be completely voluntary. The LVX functionality available to users remains the same. All LVX users pay the same fees for use of the product, which are set forth in the CBOE Fees Schedule. CBOE expects to license the applications to market participants pursuant to the same contractual terms and conditions set forth in the form license agreement once all LVX users have executed the form agreement. This rule filing has no impact on LVX customers' use of LVX; they may continue to use LVX in the same manner. It merely extends the time by which CBOE expects to complete the process of receiving executed versions of the form agreement from all LVX users. The Exchange notes that this rule filing does not amend the Exchange's rules, fees or systems.

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. This rule filing does not amend the Exchange's rules, fees or systems. CBOE continues to make LVX available to all market participants in the same manner, and use of LVX continues to be completely voluntary. The LVX functionality available to users remains the same. All LVX users currently pay the same fees for LVX as set forth in the CBOE Fees Schedule. CBOE expects to license the applications to market participants pursuant to the same contractual terms and conditions set forth in the form license agreement once all LVX users have executed the form agreement. This rule filing has no impact on LVX customers' use of LVX; they may continue to use LVX in the same manner. It merely extends the time by which CBOE expects to complete the process of receiving executed versions of the form agreement from all LVX users. Market participants continue to have the flexibility to use any order entry and management technology they choose, including LVX.

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

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[9] and paragraph (f) of Rule 19b–4[10] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission 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–2015–102 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2015–102. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing 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–2015–102, and should be submitted on or before December 15, 2015.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *Id.*

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–29844 Filed 11–23–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76472; File No. SR–NYSEArca–2015–68]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Instituting Proceedings to Determine Whether To Approve or Disapprove Proposed Rule Change Relating To Implementation of a Fee on Securities Lending and Repurchase Transactions With Respect to Shares of the CurrencyShares® Euro Trust and the CurrencyShares® Japanese Yen Trust

November 18, 2015.

On July 30, 2015, NYSE Arca, Inc. (''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 implementation of a fee on securities lending and repurchase transactions with respect to shares of the CurrencyShares® Euro Trust and the CurrencyShares® Japanese Yen Trust, which are currently listed and trading on the Exchange under NYSE Arca Equities Rule 8.202. The proposed rule change was published for comment in the **Federal Register** on August 20, 2015.[3] On September 18, 2015, 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 rule change.[5] The Commission has not received any comments on the proposal.[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.

I. Description of the Exchange's Proposal[8]

A. Background

The Exchange currently lists and trades shares (''Shares'') of the CurrencyShares® Euro Trust (''Euro Trust'' or ''FXE'') and the CurrencyShares® Japanese Yen Trust (''Yen Trust'' or ''FXY,'' and together with the Euro Trust, collectively, ''Trusts'') under NYSE Arca Equities Rule 8.202.[9]

FXE and FXY hold euros and Japanese yen, respectively, and issue Shares in baskets (''Baskets'') of 50,000 Shares in exchange for deposits of euros or yen, respectively. Each Trust redeems Baskets of Shares and distributes euros or yen, respectively. The Shares of FXE and FXY represent units of fractional undivided beneficial interests in the assets held by the relevant Trust. The investment objective of each Trust is for the Trust's shares to reflect the price in U.S. dollars (''USD'') of the foreign currency held by the Trust, plus accrued interest and minus the expenses and liabilities of such Trust. According to the Exchange, the Shares are intended to provide institutional and retail investors with economic exposure to a particular foreign currency so that they can, for example, hedge foreign currency risk in other portfolio assets or hedge against USD fluctuations more generally.

The Exchange represents that, as sponsor of the Trusts, Guggenheim Specialized Products, LLC (''Guggenheim'' or ''Sponsor'') receives a management fee that is intended to compensate Guggenheim for its service as Sponsor and to cover certain Trust expenses. The management fee is paid monthly out of a Trust's assets and is calculated as a percentage of the currency held by each Trust. Guggenheim's fee accrues daily at an annual nominal rate of 0.40% of the foreign currency held by the trust.

According to the Exchange, because the accrued but unpaid management fee is subtracted from the assets in calculating each fund's net asset value (''NAV'') on a daily basis,[10] the value of the Shares decreases at a predictable rate independent of the value of the currency held by each Trust. The Exchange refers to the rate at which the value of a Trust falls as a result of the management fee as the ''Management Fee Decay.''

Like other equity securities, Shares may be loaned by shareholders to other market participants. This securities lending activity can facilitate short selling of Shares, as well as other investment strategies.[11] Once loaned, the Shares may be (i) redeemed by the borrower for underlying Trust assets, or (ii) sold.

B. The Exchange's Description of the ''Strategy'' Allegedly Used by Some Market Participants to Profit From Management Fee Decay

According to the Exchange, the Sponsor claims to have identified a strategy (''Strategy'') that permits certain market participants (''Traders'') to profit from the reduction in the NAV of the Shares over time associated with Management Fee Decay, to the purported detriment of the value of the Shares held by shareholders who do not engage in the Strategy. Pursuant to the Strategy, a Trader borrows Shares and then either (1) sells the borrowed Shares, taking a short position in the Shares, or (2) redeems the borrowed Shares for euros or yen, as applicable.

According to the Exchange, the number of units of foreign currency

[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 75698 (Aug. 14, 2015), 80 FR 50701 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 75945, 80 FR 57645 (Sept. 24, 2015). The Commission designated a longer period within which to take action on the proposed rule change and designated November 18, 2015, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[6] Although the Commission has not yet received comments on the proposal, the Exchange represents that it issued a Regulatory Bulletin on this proposal on August 21, 2013 (regulatory bulletin available at *http://www.sec.gov/rules/sro/nysearca/2015/34-75698-ex2a.pdf*) and received two comment letters in response. *See* Notice, *supra* note 3, 80 FR at 50705 n.22. *See also* Letter from Daniel J. McCabe, President, Precidian Investments, to John Carey, Vice President-Legal, NYSE (Sept. 20, 2013) (supporting the proposed rule change); Letter from Theodore R. Lazo, Associate General Counsel, and Kyle Brandon, Managing Director, SIFMA, to John Carey, Vice President-Legal (Sept. 23, 2013) (opposing the proposal) (both letters available at *http://www.sec.gov/rules/sro/nysearca/2015/34-75698-ex2b.pdf*).

[7] 15 U.S.C. 78s(b)(2)(B).

[8] A complete description of the proposal can be found in the Notice. *See* Notice, *supra* note 3 (available at: *http://www.sec.gov/rules/sro/nysearca/2015/34-75698.pdf*).

[9] Shares of the Trusts initially were approved for listing and trading on the New York Stock Exchange, Inc. *See* Securities Exchange Act Release Nos. 52843 (Nov. 28, 2005), 70 FR 72486 (Dec. 5, 2005) (SR–NYSE–2005–65) (order approving listing and trading of Shares of FXE); and 55268 (Feb. 9, 2007), 72 FR 7793 (Feb. 20, 2007) (SR–NYSE–2007–03) (order approving listing and trading of Shares of FXY).

[10] To calculate NAV, the Trustee adds to the amount of euros/yen in the Trusts at the end of the preceding business day, accrued but unpaid interest, euros/yen receivable under pending purchase orders and the value of other Trust assets, and subtracts the accrued but unpaid management fee, euros/yen payable under pending redemption orders and other Trust expenses and liabilities, if any. *See* Notice, *supra* note 3, at 3, 80 FR at 50701.

[11] A short sale is any sale of a security that the seller does not own or any sale that is consummated by the delivery of a security borrowed by, or for the account of, the seller. Short sales are normally settled by the delivery of a security borrowed by or on behalf of the investor. The investor later closes out the position by returning the borrowed security to the stock lender, typically by purchasing securities on the open market.

underlying the Shares the Trader has sold short is reduced over time because of the Management Fee Decay. Therefore, when the Trader unwinds its short position in the Shares by creating Shares through delivery of the currency it held as a hedge, or when the Trader purchases Shares and sells the currency held as a hedge, it will do so at lower cost than when it sold (or purchased) the Shares. According to the Exchange, the Trader's profit from this Strategy is equal to the Management Fee Decay attributable to the Shares sold short, plus or minus the net cost of borrowing the Shares and other transaction costs.

According to the Exchange, the following two examples—one in which the Trader sells the borrowed Shares short, and the other in which the Trader redeems the borrowed Shares—explain how the Strategy functions.

Example 1—Selling Short FXE

Before the trade, there are 100 euros in the Euro Trust for each outstanding Share. Assuming a USD/euro exchange rate of $1.10, FXE would be trading at $110 per Share. A Trader borrows 50,000 Shares of FXE and sells them for $5.5 million to obtain a short position of 50,000 Shares. At the same time, to hedge the short exposure to euros, the Trader obtains a long position in euros by entering into a forward contract to purchase in one year 4.98 million euros for $5.478 million. The Trader holds these positions for a year, by which time the FXE has predictably decayed by the 40 basis point management fee, regardless of the change in the USD/euro exchange rate.

Payment of the management fee by the Trust results in the sale of euros, causing the number of euros per Share to fall from 100 euros for each Share to 99.6 euros for each Share. As a result, the Trader can now create 50,000 Shares by depositing only 4.98 million euros, which the Trader can purchase for $5.478 million, and return the borrowed Shares. The $20,000 difference in cost to create 50,000 Shares one year after selling short 50,000 Shares for $5.5 million is profit. The Trader's transaction costs would be the cost of the forward contract, commissions, and any fees charged by the lender.

Example 2—Redeeming FXE

Before the trade, there are 100 euros in the Euro Trust for each outstanding Share. Assuming a USD/euro exchange rate of $1.10, FXE would be trading at $110 per Share. A Trader borrows 50,000 Shares of FXE and redeems them in exchange for 5 million euros. The Trader uses the proceeds of the redemption as collateral for the stock borrow. The Trader holds this position for a year. Regardless of whether the USD/euro exchange rate rises or falls, the amount of euros per Share held by the Trust will fall because of the Management Fee Decay.

When the Trader redeemed the Shares, there were one hundred euros in the Euro Trust for each outstanding Share. During the year, the Euro Trust has had to sell euros to pay management fees, and therefore there are now only 99.6 euros per outstanding Share in the Euro Trust. As a result, the Trader will only have to deposit 4.98 million euros to create 50,000 Shares of FXE. The 20,000 euros difference between the 5 million euros received from redeeming 50,000 Shares and the 4.98 million euros cost to create 50,000 Shares one year later is the Trader's profit. The Trader's transaction costs would be commissions and any fees charged by the lender.

C. The Exchange's Description of the Alleged Harm Caused by the ''Strategy''

According to the Exchange, shareholders who do not lend their Shares to Traders subsidize the Strategy employed by the lenders and Traders. The long holder of Shares agrees to pay a management fee for exposure to the underlying currency. When a shareholder lends its Shares, it retains the benefit of exposure to the euros or yen in a Trust. However, according to the Exchange, a Trader that borrows the Shares and redeems or sells its borrowed Shares deprives a Trust of the assets against which the management fee is assessed. The lender retains a long position in the Shares even though the assets reflecting its long position are no longer in a Trust and thus do not bear a proportional cost of managing the assets in a Trust. In this way, according to the Exchange, lenders and Traders that engage in the Strategy are subsidized by long holders of the Shares that do not lend their Shares.[12]

The Exchange represents that the Sponsor continues to bear the cost of providing shareholder services to shareholders that lend Shares to Traders, even though, because Traders sell or redeem these borrowed Shares, there are no assets associated with these borrowed Shares against which a management fee is assessed to support these services. Long holders of Shares that do not lend to Traders are, according to the Exchange, bearing the costs associated with lenders' long positions in Shares that Traders redeem or sell. Through the loan arrangement, the Exchange alleges, the lender and Trader share the economics of the predictable fall in the value of the Shares due to the Management Fee Decay. Long holders of Shares that do not lend their Shares are subsidizing this Strategy through their assets against which the management fee is assessed.

According to the Exchange, this Strategy is not available with asset classes other than exchange-traded products because shares of operating companies do not charge management fees or provide investors with the ability to redeem their shares in exchange for the underlying assets. Thus, shares of a company do not have a decay that is extrinsic to the value of the company or a structure that provides the ability for the holder of a short interest to perfectly hedge its short position.

According to the Exchange, the Strategy discussed above is detrimental to liquidity in the Shares. The Exchange asserts that, because of the large outstanding short positions in the Shares, it is difficult to borrow Shares, particularly for market participants that are not Authorized Participants[13] that are seeking to engage in short selling for trading strategies other than the Strategy. According to the Exchange, the availability of the Strategy provides an incentive for third parties to short the Shares of the Trusts, thereby depleting the pool of Shares potentially available to be borrowed by market participants that are not Authorized Participants. This activity, according to the Exchange, impedes the ability of market makers that are not Authorized Participants to provide liquidity by taking short positions in the Shares, potentially resulting in market makers' public quotes being wider than would be the case if Shares were more readily borrowable. A lack of liquidity and

[12] According to the Exchange, an amendment to the depositary trust agreement (''Trust Agreement'') states that the impact on ''Beneficial Owners'' (as defined in each Trust Agreement) is that they may be subsidizing short positions to their disadvantage. The Trust Agreement defines ''Beneficial Owner'' consistent with Article 8 of the Uniform Commercial Code as ''any Person owning, through DTC, a DTC Participant, or an Indirect Participant, a Share.'' The lender of Shares would be the Beneficial Owner and would be required to pay the ''ETF Loan Fee,'' as described below. If the borrower sells the Shares, the buyer would be a Beneficial Owner under this definition. Because the loan would also be recorded on the books of Depository Trust Company (''DTC''), the borrower also is a Beneficial Owner when the Beneficial Owner takes delivery of the Shares.

[13] An ''Authorized Participant'' is a DTC Participant that is a registered broker-dealer or other securities market participant such as a bank or other financial institution that is not required to register as a broker-dealer to engage in securities transactions and has entered into a Participant Agreement with the Trustee. Only Authorized Participants may place orders to create or redeem Baskets.

wider spreads harms all investors through higher costs to buy and sell Shares.

D. The Exchange's Proffered Justification for the Proposed Rule Change

The Exchange has filed this proposed rule change to reflect a proposed fee (''ETF Loan Fee'') to be imposed on securities lending and repurchase transactions with respect to the Shares. The Sponsor would receive the proceeds of the ETF Loan Fee, minus an amount equal to 20 percent of the fee, which would be paid to Precidian Investments, LLC (''Precidian'' or ''Loan Fee Administrator''). Precidian has in turn engaged BNY Mellon to act as ''Loan Fee Collection Agent'' on its behalf. The Loan Fee Collection Agent would be paid by Precidian and would not further reduce the proceeds paid to the Sponsor. According to the Exchange, Guggenheim would use the net proceeds from the ETF Loan Fee to offset management fees otherwise payable to it by the Trusts or to pay other Trust-related expenses.

According to the Exchange, the Sponsor believes, and has advised the Trustee, that it is in the best interest of the Beneficial Owners to impose an ''ETF Loan Fee.'' [14] The Sponsor believes the ETF Loan Fee would benefit the Trusts and Beneficial Owners because ETF Loan Fee proceeds received (net of amounts retained by the Loan Fee Administrator) would be used to offset management fees. The Exchange believes that the ETF Loan Fee would compensate for the loss of a management fee against long positions held by lenders of Shares to Traders. Because Traders redeem or sell borrowed Shares, no assets relating to the borrowed Shares remain in the Trusts against which the management fee can be assessed. Nevertheless, the lender retains a long position in the Shares. Thus, according to the Exchange, the ETF Loan Fee is intended to fairly reflect the cost to a Trust and Beneficial Owners of the Strategy.

The procedures proposed by the Trusts would prohibit any shareholder from lending any Shares to another person (''Loan Transaction''), or selling any Shares to another person subject to an agreement to repurchase Shares (''Repurchase Transaction'' and, together with a Loan Transaction, collectively, ''Permissible Stock Loan''), unless the shareholder notifies the custodian or its designee of the transaction on or prior to the inception of the Permissible Stock Loan. A shareholder engaging in a Permissible Stock Loan (''Loaning Shareholder'') also would be required to notify the custodian or its designee of the termination of the Permissible Stock Loan on or prior to the termination of such transaction. For the pendency of the Permissible Stock Loan, the Loaning Shareholder would be obligated to pay the custodian the ETF Loan Fee with respect to that transaction. For these Loan Transactions, the ETF Loan Fee would accrue from the effective date of the ETF Loan Fee until the Loan Transaction is terminated.

Upon the ETF Loan Fee Effective Date, holders of Shares would be prohibited from lending Shares or selling Shares subject to an agreement to repurchase, without notifying the Loan Fee Collection Agent [15] and agreeing to pay the ETF Loan Fee. Self-reporting to the Loan Fee Collection Agent would be made by a shareholder's custodian, broker-dealer, or lending agent via a web portal and would not require identification of the individual shareholder.

According to the Exchange, the ETF Loan Fee is expected to equal Guggenheim's management fee on a per Share basis.[16] The Exchange states that Guggenheim has asserted that it is not permitted to contribute revenue collected via the ETF Loan Fee to the Trusts, but has stated that it intends to offset all fees received against management fees otherwise owed to it by the Trusts.

According to the Exchange, once the ETF Loan Fee Collection Agent is notified of a transaction subject to the ETF Loan Fee, it would convey such information to Precidian, which would accrue the ETF Loan Fee on a daily basis and report it to each Trust. On a monthly basis, Precidian or its agent would bill Depository Trust & Clearing Corporation participants based on their loan transactions or the loan transactions of their clients and distribute the net ETF Loan Fee to Guggenheim.[17]

The Exchange represents that, because the proposed ETF Loan Fee is equal to the annual management fee, the proposed ETF Loan Fee should not affect the market in the Shares, including market makers' ability to arbitrage. According to the Exchange, if, for example, FXE Shares are trading at a premium to euros, an arbitrageur, in an attempt to profit from the difference between the price of a euro and a Share of FXE, could sell FXE short, simultaneously buy euros, exchange euros for one or more Baskets of 50,000 FXE Shares, and then close out the short position with the Basket or Baskets of FXE Shares. To minimize market risk, an arbitrageur typically would not carry a position in to the next trading day. Thus, because the short position was closed out the same day, the arbitrageur would not incur the ETF Loan Fee. If FXE Shares are trading at a discount to euros, an arbitrageur could buy one or more Baskets of FXE Shares and simultaneously sell euros short, redeem the FXE Shares for euros at the end-of-day NAV, and close out the euro short position with the euros received on redemption. In this case, because the arbitrageur did not acquire a short position in FXE Shares, no ETF Loan Fee would be incurred. The Exchange also notes that market makers can create new Shares and redeem Shares if needed to facilitate market making activity.

The Exchange believes that the Strategy has had a negative impact on shareholders who do not lend their Shares because lenders of Shares maintain a long exposure to the Trust while profiting from a Strategy that eliminates the assets in trust against which a management fee is assessed. According to the Exchange, these lenders are freeriding on the

[14] According to the Exchange, the term ''ETF Loan Fee'' means that amount, accrued daily and payable monthly, equal to the annual management fee, which is an annual nominal rate of 0.40% (or such lower annual nominal rate as may be determined by the Sponsor from time to time) of the aggregate market value of the Shares involved in the ''Permissible Stock Loan'' (as defined below) based on the closing price each day from the inception date of such transaction through the termination of such transaction. The Exchange states that, based on current market valuations, the ETF Loan Fee for Shares of the Euro Trust would be approximately 1/8 cent per Share per day, and for Shares of the Yen Trust would be approximately 1/11 cent per Share per day as of March 27, 2015. The Exchange states that the proposed ETF Loan Fee would be implemented upon effectiveness of amendments to the Trust Agreements and approval of this proposed rule change and after sixty days' notice to shareholders (''ETF Loan Fee Effective Date''). The ETF Loan Fee would apply to any Shares loaned or sold subject to an agreement to repurchase after the sixty day notification period.

[15] Holders will be required to notify the Loan Fee Collection Agent at the inception and termination of all Share lending and repurchase transactions. Each Trust's Web site will specify the form and manner of delivery for notices to the Loan Fee Collection Agent.

[16] According to the Exchange, Guggenheim has informed the Exchange that it expects the ETF Loan Fee to be 40 basis points per annum.

[17] According to the Exchange, the administration and collection of the ETF Loan Fee, as a fee of the Trusts, would be the responsibility of the Sponsor, the Loan Fee Administrator and the Loan Fee Collection Agent. The Exchange would have no role in the administration or collection and would not monitor the billing, collection, or payment of the ETF Loan Fee with respect to any market participant.

management fee paid by those shareholders that do not lend Shares.

The Exchange represents that, as a consequence of the Strategy, the issuer cannot achieve economies of scale necessary to reduce management fees charged to shareholders, which are being paid only by those shareholders who do not lend their Shares. Assessing the ETF Loan Fee would have a positive impact on shareholders that do not lend their Shares because the ETF Loan Fees would be used to offset Trust expenses, bringing down the management fee.

The Exchange states that the ETF Loan Fee would eliminate the economic incentive for market participants to engage in the Strategy. Market participants could still sell FXE and FXY short, but the Traders who borrow those Shares would not be subsidized by those shareholders who do not lend their Shares. According to the Exchange, eliminating the economic distortion created by the Strategy would facilitate pricing of FXE and FXY on parity with the underlying asset (*i.e.,* euros or yen).

II. Proceedings To Determine Whether To Approve or Disapprove SR–NYSEArca–2015–68 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act [18] to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is 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,[19] 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,'' and ''to protect investors and the public interest.'' [20]

[18] 15 U.S.C. 78s(b)(2)(B).

[19] *Id.*

[20] 15 U.S.C. 78f(b)(5).

III. 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.[21]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal should be approved or disapproved by December 15, 2015. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by December 29, 2015. 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,[22] in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on the following:

1. In general, do commenters believe that the proposal is consistent with the requirements of Section 6 of the Act applicable to a national securities exchange, and in particular, Section 6(b)(5) of the Act, which requires that the rules of a national securities exchange be designed, among other things, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and Section 6(b)(8) of the Act, which requires that the rules of an exchange not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act?

2. According to the Exchange, ''a Trader that borrows the Shares and redeems or sells its borrowed Shares deprives a Trust of the assets against which the management fee is assessed.'' [23] Do commenters agree with this assertion? What, if any, broader policy implications do commenters think this assertion raises?

3. The Exchange states: ''Long holders of Shares that do not lend to Traders are bearing the costs associated with lenders' long position in Shares that Traders redeem or sell.'' Do commenters agree with this assertion? What, if any, broader policy implications do commenters think this assertion raises?

4. According to the Exchange, the Strategy permits certain Traders to profit from the reduction in the NAV of the Shares over time associated with Management Fee Decay, to the detriment of the value of the Shares held by shareholders who do not engage in the Strategy. The Exchange further represents that, as a consequence of the Strategy, the issuer cannot achieve economies of scale necessary to reduce management fees charged to shareholders, which are being paid only by those shareholders who do not lend their Shares. Assessing the ETF Loan Fee would, the Exchange asserts, have a positive impact on shareholders that do not lend their Shares because the ETF Loan Fees would be used to offset Trust expenses, bringing down the management fee. Do commenters agree with the Exchange's assertions? What, if any, broader policy implications do commenters think these assertions raise?

5. The Exchange asserts that the Strategy discussed above is detrimental to liquidity in the Shares and that the Strategy potentially results wider spreads, harming all investors through higher costs to buy and sell Shares. Based on the trading history of the Shares, do commenters agree with the Exchange's assertions? Are these assertions by the Exchange consistent with the Exchange's statement elsewhere in the Notice that it ''believes that imposition of the ETF Loan Fee would not materially impact trading of the Shares''? [24]

6. The Exchange states that eliminating the economic distortion allegedly created by the Strategy would facilitate pricing of FXE and FXY on parity with the underlying asset (*i.e.,* euros or yen). Based on past and current spreads between the market price per

[21] Section 19(b)(2) of the Act, as amended by the Securities Act Amendments of 1975, Pub. L. 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).

[22] *See supra* note 3.

[23] *See* Notice, *supra* note 3 at 7, 80 FR at 50702.

[24] *See id.* at 15, 80 FR at 50705.

Share for the Trusts and their respective NAVs, do commenters agree with the Exchange's assertions? Have commenters observed any problems with respect to the trading or valuation of FXE or FXY? For example, do commenters believe that the markets prices for these products closely track the underlying values of their portfolios?

7. Have commenters observed the Strategy being employed with respect to FXE or FXY, and if so, have commenters observed any deleterious effects of the Strategy?

8. The Exchange asserts that the Strategy is not available with asset classes other than exchange-traded products.[25] Do commenters agree with this assertion? If commenters believe that the Strategy is available for exchange-traded products, do commenters believe that certain exchange-traded products or types of exchange-traded products are more susceptible to the Strategy than others? For example, would an exchange-traded product be susceptible to Management Fee Decay if the returns on its portfolio exceeded its management fee? Does the nature of the assets held by an exchange-traded product affect its vulnerability to the alleged Strategy?

9. The Exchange states that the sponsor represents that, ''because of large outstanding short positions in the shares . . . it is difficult to borrow shares, particularly for market participants that are not Authorized Participants that are seeking to engage in short selling for trading strategies other than the Strategy.'' [26] What are commenters' views of these assertions?

10. What are the prevailing securities lending rates that commenters have observed for shares of FXE and FXY? Do commenters have a view regarding whether the Strategy is viable under these observed securities lending rates?

11. The Exchange states that, according to the sponsor, ''the ETF Loan Fee is not expected to negatively affect short selling generally, but rather only affect certain types of short selling activities conducted by certain market participants (namely the Strategy) at the expense of long investors.'' [27] What are commenters' views concerning this assertion? For example, what are commenters' views about the effect of the proposed rule change on investors who wish to express a bearish view on either the euro or the yen, or to hedge a long position in euros or yen, by holding a short position in shares of the Trusts over some period of time?

12. The proposal would prohibit any holder of the Shares from lending its shares or from entering into an agreement to repurchase the shares unless the holder (a) self-reports to an agent of the sponsor of the Trusts and (b) remits a fee to that agent equal to the sponsor's management fee. What are commenters' views regarding the policy implications of permitting an issuer of securities to place such restrictions on the transfer of shares that it has issued in a public offering and that are listed and traded on a national securities exchange? In particular, are such restrictions consistent with Sections 6(b)(5) and 6(b)(8) of the Act? What are commenters' views on whether a fee based on self-reporting of lending or repurchase activity can be administered in a manner consistent with Section 6(b)(5) of 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–2015–68 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–2015–68. 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–2015–68 and should be submitted on or before December 15, 2015. Rebuttal comments should be submitted by December 29, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

Robert W. Errett,

Deputy Secretary.

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[25] *See id.* at 7, 80 FR at 50703.

[26] *See id.* at 8, 80 FR at 50703.

[27] *See id.* at 16, 80 FR at 50705.

[28] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 31905; 812–14451]

ETF Series Solutions and U.S. Global Investors, Inc.; Notice of Application November 18, 2015

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application under Section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from Section 15(a) of the Act and Rule 18f–2 under the Act, as well as from certain disclosure requirements in Rule 20a–1 under the Act, Item 19(a)(3) of Form N–1A, Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A under the Securities Exchange Act of 1934, and Sections 6–07(2)(a), (b), and (c) of Regulation S–X (''Disclosure Requirements''). The requested exemption would permit an investment adviser to hire and replace certain sub-advisers without shareholder approval and grant relief from the Disclosure Requirements as they relate to fees paid to the sub-advisers.

APPLICANTS: ETF Series Solutions (the ''Trust''), a Delaware statutory trust registered under the Act as an open-end management investment company with multiple series, and U.S. Global Investors, Inc., a Texas corporation registered as an investment adviser under the Investment Advisers Act of 1940 (''the ''Adviser,'' and, collectively with the Trust, the ''Applicants'').

FILING DATES: The application was filed April 28, 2015, and amended on September 25, 2015.

HEARING OR NOTIFICATION OF HEARING: An order granting the application 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 December 14, 2015, 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: Susan B. McGee and James L. Love, U.S. Global Investors, Inc., 7900 Callaghan Road, San Antonio, TX 78229; and Michael D. Barolsky, ETF Series Solutions, 615 E. Michigan Street, Milwaukee, WI 53202.

FOR FURTHER INFORMATION CONTACT: Emerson S. Davis, Senior Counsel, at (202) 551–6868, or Daniele Marchesani, 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 an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Summary of the Application

1. The Adviser will serve as the investment adviser to the Funds pursuant to an investment advisory agreement with the Trust (the ''Investment Management Agreement'').[1] The Adviser will provide the Funds with continuous and comprehensive investment management services subject to the supervision of, and policies established by, each Fund's board of trustees (''Board'').[2] The Investment Management Agreement permits the Adviser, subject to the approval of the Board, to delegate to one or more sub-advisers (each, a ''Sub-Adviser'' and collectively, the ''Sub-Advisers'') the responsibility to provide the day-to-day portfolio investment management of each Fund, subject to the supervision and direction of the Adviser. The primary responsibility for managing the Funds will remain vested in the Adviser. The Adviser will hire, evaluate, allocate assets to and oversee the Sub-Advisers, including determining whether a Sub-Adviser should be terminated, at all times subject to the authority of the Board.

2. Applicants request an exemption to permit the Adviser, subject to Board approval, to hire certain Sub-Advisers pursuant to Sub-Advisory Agreements and materially amend existing Sub-Advisory Agreements without obtaining the shareholder approval required under Section 15(a) of the Act and Rule 18f–2 under the Act.[3] Applicants also seek an exemption from the Disclosure Requirements to permit a Fund to disclose (as both a dollar amount and a percentage of the Fund's net assets): (a) The aggregate fees paid to the Adviser and any Wholly-Owned Sub-Advisers; and (b) the aggregate fees paid to Sub-Advisers other than Affiliated Sub-Advisers and Wholly-Owned Sub-Advisers; and (c) the fee paid to each Affiliated Sub-Adviser (collectively, ''Aggregate Fee Disclosure*'').*

3. Applicants agree that any order granting the requested relief will be subject to the terms and conditions stated in the Application. Such terms and conditions provide for, among other safeguards, appropriate disclosure to Fund shareholders and notification about sub-advisory changes and enhanced Board oversight to protect the interests of the Funds' shareholders.

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 provisions of the Act, or any rule thereunder, if such relief is necessary or appropriate in the public interest and consistent with the protection of investors and purposes fairly intended by the policy and provisions of the Act. Applicants believe that the requested relief meets this standard because, as further explained in the Application, the Advisory Agreements will remain subject to shareholder approval, while the role of the Sub-Advisers is substantially similar to that of individual portfolio managers, so that requiring shareholder approval of Sub-Advisory Agreements would impose unnecessary delays and expenses on the Funds. Applicants believe that the requested relief from the Disclosure Requirements meets this standard because it will improve the Adviser's ability to negotiate fees paid to the Sub-Advisers that are more advantageous for the Funds.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–29868 Filed 11–23–15; 8:45 am]

BILLING CODE 8011–01–P

[1] Applicants request relief with respect to any existing and any future series of the Trust and any other registered open-end management company or series thereof that: (a) Is advised by the Adviser or its successor or by a person controlling, controlled by, or under common control with the Adviser or its successor (each, also an ''Adviser''); (b) uses the manager of managers structure described in the application; and (c) complies with the terms and conditions of the application (any such series, a ''Fund'' and collectively, the ''Funds''). For purposes of the requested order, ''successor'' is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[2] Certain Funds (each, a ''Feeder Fund'') may invest substantially all of their assets in a ''Master Fund'' pursuant to Section 12(d)(1)(E) of the Act.

[3] The requested relief will not extend to any Sub-Adviser, other than a Wholly-Owned Sub-Adviser, that is an affiliated person, as defined in Section 2(a)(3) of the Act, of a Fund, a Feeder Fund or the Adviser, other than by reason of serving as a sub-adviser to one or more of the Funds (''Affiliated Sub-Adviser''). A ''Wholly-Owned Sub-Adviser'' is (1) an indirect or direct ''wholly owned subsidiary'' (as such term is defined in Section 2(a)(43) of the Act) of the Adviser for that Fund, or (2) a sister company of the Adviser for that Fund that is an indirect or direct wholly-owned subsidiary of the same company that, indirectly or directly, wholly owns the Adviser.

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14541 and #14542]

California Disaster #CA–00241

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of California dated 11/17/2015.

Incident: Severe Rain, Flooding and Debris Flows.

Incident Period: 10/15/2015.

Effective Date: 11/17/2015.

Physical Loan Application Deadline Date: 01/19/2016.

Economic Injury (EIDL) Loan Application Deadline Date: 08/17/2016.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance,

U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Los Angeles.
Contiguous Counties: California: Kern, Orange, San Bernardino, Ventura.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.750
Homeowners Without Credit Available Elsewhere	1.875
Businesses With Credit Available Elsewhere	6.000
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	2.625
Non-Profit Organizations Without Credit Available Elsewhere	2.625
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.625

The number assigned to this disaster for physical damage is 14541 B and for economic injury is 14542 0.

The States which received an EIDL Declaration # are California.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: November 17, 2015.

Maria Contreras-Sweet,

Administrator.

[FR Doc. 2015–29860 Filed 11–23–15; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 9352]

Culturally Significant Objects Imported for Exhibition Determinations: ''Keir Collection of Art of the Islamic World'' Exhibitions

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that objects to be included in multiple exhibitions of the Keir Collection of Art of the Islamic World, imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at the Dallas Museum of Art, Dallas, Texas, and at possible additional exhibitions or venues yet to be determined, from on about December 17, 2016, until on or about November 23, 2020, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the objects covered under this notice, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: November 18, 2015.

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015–29900 Filed 11–23–15; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 9353]

Additional Culturally Significant Objects Imported for Exhibition Determinations: ''Power and Pathos: Bronze Sculpture of the Hellenistic World'' Exhibition

ACTION: Notice; correction.

SUMMARY: On May 21, 2015, notice was published on pages 29379 and 29380 of the **Federal Register** (volume 80, number 98) of determinations made by the Department of State pertaining to certain objects imported for temporary display in the exhibition ''Power and Pathos: Bronze Sculpture of the Hellenistic World.'' The referenced notice is corrected here to include additional objects as part of the exhibition. Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the additional objects to be included in the exhibition ''Power and Pathos: Bronze Sculpture of the Hellenistic World,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The additional objects are imported pursuant to loan agreements with the foreign owner or custodian. I also determine that the exhibition or display of the additional exhibit objects at the National Gallery of Art, Washington, District of Columbia, from on or about December 13, 2015, until on or about March 20, 2016, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the additional imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: November 18, 2015.

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015–29899 Filed 11–23–15; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 9354]

Culturally Significant Object Imported for Exhibition Determinations: ''Jan Van Eyck's Crucifixion and Last Judgment: New Discoveries'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and

Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the object to be included in the exhibition ''Jan Van Eyck's Crucifixion and Last Judgment: New Discoveries,'' imported from abroad for temporary exhibition within the United States, is of cultural significance. The object is imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit object at The Metropolitan Museum of Art, New York, New York, from on about January 25, 2016, until on or about April 24, 2016, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a description of the imported object, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: November 16, 2015.

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015–29898 Filed 11–23–15; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 9355]

Culturally Significant Objects Imported for Exhibition Determinations: ''Titanosaur'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition ''Titanosaur,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at the American Museum of Natural History, New York, New York, from on or about January 15, 2016, until on or about December 1, 2016, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: November 16, 2015.

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015–29919 Filed 11–23–15; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: B4UFLY Smartphone App

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The FAA's B4UFLY smartphone app will provide situational awareness of flight restrictions—including locations of airports, restricted airspace, special use airspaces, and temporary flight restrictions—based on a user's current or planned flight location.

DATES: Written comments should be submitted by January 25, 2016.

ADDRESSES: Send comments to the FAA at the following address: Ronda Thompson, Room 441, Federal Aviation Administration, ASP–110, 950 L'Enfant Plaza SW., Washington, DC 20024.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Ronda Thompson at (202) 267–1416, or by email at: *Ronda.Thompson@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0764.

Title: B4UFLY Smartphone App.

Form Numbers: There are no forms associated with this collection.

Type of Review: Renewal of an information collection.

Background: Public Law 112–95, section 336 requires model aircraft operators to notify the airport operator and air traffic control tower (if one is located at the airport) prior to operating within 5 miles of an airport. The FAA's B4UFLY smartphone app will provide situational awareness of flight restrictions—including locations of airports, restricted airspace, special use airspaces, and temporary flight restrictions—based on a user's current or planned flight location. In order to maintain NAS safety in proximity to airports, air traffic control personnel would need certain basic information about a UAS operator's intended flight in order to assess whether the UAS may disrupt or endanger manned air traffic.

Respondents: Approximately 1000 beta testers.

Frequency: 5 submissions per week.

Estimated Average Burden per Response: approximately 2 minutes.

Estimated Total Annual Burden: 1,485 hours.

Issued in Washington, DC on November 18, 2015.

Ronda Thompson,

FAA Information Collection Clearance Officer, Performance, Policy, and Records Management Branch, ASP–110.

[FR Doc. 2015–29924 Filed 11–23–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Dealer's Aircraft Registration Certificate Application

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to reinstate a previously discontinued information collection. AC Form 8050–5 is an application for a dealer's Aircraft Registration Certificate which, under 49 United States Code 1404, may be issued to a person engaged in manufacturing, distributing, or selling aircraft.

DATES: Written comments should be submitted by January 25, 2016.

ADDRESSES: Send comments to the FAA at the following address: Ronda Thompson, Room 441, Federal Aviation Administration, ASP–110, 950 L'Enfant Plaza SW., Washington, DC 20024.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Ronda Thompson at (202) 267–1416, or by email at: *Ronda.Thompson@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0024.

Title: Dealer's Aircraft Registration Certificate Application.

Form Numbers: FAA Form 8050–5.

Type of Review: Reinstatement of an information collection.

Background: Federal Aviation Regulation part 47 prescribes procedures that implement 103, which provides for the issuance of dealer's aircraft registration certificates and for their use in connection with aircraft eligible for registration under this Act by persons engaged in manufacturing, distributing or selling aircraft. Dealer's certificates enable such persons to fly aircraft for sale immediately without having to go through the paperwork and expense of applying for and securing a permanent Certificate of Aircraft Registration. It also provides a system of identification of aircraft dealers.

Respondents: Approximately 3,904 applicants.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 45 minutes.

Estimated Total Annual Burden: 2,928 hours.

Issued in Washington, DC on November 18, 2015.

Ronda Thompson,

FAA Information Collection Clearance Officer, Performance, Policy, and Records Management Branch, ASP–110.

[FR Doc. 2015–29913 Filed 11–23–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Approval of Noise Compatibility Program, Ted Stevens Anchorage International Airport and Lake Hood Seaplane Base, Anchorage, AK

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its findings on the Noise Compatibility Program submitted by the Alaska Department of Transportation & Public Facilities (ADOT&PF) under the provisions of 49 U.S.C. (the Aviation Safety and Noise Abatement Act, hereinafter referred to as ''the Act'') and 14 CFR Part 150. These findings are made in recognition of the description of Federal and nonfederal responsibilities in Senate Report No. 96–52 (1980). On July 27, 2015, the FAA determined that the noise exposure maps (NEM) submitted by the ADOT&PF under Part 150 were in compliance with applicable requirements. On November 17, 2015, the FAA approved the Ted Stevens Anchorage International Airport (ANC) and Lake Hood Seaplane Base (LHD) noise compatibility program (NCP). Most of the recommendations of the program were approved.

DATES: *Effective Date:* The effective date of the FAA's approval of the ANC and LHD NCP is November 17, 2015.

FOR FURTHER INFORMATION CONTACT: Leslie Grey, Federal Aviation Administration, Alaskan Region Airports Division, 222 W. 7th Avenue, Annex Building, Rm. A36, Anchorage, Alaska 99513, phone number: 907–271–5453. Documents reflecting this FAA action may be reviewed at this same location by appointment with the above contact.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA has given its overall approval to the NCP for ANC and LHD effective November 17, 2015.

Under Section 47504 of the Act, an airport operator who has previously submitted a NEM may submit to the FAA a NCP which sets forth the measures taken or proposed by the airport operator for the reduction of existing non-compatible land uses and prevention of additional non-compatible land uses within the area covered by the NEM. The Act requires such programs to be developed in consultation with interested and affected parties including local communities, government agencies, airport users, and FAA personnel.

Each airport NCP developed in accordance with Title 14 Code of Federal Regulations (CFR) Part 150 is a local program, not a Federal Program. The FAA does not substitute its judgment for that of the airport operator with respect to which measures should be recommended for action. The FAA's approval or disapproval of each specific measure proposed by an airport sponsor in an Record of Approval (ROA) is determined by applying approval criteria prescribed in 14 CFR 150.35(b):

The Administrator approves programs under this part, if—

(1) It is found that the program measures to be implemented would not create an undue burden on interstate or foreign commerce (including any unjust discrimination) and are reasonably consistent with achieving the goals of reducing existing noncompatible land uses around the airport and of preventing the introduction of additional noncompatible land uses;

(2) The program provides for revision if made necessary by the revision of the noise map; and

(3) Those aspects of programs relating to the use of flight procedures for noise control can be implemented within the period covered by the program and without—

(i) Reducing the level of aviation safety provided;

(ii) Derogating the requisite level of protection for aircraft, their occupants and persons and property on the ground;

(iii) Adversely affecting the efficient use and management of the Navigable

Airspace and Air Traffic Control Systems; or

(iv) Adversely affecting any other powers and responsibilities of the Administrator prescribed by law or any other program, standard, or requirement established in accordance with law.

Approval is not a determination concerning the acceptability of land uses under Federal, state, or local law. Approval does not by itself constitute an FAA implementing action. A request for Federal action or approval to implement specific noise compatibility measures may be required, and an FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the program nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA. Where Federal funding is sought, requests for project grants must be submitted to the FAA Airports District Office in Anchorage, AK.

ADOT&PF submitted to the FAA on December 19, 2014, the NEM, descriptions, and other documentation produced during the NCP planning study conducted from November 17, 2011 through December 19, 2014. The ANC and LHD NEMs were determined by FAA to be in compliance with applicable requirements on July 27, 2015. Notice of this determination was published in the Federal Register on July 31, 2015.

The ANC and LHD study contains a proposed NCP comprised of actions designed for phased implementation by airport management and adjacent jurisdictions from November 17, 2015 to the year 2020. It was requested that FAA evaluate and approve this material as a NCP as described in Section 47504 of the Act. The FAA began its review of the NCP on July 27, 2015, and was required by provisions of the Act to approve or disapprove the program within 180-days (other than the use of new or modified flight procedures for noise control). Failure to approve or disapprove such program within the 180-day period shall be deemed to be an approval of such program.

The submitted program contained fifteen (15) proposed actions for noise mitigation on and off the airport. The FAA completed its review and determined that the procedural and substantive requirements of the Act and 14 CFR Part 150 have been satisfied. The overall program, therefore, was approved by the FAA effective November 17, 2015.

Outright approval was granted for twelve (12) proposed actions on and/or off the airport. Two of the proposed measures in the NCP were disapproved for purposes of 14 CFR Part 150 because the measures benefit land uses with noise levels below the 65 DNL. Another measure was disapproved because it is eligible for funding as a terminal improvement per the AIP Handbook. However, these measures could be implemented by the Airport Sponsor on a voluntary basis.

These determinations are set forth in detail in a Record of Approval (ROA) signed by the FAA on November 17, 2015. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal, are available for review at the FAA office listed above and at the administrative office of the ADOT&PF. The Record of Approval also will be available on-line at: *http://www.faa.gov/airports/environmental/airport_noise/part_150/states/ak/.*

Issued in Anchorage, Alaska on November 17, 2015.

Kristi A. Warden,

Acting Division Manager, Alaskan Region Airports Division.

[FR Doc. 2015–29916 Filed 11–23–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Operating Requirements: Commuter and On-Demand Operation

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. Title 49 U.S.C., section 44702 authorizes issuance of air carrier operating certificates. 14 CFR part 135 prescribes requirement for Air Carrier/Commercial Operators. The info collected shows compliance and applicant eligibility.

DATES: Written comments should be submitted by January 25, 2016.

ADDRESSES: Send comments to the FAA at the following address: Ronda Thompson, Room 441, Federal Aviation Administration, ASP–110, 950 L'Enfant Plaza SW., Washington, DC 20024.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Ronda Thompson at (202) 267–1416, or by email at: *Ronda.Thompson@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0039.

Title: Operating Requirements: Commuter and On-Demand Operation.

Form Numbers: There are no forms associated with this collection.

Type of Review: Renewal of an information collection.

Background: Title 49 U.S.C., section 44702 authorizes issuance of air carrier operating certificates. 14 CFR part 135 prescribes requirement for Air Carrier/Commercial Operators. Each operator which seeks to obtain, or is in possession of, an air carrier or FAA operating certificate must comply with the requirements of 14 CFR part 135 in order to maintain data which is used to determine if the carrier is operating in accordance with minimum safety standards. Air carrier and commercial operator certification is completed in accordance with 14 CFR part 119. Part 135 contains operations and maintenance requirements.

Respondents: Approximately 2,426 operators.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: approximately 7.7 minutes.

Estimated Total Annual Burden: 1,154,674 hours.

Issued in Washington, DC, on November 18, 2015.

Ronda Thompson,

FAA Information Collection Clearance Officer, Performance, Policy, and Records Management Branch, ASP–110.

[FR Doc. 2015–29922 Filed 11–23–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Pilot Schools—FAR 141

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. 49 U.S.C. 44707 empowers the Administrator of the Federal Aviation Administration (FAA) to provide for the examination and rating of civilian schools giving instruction in flying. This CFR prescribes the requirements for issuing pilot school certificates, provisional pilot school certificates and associated ratings to qualified applicants.

DATES: Written comments should be submitted by January 25, 2016.

ADDRESSES: Send comments to the FAA at the following address: Ronda Thompson, Room 441, Federal Aviation Administration, ASP–110, 950 L'Enfant Plaza SW., Washington, DC 20024.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Ronda Thompson at (202) 267–1416, or by email at: *Ronda.Thompson@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0009.

Title: Pilot Schools—FAR 141.

Form Numbers: FAA Form 8420–8.

Type of Review: Renewal of an information collection.

Background: The information on FAA Form 8420–8, Application for Pilot School Certificates, is required from applicants who wish to be issued pilot school certificates and associated ratings. Pilot schools train private, commercial, flight instructor, and airline transport pilots, along with training for associated ratings in various types of aircraft. The form is also necessary to assure continuing compliance with part 141, renewal of certificates every 24 months, and for any amendments to pilot school certificates, FAA approval of pilot school certificate amendments enables schools to provide new training courses not previously approved.

Respondents: Approximately 546 applicants.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 27 hours.

Estimated Total Annual Burden: 29,770 hours.

Issued in Washington, DC, on November 18, 2015.

Ronda Thompson,

FAA Information Collection Clearance Officer, Performance, Policy, and Records Management Branch, ASP–110.

[FR Doc. 2015–29923 Filed 11–23–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA 2015–0007–N–29]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Requests (ICRs) abstracted below are being forwarded to the Office of Management and Budget (OMB) for review and comment. The ICRs describes the nature of the information collections and their expected burdens. The **Federal Register** notice with a 60-day comment period soliciting comments on the following collections of information was published on March 3, 2015 (80 FR 11518).

DATES: Comments must be submitted on or before December 24, 2015.

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly Toone, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Ave. SE., Mail Stop 35, Washington, DC 20590 (telephone: (202) 493–6132). (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, sec. 2, 109 Stat. 163 (1995) (codified as revised at 44 U.S.C. 3501–3520), and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. 44 U.S.C. 3506, 3507; 5 CFR 1320.5, 1320.8(d)(1), 1320.12. On September 21, 2015, FRA published a 60-day notice in the **Federal Register** soliciting comment on ICR that the agency was seeking OMB approval. *See* 80 FR 57044. FRA received no comments after issuing this notice. Accordingly, these information collection activities have been re-evaluated and certified under 5 CFR 1320.5(a) and are being forwarded to OMB for review and approval pursuant to 5 CFR 1320.12(c).

Before OMB decides whether to approve these proposed collections of information, it must provide 30 days for public comment. 44 U.S.C. 3507(b); 5 CFR 1320.12(d). Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30 day notice is published. 44 U.S.C. 3507 (b)–(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983, Aug. 29, 1995. OMB believes that the 30 day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983, Aug. 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect. 5 CFR 1320.12(c); *see also* 60 FR 44983, Aug. 29, 1995.

Below is a brief summary of the information collection activities that FRA will submit for clearance by OMB as required under the PRA:

Title: Grant Awards and Cooperative Agreements.

Abstract: FRA solicits grant applications for viable projects including, but not limited to, preconstruction planning activities, safety improvements, congestion relief, improvement of grade crossings, rail line relocation, as well as projects that encourage development, expansion, and upgrades to passenger and freight rail infrastructure and services. Funded projects are those that meet FRA and government wide evaluation standards and align with the President's key strategic transportation goals to create safe and efficient transportation choices, build a foundation for economic competitiveness, promote energy efficiency and environmental quality, and support interconnected livable communities.

FRA administers award agreements for both construction and non-construction projects that will result in service benefits or other tangible improvements in rail corridors. These projects include completion of preliminary engineering, environmental research and development, final design, and construction.

To ensure accountability of Federal award recipients through performance and results, including expenditures in support of agreed-upon activities and allowable costs outlined in a FRA Notice of Grant Award (NGA), FRA requires systematic and uniform collection and submission of information, as approved by the OMB. Included in this information collection are reports and documentation mandated by OMB for completion, as well as additional resources to compile evidence relevant to addressing FRA's important policy challenges, promoting cost-effectiveness in FRA programs, and providing effective oversight of programmatic and financial performance. This justification draws on innovative FRA program designs to use sophisticated practices in delivering Federal financial assistance and encourage continuous improvements in service delivery.

FRA issues and manages awards in compliance with Title 2 of the Code of Federal Regulations (CFR): Grants and Agreements. This justification includes one document package for collection over the entire lifecycle of the award process, in adherence to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (78 FR 78589, Dec. 26, 2013; 79 FR 75871, Dec. 19, 2014). All non-research awards are subject to the application, reporting, closeout, and other processes described in this justification.

Additionally, the collection detailed in this justification represents a combination of previous FRA collection requests, including: OMB Control Number 2130–0578, OMB Control Number 2130–0580, OMB Control Number 2130–0584, and OMB Control Number 0587. Combining these collections under a new collection enables FRA to consolidate documentation under one collection, which allows for efficiency and provides a uniform period until expiration of this justification request.

Form Number(s): FRA forms 30, 31, 32, 33, 34, 35, and 229. SF forms 270, 424, 424A, 424B, 424C, 424D, 425, and LLL.

Affected Public: State and local governments, government sponsored authorities and corporations, and railroads.

Total Estimated Annual Burden: 39,521 hours.

Pursuant to 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Rebecca Pennington,

Chief Financial Officer.

[FR Doc. 2015–29892 Filed 11–23–15; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

[Docket No. TTB–2015–0001]

Proposed Information Collections; Comment Request (No. 56)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau (TTB); Treasury.

ACTION: Notice and request for comments.

SUMMARY: As part of our continuing effort to reduce paperwork and respondent burden, and as required by the Paperwork Reduction Act of 1995, we invite comments on the proposed or continuing information collections listed below in this notice.

DATES: We must receive your written comments on or before January 25, 2016.

ADDRESSES: As described below, you may send comments on the information collections listed in this document using the ''Regulations.gov'' online comment form for this document, or you may send written comments via U.S. mail or hand delivery. TTB no longer accepts public comments via email or fax.

- *http://www.regulations.gov:* Use the comment form for this document posted within Docket No. TTB–2015–0001 on ''Regulations.gov,'' the Federal e-rulemaking portal, to submit comments via the Internet;
- *U.S. Mail:* Michael Hoover, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005.
- *Hand Delivery/Courier in Lieu of Mail:* Michael Hoover, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 400, Washington, DC 20005.

Please submit separate comments for each specific information collection listed in this document. You must reference the information collection's title, form or recordkeeping requirement number, and OMB number (if any) in your comment.

You may view copies of this document, the information collections listed in it and any associated instructions, and all comments received in response to this document within Docket No. TTB–2015–0001 at *http://www.regulations.gov.* A link to that docket is posted on the TTB Web site at *http://www.ttb.gov/forms/comment-on-form.shtml.* You may also obtain paper copies of this document, the information collections described in it and any associated instructions, and any comments received in response to this document by contacting Michael Hoover at the addresses or telephone number shown below.

FOR FURTHER INFORMATION CONTACT: Michael Hoover, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; telephone 202–453–1039, ext. 135; or email *informationcollections@ttb.gov* (please *do not* submit comments on this notice to this email address).

SUPPLEMENTARY INFORMATION:

Request for Comments

The Department of the Treasury and its Alcohol and Tobacco Tax and Trade Bureau (TTB), as part of their continuing effort to reduce paperwork and respondent burden, invite the general public and other Federal agencies to comment on the proposed or continuing information collections listed below in this notice, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Comments submitted in response to this notice will be included or summarized in our request for Office of Management and Budget (OMB) approval of the relevant information collection. All comments are part of the public record and subject to disclosure. Please do not include any confidential or inappropriate material in your comments.

We invite comments on: (a) Whether this information collection is necessary for the proper performance of the agency's functions, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the information collection's burden; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the information collection's burden on respondents, including through the use of automated

collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide the requested information.

Information Collections Open for Comment

Currently, we are seeking comments on the following forms, recordkeeping requirements, or questionnaires:

Title: Letterhead Applications and Notices Filed by Brewers, TTB REC 5130/2; and Brewer's Notice.

OMB Number: 1513–0005.

TTB Form Number: F 5130.10.

TTB Recordkeeping Requirement Number: REC 5130/2.

Abstract: The Internal Revenue Code (IRC) requires brewers to file a notice of intent to operate a brewery. TTB F 5130.10, the Brewer's Notice, collects information similar to that collected on a permit application and, when approved by TTB, is a brewer's authorization to operate. The brewer shall maintain the approved Brewer's Notice and all associated documents at the brewery premises, in complete and current condition, readily available for inspection by an appropriate TTB officer. The regulations also require that a brewer submit a letterhead application or notice to conduct certain activities, such as to vary from regulatory requirements or to alternate brewery premises. Letterhead applications and notices are necessary to identify brewery activities so that TTB may ensure that proposed operations would comply with the IRC and would not jeopardize Federal revenues.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated number of burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 2,974.

Estimated Total Annual Burden Hours: 14,870.

Title: Formula and Process for Wine.

OMB Number: 1513–0010.

TTB Form Number: F 5120.29.

Abstract: Proprietors intending to produce a special wine, other than standard wine or nonbeverage wine, must obtain TTB's prior approval of the formula by which the wine, or wine product made from wine, is to be made. Such proprietors may file formula approval requests on TTB F 5120.29, which describes the person filing, the type of product to be made, and the ingredients and process by which the product is to be made. TTB also may use the form to audit the product.

Current Actions: TTB is submitting this collection as a revision. The information collection requirement remains unchanged. However, we are revising the burden estimate to reflect a decrease in the number of respondents to this information collection and the resulting burden hours. Industry members are increasingly using TTB F 5100.51 or Formulas Online to submit formula approval requests to TTB (see 1513–0122), which has resulted in a decrease in the number of respondents submitting this form.

Type of Review: Revision of a currently-approved collection.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 30.

Estimated Total Annual Burden Hours: 60.

Title: Power of Attorney.

OMB Number: 1513–0014.

TTB Form Number: F 5000.8.

Abstract: The Internal Revenue Code (IRC) at 26 U.S.C. 6061 provides that any documents filed by industry members under the provisions of the IRC must be signed and filed in accordance with the forms and regulations prescribed by the Secretary of the Treasury. Also, the Federal Alcohol Administration Act at 27 U.S.C. 204(c) states that the Secretary shall prescribe the manner and form of all applications for basic permits under the Act. The TTB regulations require individuals signing documents and forms filed with TTB on behalf of an applicant or principal to have specific authority to do so on their behalf. TTB F 5000.8 is used to delegate authority to a specific individual to sign documents on behalf of an applicant or principal.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated number of burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 5,000.

Estimated Total Annual Burden Hours: 3,250.

Title: Letterhead Applications and Notices Relating to Wine.

OMB Number: 1513–0057.

TTB Recordkeeping Requirement Number: REC 5120/2.

Abstract: The Internal Revenue Code (IRC) regulates certain aspects of wine production and treatment because the production and treatment affect the volume of taxable wine produced. The IRC also imposes standards for natural wine, cellar treatment of natural wine, agricultural wine, and the labeling of all wines in order to protect consumers and protect the product integrity of the wine. TTB therefore requires proprietors to file letterhead applications and notices relating to certain production and treatment activities to ensure that the intended activity will not jeopardize the revenue or defraud consumers.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated number of burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 1,650.

Estimated Total Annual Burden Hours: 825.

Title: Airlines Withdrawing Stock from Customs Custody.

OMB Number: 1513–0074.

TTB Recordkeeping Number: REC 5620/2.

Abstract: Airlines may withdraw tax exempt distilled spirits, wine, and beer from Customs custody for foreign flights. The required record shows, among other things, the amount of spirits and wine withdrawn, flight identification, and Customs certification. As a result, it maintains accountability over distilled spirits and wine and protects tax revenue.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated number of burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 25.

Estimated Total Annual Burden Hours: 2,500.

Title: Alcohol, Tobacco, and Firearms Related Documents for Tax Returns and Claims.

OMB Number: 1513–0088.

TTB Recordkeeping Requirement Number: REC 5000/24.

Abstract: TTB is responsible for the collection of Federal excise taxes on firearms, ammunition, distilled spirits,

wine, beer, tobacco products, and cigarette papers and tubes, and the collection of special occupational taxes related to tobacco products and cigarette papers and tubes. The Internal Revenue Code (IRC) requires that these excise and special occupational taxes be collected on the basis of a return and requires taxpayers to maintain records that support the information in the return. The IRC also allows for the filing of claims for the abatement or refund of taxes under certain circumstances, and the IRC requires claimants to maintain records to support such claims. The maintenance of records is necessary to determine the appropriate tax liability, verify computations on tax returns, determine the adequacy of bond coverage, and verify the correctness of claims and other adjustments to tax liability.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated number of burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits; Not-for-profit institutions, Individuals or Households.

Estimated Number of Respondents: 503,921.

Estimated Total Annual Burden Hours: 503,921.

Dated: November 17, 2015.

Amy R. Greenberg,

Director, Regulations and Rulings Division.

[FR Doc. 2015–29879 Filed 11–23–15; 8:45 am]

BILLING CODE 4810–31–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 510

Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 510

[CMS–5516–F]

RIN 0938–AS64

Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements a new Medicare Part A and B payment model under section 1115A of the Social Security Act, called the Comprehensive Care for Joint Replacement (CJR) model, in which acute care hospitals in certain selected geographic areas will receive retrospective bundled payments for episodes of care for lower extremity joint replacement (LEJR) or reattachment of a lower extremity. All related care within 90 days of hospital discharge from the joint replacement procedure will be included in the episode of care. We believe this model will further our goals in improving the efficiency and quality of care for Medicare beneficiaries with these common medical procedures.

DATES: These regulations are effective on January 15, 2016, and applicable on April 1, 2016 when the first model performance period begins.

FOR FURTHER INFORMATION CONTACT: Claire Schreiber, *Claire.Schreiber@cms.hhs.gov*, 410 786 8939.

Gabriel Scott, *Gabriel.Scott@cms.hhs.gov*, 410 786 3928.

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Printing Office. This database can be accessed via the internet at *http://www.gpo.gov/fdsys/.*

Alphabetical List of Acronyms

Because of the many terms to which we refer by acronym, abbreviation, or short form in this final rule, we are listing the acronyms, abbreviations and short forms used and their corresponding terms in alphabetical order.

μSA Micropolitan Statistical Area
ACE Acute Care Episode
ACO Accountable Care Organization
APM Alternative Payment Model
ASC Ambulatory Surgical Center
ASPE Assistant Secretary for Planning and Evaluation
BPCI Bundled Payments for Care Improvement
CAH Critical Access Hospital
CBSA Core-Based Statistical Area
CCN CMS Certification Number
CFR Code of Federal Regulations
CJR Comprehensive Care for Joint Replacement
CMHC Community Mental Health Center
CMI Case Mix Index
CMMI Center for Medicare and Medicaid Innovation
CMP Civil Monetary Penalty
CMS Centers for Medicare & Medicaid Services
CoPs Conditions of Participation
CPCi Comprehensive Primary Care Initiative
CPT Current Procedural Terminology
CSA Combined Statistical Area
DME Durable Medical Equipment
DMEPOS Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
eCQM Electronic Clinical Quality Measures
EFT Electronic funds transfer
ESRD End-Stage Renal Disease
FFS Fee-for-service
GAAP Generally Accepted Accounting Principles
GEM General Equivalence Mapping
GPCI Geographic Practice Cost Index
HAC Hospital-Acquired Condition
HACRP Hospital-Acquired Condition Reduction Program
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCC Hierarchical Condition Category
HCPCS Healthcare Common Procedure Coding System
HHA Home health agency
HHPPS Home Health Prospective Payment System
HHRG Home Health Resource Group
HHVBP Home Health Value-Based Purchasing
HIT Health Information Technology
HIQR Hospital Inpatient Quality Reporting
HLMR HCAHPS Linear Mean Roll Up
HOOS Hip Dysfunction and Osteoarthritis Outcome Score
HOPD Hospital outpatient department
HRR Hospital Referral Region
HRRP Hospital Readmissions Reductions Program
HVBP Hospital Value Based Purchasing Program
ICD–9–CM International Classification of Diseases, 9th Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, 10th Revision, Clinical Modification
IPPS Inpatient Prospective Payment System
IPF Inpatient psychiatric facility
IRF Inpatient rehabilitation facility
KOOS Knee Injury and Osteoarthritis Outcome Score
LEJR Lower extremity joint replacement
LOS Length of stay
LTCH Long term care hospital
LUPA Low Utilization Payment Adjustment
MAC Medicare Administrative Contractor
MACRA Medicare Access and Chip Reauthorization Act of 2015
MAPCP Multi-Payer Advanced Primary Care Practice model
MCC Major Complications or Comorbidities
MCCM Medicare Care Choices Model
MDH Medicare-Dependent Hospital
MedPAC Medicare Payment Advisory Commission
MIPS Merit-based Incentive Payment System
MP Malpractice
MPFS Medicare Physician Fee Schedule
MSA Metropolitan Statistical Area
MS–DRG Medical Severity Diagnosis-Related Group
NPI National Provider Identifier
NPP Nonphysician Practitioner
NPRA Net Payment Reconciliation Amount
NQF National Quality Forum
OCM Oncology Care Model
OPPS Outpatient Prospective Payment System
PAC Post-Acute Care
PBPM Per Beneficiary Per Month
PE Practice Expense
PGP Physician Group Practice
PHA Partial hip arthroplasty
PPS Prospective Payment System
PRO Patient-Reported Outcome
PROMIS Patient-Reported Outcomes Measurement Information Systems
PRO–PM Patient-Reported Outcome Performance Measure
QIO Quality Improvement Organization
RAC Recovery Audit Contractor
RRC Rural Referral Center
RSCR Risk-Standardized Complication Rate
RSRR Risk-Standardized Readmission Rate
RVU Relative Value Unit
SCH Sole Community Hospital
SNF Skilled nursing facility
THA Total hip arthroplasty
TIN Taxpayer identification number
TKA Total knee arthroplasty
TP Target price
VR–12 Veterans Rand 12 Item Health Survey

Table of Contents

I. Executive Summary

A. Purpose

The purpose of this final rule is to implement a new payment model called the Comprehensive Care for Joint Replacement (CJR) model under the authority of the Center for Medicare and Medicaid Innovation (CMMI). Section 1115A of the Social Security Act (the Act) authorizes CMMI to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. The intent of the CJR model is to promote quality and financial accountability for episodes of care surrounding a lower-extremity joint replacement (LEJR) or reattachment of a lower extremity procedure.[1] CJR will test whether bundled payments to acute care hospitals for LEJR episodes of care will reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate the CJR model will benefit Medicare beneficiaries by improving the coordination and transition of care, improving the coordination of items and services paid for through Medicare Fee-For-Service (FFS), encouraging more provider investment in infrastructure and redesigned care processes for higher quality and more efficient service delivery, and incentivizing higher value care across the inpatient and post-acute care (PAC) spectrum spanning the episode of care. We will test the CJR model for 5 performance periods, beginning April 1, 2016, and ending December 31, 2020. Under FFS, Medicare makes separate payments to providers and suppliers for the items and services furnished to a beneficiary over the course of treatment (an episode of care). With the amount of payments dependent on the volume of services delivered, providers may not have incentives to invest in quality improvement and care coordination activities. As a result, care may be fragmented, unnecessary, or duplicative.

We have previously used our statutory authority under section 1115A of the Act to test bundled payment models such as the Bundled Payments for Care Improvement (BPCI) initiative. Bundled payments, for multiple services in an episode of care, hold participating organizations financially accountable for an episode of care. They also allow participants to receive payment, in part, based on the reduction in expenditures for Medicare arising from their care redesign efforts.

We believe the CJR model will further the mission of CMMI and the Secretary's goal of increasingly paying for value rather than for volume,[2] because it will promote the alignment of financial and other incentives for all health care providers and suppliers caring for a beneficiary during an LEJR episode. In the CJR model, the acute care hospital that is the site of surgery will be held accountable for spending during the episode of care. Participant hospitals will be afforded the opportunity to earn performance-based payments by appropriately reducing expenditures and meeting certain quality metrics. They will also gain access to data and educational resources to better understand LEJR patients' PAC needs and associated spending. Payment approaches that reward providers that assume financial and performance accountability for a particular episode of care create incentives for the implementation and coordination of care redesign between hospitals and other providers and suppliers.

The CJR model requires the participation of hospitals in multiple geographic areas that might not otherwise participate in the testing of bundled payments for episodes of care for LEJR procedures. Other episode-based, bundled payment models being tested by the Centers for Medicare & Medicaid Services (CMS), such as the BPCI initiative, are voluntary in nature. Interested participants must apply to such models to participate. To date, we have not tested an episode payment model with bundled payments in which providers are required to participate. We recognize that realizing the full potential of new payment models will require the engagement of an even broader set of providers than have participated to date, providers who may only be reached when new payment models are applied to an entire class of providers of a service. As such, we are interested in testing and evaluating the impact of a bundled payment approach for LEJR procedures in a variety of circumstances, especially among those hospitals that may not otherwise participate in such a test.

This model will allow CMS to gain experience with making bundled payments to hospitals who have a variety of historic utilization patterns; different roles within their local markets; various volumes of services; different levels of access to financial, community, or other resources; and various levels of population and health provider density including local variations in the availability and use of different categories of PAC providers. We believe that by requiring the participation of a large number of hospitals with diverse characteristics, the CJR model will result in a robust data set for evaluation of this bundled payment approach, and will stimulate the rapid development of new evidence-based knowledge. Testing the model in this manner will also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize the improvement of

[1] In this final rule, we use the term LEJR to refer to all procedures within the Medicare Severity-Diagnosis Related Groups (MS–DRGs) we selected for the model, including reattachment of a lower extremity, as described in section III.B.2.a. of this final rule.

[2] Sylvia Mathews Burwell, *HHS Secretary, Progress Towards Achieving Better Care, Smarter Spending, Healthier People, http://www.hhs.gov/blog/2015/01/26/progress-towards-better-care-smarter-spending-healthier-people.html* (January 26, 2015).

quality for common LEJR procedure episodes. This learning potentially could inform future Medicare payment policy.

This final rule implements a model focused on episodes of care for LEJR procedures. We chose LEJR episodes for the CJR model because as discussed in depth in section III.C. of this final rule, these are high-expenditure, high utilization procedures commonly furnished to Medicare beneficiaries,[3] where significant variation in spending for procedures is currently observed. The high volume of episodes and variation in spending for LEJR procedures create a significant opportunity to test and evaluate the CJR model that specifically focuses on a defined set of procedures. Moreover, there is substantial regional variation in PAC referral patterns and the intensity of PAC provided for LEJR patients, thus resulting in significant variation in PAC expenditures across LEJR episodes initiated at different hospitals. The CJR model will enable hospitals to consider the most appropriate PAC for their LEJR patients. The CJR model additionally will offer hospitals the opportunity to better understand their own processes with regard to LEJR, as well as the processes of post-acute providers. Finally, while many LEJR procedures are planned, the CJR model will provide a useful opportunity to identify efficiencies both for when providers can plan for LEJR procedures and for when the procedure must be performed urgently.

The following is a summary of the comments received on the proposed model as a whole, including the authority for the model and general comments on CMS' implementation of the CJR model at this time and our responses.

Comment: A commenter stated that while the proposed rule emphasized the learning CMS hoped to gain from implementing and testing the CJR model, it made inadequate mention of the potential benefits to beneficiaries, providers, hospitals, and other stakeholders. Other commenters contended that bundled payment models encourage hospitals to engage in care stinting and potentially stifle innovation.

Response: We appreciate the commenters' concerns. We refer readers to section III.F. of this final rule for discussion of monitoring and beneficiary protections under this model which we believe will address the commenters' concerns about care stinting. We expect that the CJR model will benefit not just CMS, but also beneficiaries, hospitals, and other providers in the health care system. The goals of this model are to improve the quality of care furnished to beneficiaries and reduce spending during LEJR episodes. Beneficiaries would directly benefit from improved care coordination and care redesign activities that reduce readmissions and complications rates, for example, as well as provide an improved care experience during the inpatient hospitalization and post-discharge period. Hospitals also stand to benefit from the CJR model, in the form of the opportunity to earn reconciliation payments if successful under the model, and a structured incentive to redesign care processes for beneficiaries receiving LEJR procedures. For example, section III.C.11. of this final rule details waivers of Medicare program rules that would allow hospitals to test additional ways to introduce flexibility into care processes and improve the quality of care for beneficiaries. In addition, providers and suppliers across the spectrum of care provided during an LEJR episode could also benefit from the care redesign strategies as well as the financial arrangements as detailed in section III.C.10. of this final rule. Finally, we disagree with commenters that the CJR model will stifle innovation for care furnished during an LEJR episode. We proposed, and are finalizing in this final rule, a payment methodology that will account for changes in care patterns and utilization trends for LEJR episodes by updating the historical performance periods used throughout the model, as described in section III.C.4. of this final rule. In addition, the CJR financial incentives would be consistent with clinical practices that result in reductions of spending during LEJR episodes, allowing hospitals that engage in such practices to earn reconciliation payments and engage with other providers furnishing services during the episode, as discussed in section III.C.10. of this final rule.

Comment: Several commenters questioned CMS' legal authority to require participation in a model. Commenters stated that CMS lacks the legal authority to compel participation in a model, and that CMS misreads section 1115A(a)(5) of the Act as the legal basis for compelling providers in selected Metropolitan Statistical Area (MSAs) to participate in the CJR model. A commenter stated that language in the Act has never been interpreted to afford the Secretary the authority to compel provider participation in a Medicare demonstration project or model, and that the Congress intended for model tests to be voluntary, not mandatory, when authorizing CMS to test new models. The commenter noted that requiring providers to participate in a model that would encompass a substantial proportion of a particular service would render the statutory distinction between testing and expanding models meaningless. The commenter also expressed concern about the model's potential effect on beneficiaries' appeal rights. Several commenters stated that CMS is sidestepping the legal safeguards designed to prevent the Agency from imposing novel or haphazard models on providers prior to adequate testing and evaluation. Commenters also claimed that CMS had exceeded its statutory authority because under section 1115A of the Act, providers are precluded from appealing their selection in a model, raising further concern that CMS is overreaching by requiring participation in the CJR model. Commenters also noted that there is no precedent for a CMS demonstration or model that requires providers to participate. Finally, several commenters stated that CMS has reversed the intended sequence of testing and then expanding models.

Response: We disagree with commenters that we lack the legal authority to test the CJR model as proposed and specifically, to require the participation of selected hospitals. We note that although CJR will be the first Innovation Center model in which acute care hospitals are required to participate, we refer readers to the 2016 Home Health Prospective Payment System (HHPS) Final Rule, which finalizes the Home Health Value-Based Purchasing (HHVBP) model. Home health agencies in selected states will be required to participate in the HHVBP model beginning in January 2016.

We believe that both section 1115A and the Secretary's existing authority to operate the Medicare program authorize the CJR model as we have proposed and are finalizing it. Section 1115A of the Act authorizes the Secretary to test payment and service delivery models intended to reduce Medicare costs while preserving quality. The statute does not

[3] For example, total hip arthroplasty and total knee arthroplasty procedures are very high volume LEJR procedures that together represent the largest payments for procedures under Medicare. Suter L, Grady JL, Lin Z *et al.*: 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). 2013. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*; Bozic KJ, Rubash HE, Sculco TP, Berry DJ., An analysis of Medicare payment policy for total joint arthroplasty. J Arthroplasty. Sep 2008; 23(6 Suppl 1):133–138.

require that models be voluntary, but rather gives the Secretary broad discretion to design and test models that meet certain requirements as to spending and quality. Although section 1115A(b) of the Act describes a number of payment and service delivery models that the Secretary may choose to test, the Secretary is not limited to those models. Rather, models to be tested under section 1115A of the Act must address a defined population for which there are either deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. Here, the CJR model addresses a defined population (FFS Medicare beneficiaries undergoing LEJR procedures) for which there are potentially avoidable expenditures (arising from less than optimal care coordination). For the reasons described elsewhere in this rule, we have determined that it is necessary to test this model among varying types of hospitals that have not chosen to voluntarily participate in another episode payment model such as BPCI. As noted elsewhere in this final rule, we are testing an episode approach for LEJR episodes through the voluntary BPCI models. We have designed the CJR model to require participation by hospitals in order to avoid the selection bias inherent to any model in which providers may choose whether to participate. Such a design will allow for testing of how a variety of hospitals will fare under an episode payment approach, leading to a more robust evaluation of the model's effect on all types of hospitals. We believe this is the most prudent approach for the following reasons. The information gained from testing of the CJR model will allow CMS to more comprehensively assess whether LEJR episode payment models are appropriate for any potential national expansion. We will have evaluation information on results for providers who are participating in such models voluntarily (under BPCI) as well as for hospitals that are required to participate in CJR. Under CJR, we will have tested and evaluated such a model across a wide range of hospitals representing varying degrees of experience with episode payment. We believe it is important to gain knowledge from a variety of perspectives in considering whether and which models merit national expansion. Thus, the CJR model meets the criteria required for initial model tests.

Moreover, the Secretary has the authority to establish regulations to carry out the administration of Medicare. Specifically, the Secretary has authority under both sections 1102 and 1871 of the Act to implement regulations as necessary to administer Medicare, including testing this Medicare payment and service delivery model. We note that while CJR will be a model, and not a permanent feature of the Medicare program, the model will test different methods for delivering and paying for services covered under the Medicare program, which the Secretary has clear legal authority to regulate. The proposed rule went into great detail about the provisions of the proposed CJR model, enabling the public to fully understand how the proposed model was designed and could apply to affected providers. We acknowledge section 1115A(d)(2) of the Act, which states that there shall be no administrative or judicial review of, among other things, ''the selection of organizations, sites, or participants to test . . . models selected,'' as well as the commenter's concern that this provision would preclude a participant hospital from appealing its selection as a participant in the CJR model. However, it is precisely because the model will impose new requirements upon participant hospitals that we undertook notice and comment rulemaking to implement it.

In response to the comment indicating that we misread section 1115A(a)(5) of the Act, we believe that the commenter misunderstood the reference to that provision in the proposed rule. The reference to section 1115A(a)(5) of the Act was made in the context of the discussion of selecting certain MSAs within which we will test the model. We do not rely on section 1115A(a)(5) of the Act specifically as the authority for a model in which participation is not voluntary; rather, as noted previously, we rely on section 1115A of the Act as a whole, as well as the Secretary's existing authority to carry out her duties and administer the Medicare program.

We disagree with commenters that implementing the CJR model will negatively affect beneficiaries' appeal rights. We note that normal claims processes will continue under this model, including beneficiary and provider appeal rights. We also refer readers to section III.C.9. of this final rule for discussion of hospital appeals procedures under the CJR model.

With regard to the comment about CMS sidestepping safeguards designed to prevent imposing haphazard models prior to appropriate vetting and testing, we reiterate that we have undertaken rulemaking to solicit comprehensive public input on all aspects of the CJR model. In addition, as previously noted, the CJR model has been designed to limit selection bias, which will allow for more robust evaluation results across a variety of providers.

We note that this is a new model, not an expansion of an existing model. We disagree with the commenters who believe that we have reversed the order of testing and expansion of Innovation Center models. As permitted by section 1115A of the Act, we are testing the CJR model within specified limited geographic areas. The fact that the model will require the participation of certain hospitals does not mean it is not an initial model test. If the model is successful such that it meets the statutory requirements for expansion, and the Secretary determines that expansion is warranted, we would undertake rulemaking to implement the expansion, as required by section 1115A(c) of the Act.

Comment: Several commenters questioned how the proposed CJR model relates to the potential for expansion of BPCI. Commenters also noted that CMS included language in the FY 2016 IPPS/LTCH PPS proposed rule requesting public input on an eventual expansion of BPCI.

Response: CMMI's three major priorities include testing new payment and service delivery models, evaluating results and advancing best practices, and engaging stakeholders. Since 2011, we have been working to develop and test models of bundling Medicare payments under the authority of section 1115A of the Act. Consistent with its ongoing commitment to develop new models and refine existing models based on additional information and experience, we may modify existing models or test additional models under our authority under section 1115A of the Act. The CJR model is a new, additional episode payment model being tested under the authority of section 1115A of the Act. As such, it is not an expansion of the BPCI initiative, which needs further evaluation to determine its impact on both Medicare cost and quality before the Secretary can determine whether the findings from the evaluation of the initiative demonstrate that it meets all criteria for expansion, consistent with the requirements of section 1115A(c) of the Act, and that, based on these findings and other pertinent factors, expansion is warranted.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24414 through 24418), we solicited public comments regarding policy and operational issues related to a potential expansion of the BPCI initiative in the future. We explained that as we initiated discussions about potential expansion, we continued to value stakeholder

engagement within the framework of our three priorities. With respect to expansion, section1115A(c) of the Act, as added by section 3021 of the Affordable Care Act, provides the Secretary with the authority to expand through rulemaking the duration and scope of a model that is being tested under section 1115A(b) of the Act, such as the BPCI initiative (including implementation on a nationwide basis), if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) The Secretary determines that the expansion is expected to either reduce Medicare spending without reducing the quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net Medicare program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of Medicare benefits. The decision of whether or not to expand BPCI will be made by the Secretary in coordination with CMS and the Office of the Chief Actuary based on whether findings about the initiative meet the statutory criteria for expansion under section 1115A(c) of the Act. We did not propose an expansion of any of the BPCI models or any policy changes associated with those models in the FY 2016 IPPS/LTCH PPS proposed rule.

Although BPCI and the CJR model both include testing episode payment for LEJR episodes of care, CJR differs from BPCI in significant ways, as detailed throughout this final rule. Providers elected to participate in BPCI, and were given a choice of various design features, such as the clinical episodes included and the episode length. The CJR model was designed in part based on feedback and experience from BPCI, and will provide additional information on the impact of episode payment for LEJR episodes across a variety of hospitals, including those who may not have elected to participate in the model. As previously discussed in this section, it is necessary to require participation in the CJR model in order to avoid the selection bias inherent to any voluntary model. When the CJR model begins on April 1, 2016, we will be testing both episode payment models concurrently for a period of time, as well as many other payment and service delivery models, in order to gain information about the most successful strategies to improve the quality of care and reduce spending. The different design features of BPCI and the CJR model will aid us in evaluating the success of episode-based payment across a range of provider types and in a range of geographic areas. As evaluation results addressing the impact of each model on Medicare quality and cost become available, the Secretary will review this information to determine whether the findings from the evaluation of the model demonstrate that it meets all criteria for expansion, consistent with the requirements of section 1115A(c) of the Act, and that, based on these findings and other pertinent factors, expansion is warranted.

Comment: Many commenters requested changes to the BPCI model in response to the proposed rule. Commenters also requested clarification on how BPCI awardees would be transitioned into the CJR model; for example, which performance year policies would apply to the new model participants.

Response: We will not address comments about BPCI policies in this final rule. We will address commenters' suggestions on BPCI through our usual processes for informing BPCI participants and the public of any changes to BPCI. As discussed in section III.A of this final rule, all Inpatient Prospective Payment System (IPPS) hospitals in the selected MSAs that are not participating in BPCI Model 1 or Phase II of Models 2 or 4 for LEJR episodes would be included in the CJR model. We intend for the current performance year's policies to be in effect for any new entrants in the CJR model. We also note that an acute care hospital formerly participating in BPCI for the LEJR episode will have likely established care coordination and redesign strategies for success. As such, it would not be necessary to grant such hospitals additional time to transition from BPCI into the CJR model.

Comment: Numerous commenters requested that physicians who enter into sharing arrangements with CJR hospitals qualify as eligible professionals under the Medicare Access and Chip Reauthorization Act of 2015 (MACRA) beginning in 2019. A commenter requested that all CJR collaborators qualify as eligible professionals under MACRA. Several commenters outlined wholly different structures for the proposed CJR model, including provisions that would allow for the CJR model to qualify as an alternative payment model (APM) under MACRA.

Response: We interpret commenters' requests as follows: That collaborators under the CJR model would be able to meet the requirements that would otherwise apply under the Merit-based Incentive Payment System (MIPS) or, alternatively, qualify as APM participants under section 1833(z)(2) of the Act (and therefore be excluded from MIPS) through their participation in CJR. We further interpret commenters' requests as follows: That CJR would include eligible alternative payment entities, and therefore that eligible professionals in CJR would potentially be qualifying APM participants. We note that the statute specifies which types of individuals qualify as eligible professionals (EPs) under section 1848(k)(3)(B) of the Act or as MIPS EPs under section 1848(q)(1)(C) of the Act. We plan to develop regulations under MACRA through notice and comment rulemaking. We will be releasing further guidance on the implementation of MACRA, and through such guidance, will be clarifying the parameters for eligibility under MACRA.

Comment: Several commenters presented different episode payment models for CMS' consideration to be tested in addition to or instead of the CJR model, or suggested such major changes to the proposed CJR model design elements that the result of their adoption would be a wholly different test of episode payment than CMS proposed. A few commenters recommended that CMS consider testing a model that emphasizes the role of PAC providers in managing episode care for beneficiaries, instead of just the hospital. Such a model would assign financial responsibility during an episode to a PAC entity with capabilities to coordinate care across a wide range of post-acute settings. Other commenters suggested that CMS test a model that would create physician-led organizations to manage financial risk for LEJR episodes of care, instead of assigning risk to hospitals. These organizations would receive prospective episodic payments and allocate such payments among the providers and suppliers furnishing care to beneficiaries during an LEJR episode. Several commenters recommended CMS implement a population-based model similar to an Accountable Care Organization (ACO) model, in lieu of an episode-based payment model. Finally, a commenter requested that instead of including rural and low-volume hospitals in the CJR model, CMS develop a model tailored to this subset of providers.

Response: We appreciate the suggestions for alternatives to the CJR model design that were recommended by the commenters, including the details and rationale provided about many features of those models. We are

not adopting these approaches to an episode payment model under this final rule as we did not propose the design elements of such models for public notice and comment nor did we propose the additional policies that would be required to implement such features that do not rely on existing Medicare definitions (for example, the definition of a physician-led organization to manage risk). However, we note that we are constantly considering modifications to existing models and designing new models under our testing authority under section 1115A of the Act, taking into consideration stakeholder input received through many channels, including public comments on this proposed rule and the FY 2016 IPPS/LTCH PPS proposed rule discussion item on potential BPCI expansion considerations, as well as feedback from providers participating in existing models. We note that potential modifications to the CJR model would go through notice and comment rulemaking as necessary. As we consider developing additional payment service and delivery models, we will continue to engage with stakeholders and review all of the information available to us about alternative approaches to episode payment that could be tested.

B. Summary of the Major Provisions

1. Model Overview: LEJR Episodes of Care

LEJR procedures are currently paid under the IPPS (IPPS) through one of two Medicare Severity-Diagnosis Related Groups (MS–DRGs): MS–DRG 469 (Major joint replacement or reattachment of lower extremity with Major Complications or Comorbidities (MCC)) or MS–DRG 470 (Major joint replacement or reattachment of lower extremity without MCC). Under the CJR model, as described further in section III.B of this final rule, episodes will begin with admission to an acute care hospital for an LEJR procedure that is assigned to MS–DRG 469 or 470 upon beneficiary discharge and paid under the IPPS and will end 90 days after the date of discharge from the acute care hospital. This episode of care definition offers operational simplicity for providers and CMS. The episode will include the LEJR procedure, inpatient stay, and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, PAC, and physician services.

2. Model Scope

We have finalized that participant hospitals will be the episode initiators and bear financial risk under the CJR model. In comparison to other health care facilities, hospitals are more likely to have resources that will allow them to appropriately coordinate and manage care throughout the episode, and hospital staff members are already involved in hospital discharge planning and PAC recommendations for recovery, key dimensions of high quality and efficient care for the episode. We require all hospitals paid under the IPPS in selected geographic areas to participate in the CJR model, with limited exceptions. Eligible beneficiaries who elect to receive care at these hospitals will automatically be included in the model. We have selected geographic areas based on a stratified random sampling methodology within strata using the following criteria: historical wage adjusted episode payments and population size. Our geographic area selection process is detailed further in section III.A of this final rule.

3. Payment

We will test the CJR model for 5 performance years. We have finalized an alternative start date for the model from the timeline set forth in the proposed rule. As discussed in further detail in section III.C.2.a. of this final rule, the first performance year for the CJR model will begin on April 1, 2016 and end on December 31, 2016. During these performance years we will continue paying hospitals and other providers and suppliers according to the usual Medicare FFS payment systems. However, after the completion of a performance year, the Medicare claims payments for services furnished to the beneficiary during the episode, based on claims data, will be combined to calculate an actual episode payment. The actual episode payment is defined as the sum of related Medicare claims payments for items and services furnished to a beneficiary during a CJR episode. The actual episode payment will then be reconciled against an established CJR target price that is stratified based on the beneficiary's fracture status, with consideration of additional payment adjustments based on quality performance, post-episode spending, and policies to limit hospital financial responsibility. The amount of this calculation, if positive, will be paid to the participant hospital. This payment will be called a reconciliation payment. If negative, we will require repayment from the participant hospital. Medicare will require repayment of the difference between the actual episode payments and the CJR target price from a participant hospital if the CJR target price is exceeded.

We will make reconciliation payments to participant hospitals that achieve quality outcomes and cost efficiencies relative to the established CJR target prices in all performance years of the model. We will also phase in the requirement that participant hospitals whose actual episode payments exceed the applicable CJR target price pay the difference back to Medicare beginning in performance year 2. Under this final rule, Medicare will not require repayment from hospitals for performance year 1 for actual episode payments that exceed their target price in performance year 1.

We will also limit how much a hospital can gain or lose based on its actual episode payments relative to target prices. We have also put in place additional policies to further limit the risk of high payment cases for all participant hospitals and for special categories of participant hospitals as described in section III.C. of this final rule.

4. Similar, Previous, and Concurrent Models

The CJR model is informed by other models and demonstrations currently and previously conducted by CMS and will explore additional ways to enhance coordination of care and improve the quality of services through bundled payments. We recently announced the Oncology Care Model (OCM), a new voluntary payment model for physician practices administering chemotherapy. Under OCM, practices will enter into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients. We plan to coordinate with other payers to align with OCM in order to facilitate enhanced services and care at participating practices. More information on the OCM can be found on CMMI's Web site at: *http://innovation.cms.gov/initiatives/Oncology-Care/*. Medicare tested innovative approaches to paying for orthopedic services in the Medicare Acute Care Episode (ACE) demonstration, a prior demonstration, and is currently testing additional approaches under BPCI. Both of these models have also informed the design of the CJR model.

Under the authority of section 1866C of the Act, we conducted a 3-year demonstration, the ACE Demonstration. The demonstration used a prospective global payment for a single episode of care as an alternative approach to payment for service delivery under traditional Medicare FFS. The episode

of care was defined as a combination of Part A and Part B services furnished to Medicare FFS beneficiaries during an inpatient hospital stay for any one of a specified set of cardiac and orthopedic MS–DRGs. The MS–DRGs tested included 469 and 470, which are included in the CJR model. The discounted bundled payments generated an average gross savings to Medicare of $585 per episode for a total of $7.3 million across all episodes (12,501 episodes) or 3.1 percent of the total expected costs for these episodes. After accounting for increased PAC costs that were observed at two sites, Medicare saved approximately $4 million, or 1.72 percent of the total expected Medicare spending. More information on the ACE Demonstration can be found on CMMI's Web site at: *http://innovation.cms.gov/initiatives/ACE/*.

We are currently testing the BPCI initiative. The BPCI initiative is comprised of four related payment models, which link payments for multiple services that Medicare beneficiaries receive during an episode of care into a bundled payment. Under the initiative, entities enter into payment arrangements with CMS that include financial and performance accountability for episodes of care. Episodes of care under the BPCI initiative begin with either—(1) An inpatient hospital stay; or (2) PAC services following a qualifying inpatient hospital stay. The BPCI initiative is evaluating the effects of episode-based payment approaches on patient experience of care, outcomes, and cost of care for Medicare FFS beneficiaries. Each of the four models tests LEJR episodes of care. While final evaluation results for the models within the BPCI initiative are not yet available, we believe that CMS' experiences with BPCI support the design of the CJR model. Under section 1115A(c) of the Act, the Secretary may, taking into consideration an evaluation conducted under section 1115A (b)(4) of the Act, ''through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested under'' CMMI's authority. CJR is not an expansion of BPCI, and BPCI may be expanded in the future. We published a discussion item soliciting public comment on a potential future expansion of one or more of the models within BPCI in the FY2016 IPPS rule, 80 FR 24414 through 24418. CJR will not be an expansion or modification of BPCI; nor does it reflect comments received in response to the proposed rule for the 2016 IPPS Rule. CJR is a unique model that tests a broader, different group of hospitals than BPCI. It is necessary to provide CMS with information about testing bundled payments to hospitals that are required to participate in an APM. For a discussion of why we are requiring hospitals to participate in the CJR model, see section III.A. of this final rule.

The CJR model's design was informed to a large degree by our experience with BPCI Model 2. BPCI's Model 2 is a voluntary episode payment model in which a qualifying acute care hospitalization initiates a 30, 60 or 90 day episode of care. The episode of care includes the inpatient stay in an acute care hospital and all related services covered under Medicare Parts A and B during the episode, including PAC services. More information on BPCI Model 2 can be found on CMMI's Web site at: *http://innovation.cms.gov/initiatives/BPCI-Model-2/*.

Further information of why elements of the OCM, the ACE Demonstration, and BPCI Model 2 were incorporated into the design of the CJR model appears later in this final rule.

5. Overlap With Ongoing CMS Efforts

We are excluding from participation in CJR certain hospitals participating in the risk-bearing phase of BPCI Models 2 and 4 for LEJR episodes, as well as acute care hospitals participating in BPCI Model 1. We are not excluding beneficiaries in CJR model episodes from being included in other Innovation Center models or CMS programs, such as the Medicare Shared Savings Program (Shared Savings Program), as detailed later in this final rule. We will account for overlap, that is, where CJR beneficiaries are also included in other models and programs, to ensure the financial policies of CJR are maintained and results and spending reductions are attributed to the correct model or program.

6. Quality Measures and Reporting Requirements

We are adopting two hospital-level quality of care measures for the CJR model. Those measures include a complications measure and a patient experience survey measure. We will use these measures in the model pay-for-performance payment methodology, as well as to test the success of the model in achieving its goals under section 1115A of the Act and to monitor for beneficiary safety. We intend to publicly report this information on the *Hospital Compare* Web site. Additionally, we will encourage the voluntary submission of data to support the development of a hospital-level measure of patient-reported outcomes following an elective primary total hip (THA) or total knee arthroplasty (TKA) through incorporation of the measure in the composite quality scoring methodology described in III.C.5. of this final rule.

7. Data Sharing Process

We will share data with participant hospitals upon request throughout the performance period of the CJR model to the extent permitted by the HIPAA Privacy Rule and other applicable law. We will share upon request both raw claims-level data and claims summary data with participants. This approach will allow participant hospitals without prior experience analyzing claims to use summary data to receive useful information, while allowing those participant hospitals who prefer raw claims-level data the opportunity to analyze claims. We will provide hospitals with up to 3 years of retrospective claims data upon request that will be used to develop their target price, as described in section III.C. of this final rule. In accordance with the HIPAA Privacy Rule, we will limit the content of this data set to the minimum data necessary for the participant hospital to conduct quality assessment and improvement activities and effectively coordinate care of its patient population.

8. Beneficiary Protections

Under the CJR model, beneficiaries retain the right to obtain health services from any individual or organization qualified to participate in the Medicare program. Under the CJR model, eligible beneficiaries who receive services from a participant hospital will not have the option to opt out of inclusion in the model. We require participant hospitals to supply beneficiaries with written information regarding the design and implications of this model as well as their rights under Medicare, including their right to use their provider of choice. We will also make a robust effort to reach out to beneficiaries and their advocates to help them understand the CJR model.

We also will use our existing authority, if necessary, to audit participant hospitals if claims analysis indicates an inappropriate change in delivered services. Beneficiary protections are discussed in greater depth in section III.E. of this final rule.

9. Financial Arrangements and Program Policy Waivers

We will hold participant hospitals financially responsible for CJR LEJR episodes as participants in the model as discussed in section III.C.6. of this final

rule. Specifically, only these hospital participants will be directly subject to the requirements of this final rule for the CJR model. Participant hospitals will be responsible for ensuring that other providers and suppliers collaborating with the hospital on LEJR episode care redesign are in compliance with the terms and conditions of the model, including any applicable program policy waivers.

Several of the Medicare program policy waivers outline the conditions under which SNFs and physicians could furnish and bill for certain services furnished to CJR beneficiaries where current Medicare programs rules will not permit such billing. We draw the attention of SNFs and physicians to these waivers, which are included in section III.C.11.b.(5). of this final rule.

C. Summary of Economic Effects

As shown in our impact analysis, we expect the CJR model to result in savings to Medicare of $343 million over the 5 performance years of the model. We note that a composite quality score will be calculated for each hospital in order to determine eligibility for a reconciliation payment and whether the hospital qualifies for quality incentive payments that will reduce the effective discount percentage experience by the hospital at reconciliation for a given performance year.

More specifically, in performance year 1 of the model, we estimate a Medicare cost of approximately $11 million, as hospitals will not be subject to downside risk in the first year of the model. As we introduce downside risk beginning in performance year 2 of the model, we estimate Medicare savings of approximately $36 million. In performance year 3 of the model, we estimate Medicare savings of $71 million. In performance years 4 and 5 of the model, we will move from target episode pricing that is based on a hospital's experience to target pricing based on regional experience, we estimate Medicare savings of $120 million and $127 million, respectively.

As a result, we estimate the net savings to Medicare to be $343 million over the 5 performance years of the model. We anticipate there will be a broader focus on care coordination and quality improvement for LEJR episodes among hospitals and other providers and suppliers within the Medicare program that will lead to both increased efficiency in the provision of care and improved quality of the care provided to beneficiaries.

We note that under section 1115A(b)(3)(B) of the Act, the Secretary is required to terminate or modify a model unless certain findings can be made with respect to savings and quality after the model has begun. If during the course of testing the model it is determined that termination or modification is necessary, such actions will be undertaken through rulemaking as necessary.

II. Background

A General Background

This final rule finalizes the implementation of a new innovative health care payment model under the authority of section 1115A of the Act. Under the model, called the CJR model, acute care hospitals in certain selected geographic areas will receive bundled payments for episodes of care where the diagnosis at discharge includes a lower extremity joint replacement (LEJR) or reattachment of a lower extremity that was furnished by the hospital. The bundled payment will be paid retrospectively through a reconciliation process; hospitals and other providers and suppliers will continue to submit claims and receive payment via the usual Medicare FFS payment systems. All related care covered under Medicare Part A and Part B within 90 days after the date of hospital discharge from the joint replacement procedure will be included in the episode of care. We believe this model will further our goals of improving the efficiency and quality of care for Medicare beneficiaries for these common medical procedures.

B. Acronym of This Model

We have changed the acronym of this model to ''CJR'' and have updated all references in this rule and the regulations to reflect this change.

C. Public Comments Received in Response to the CJR Proposed Rule

We received approximately 400 timely pieces of correspondence containing multiple comments on the CJR proposed rule. We note that some of these public comments were outside of the scope of the proposed rule. These out-of-scope public comments are mentioned but not addressed with the policy responses in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading.

III. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

A. Definition of the Episode Initiator and Selected Geographic Areas

1. Background

The CJR model is different from BPCI because it would require participation of all hospitals (with limited exceptions) throughout selected geographic areas, which would result in a model that includes varying hospital types. However, a discussion of BPCI is relevant because its design informs and supports the proposed CJR model. The BPCI model is voluntary, and under that model we pay a bundled payment for an episode of care only to entities that have elected to participate in the model. We are interested in testing and evaluating the impact of an episode payment approach for LEJRs in a variety of other circumstances, including among those hospitals that have not chosen to voluntarily participate because we have not tested bundled payments for these hospitals previously. This would allow CMS and participants to gain experience testing and evaluating episode-based payment for LEJR procedures furnished by hospitals with a variety of historic utilization patterns; roles within their local markets; volume of services provided; access to financial, community, or other resources; and population and health care provider density. Most importantly, participation of hospitals in selected geographic areas will allow CMS to test bundled payments without introducing selection bias such as the selection bias inherent in the BPCI model due to self-selected participation.

2. Definition of Episode Initiator

Under the CJR model, as described further in section III.B. of this final rule, episodes will begin with admission to an acute care hospital for an LEJR procedure that is paid under the IPPS through Medical Severity Diagnosis-Related Group (MS–DRG) 469 (Major joint replacement or reattachment of lower extremity with MCC) or 470 (Major joint replacement or reattachment of lower extremity without MCC) and end 90 days after the date of discharge from the hospital. For the CJR model, we proposed that hospitals would be the only episode initiators. For purposes of CJR, the term ''hospital'' means a hospital as defined in section 1886(d)(1)(B) of the Act. This statutory definition of hospital includes only acute care hospitals paid under the IPPS. We proposed that all acute care hospitals in Maryland would be

excluded from CJR. The state of Maryland entered into an agreement with CMS, effective January 1, 2014, to participate in CMS' new Maryland All-Payer Model. In order to implement the Maryland All-Payer Model, CMS waived certain requirements of the Act, and the corresponding implementing regulations, as set forth in the agreement between CMS and Maryland. Specifically, under the Maryland All-Payer Model, Maryland acute care hospitals are not paid under the IPPS or Outpatient Prospective Payment System (OPPS) but rather are paid under rates set by the state. Following the model's performance period, Maryland will transition to a new model that incorporates the full spectrum of care, not just hospital services. As such, with respect to Maryland hospitals, CMS intends to test and develop new payment and delivery approaches that can incorporate non-hospital services in a manner that accounts for Maryland's unique hospital rate setting system and permit Maryland to develop its own strategy to incentivize higher quality and more efficient care across clinical situations within and beyond hospitals, including but not limited to LEJR episodes of care. We proposed that because Maryland hospitals are not paid under the IPPS or OPPS, payments to Maryland hospitals will be excluded in the regional pricing calculations as described in section III.C.4. of this final rule. We sought comment on whether there were potential approaches for including Maryland acute care hospitals in CJR. In addition, we sought comment on whether Maryland hospitals should be included in CJR in the future upon any termination of the Maryland All-Payer Model.

The following is a summary of the comments received and our responses.

Comment: Several commenters commented on the proposed exclusion of Maryland hospitals in the All-Payer model from the model. A commenter requested that if we are considering approaches for including Maryland acute care hospitals in the CJR model that we ensure that the inclusion of such hospitals would not jeopardize the current all-payer system in Maryland. If such an approach were to be developed, the commenter noted that it would welcome the opportunity to participate in the CJR model and further stated that it is confident that it would be successful under the CJR model in helping to further to goals of providing high quality care at lower costs to better patient outcomes and population health. Another commenter noted that Maryland's All-Payer Model Agreement is focused on holding hospitals accountable for improving care, improving health, and reducing the total cost of hospital care for all payers. Under the All-Payer model, Maryland has shifted its long-standing hospital rate-setting system from a volume-based system, focused on cost per case, to a global population-based system that incorporates performance requirements for quality and outcomes. The Maryland system will be held accountable for the total cost of care for Medicare patients under its contract with CMS and thus already has two-sided risk for hospital costs. The commenter stated that Maryland wants to work with CMS to develop a unique approach to achieving the goals of the model, but under the All-Payer model. Lastly, another commenter expressed confusion if we were announcing a plan to have Maryland transition to a new model that incorporates the full spectrum of care, not just hospital services.

Response: Under the All-Payer model, Maryland has facilitated the movement of regulated hospital revenue into population-based payment reimbursement under a hospital global budget model. We appreciate the state's efforts to move away from volume-based payments and to focus on reducing total cost of care and improving quality of care, and we have seen improvement on these areas in the first year of the All-Payer model. However, we remain concerned that certain aspects of the All-Payer Model make it challenging for Maryland to be included in other payment and delivery innovations being launched by the CMS Innovation Center. As we anticipate testing more models across the country, we do not want Maryland to fall behind in payment and delivery innovation. We are very interested in Maryland's strategy to be accountable for total cost of care beyond hospital services, which we intend to implement under the All-Payer model in 2019. We note that we are not announcing a new model for Maryland in this rule, but rather the CMS Innovation Center looks forward to working with Maryland on its total cost of care model.

Comment: Several commenters agreed with CMS that Maryland hospitals should not be included in our definition of ''hospital'' and, instead, the state of Maryland should be allowed to develop its own strategy to encourage higher quality care and efficiencies across clinical settings.

Response: We agree that for the purposes of the CJR model, the term ''hospital'' should only encompass hospitals currently paid under the IPPS and we are finalizing as proposed to exclude Maryland hospitals from the CJR model.

Final Decision: After consideration of the public comments we received, we are finalizing, for purposes of the CJR model, the term ''hospital'' to mean a hospital subject to the IPPS as defined in section 1886(d)(1)(B) of the Act. This statutory definition of hospital includes only acute care hospitals paid under the IPPS, thus excluding Maryland hospitals from participating in CJR and excluding payments to Maryland hospitals in regional pricing calculations described in section III.C.4 of this final rule. This definition will be codified in § 510.2

We proposed to designate IPPS hospitals as the episode initiators to ensure that all Medicare FFS LEJR services furnished by participant hospitals in selected geographic areas to beneficiaries who do not meet the exclusion criteria (specified in section III.B.3. and section III.C.7. of this final rule) are included in the CJR model. Given that our proposal that the LEJR episode begins with an admission to a hospital paid under the IPPS that results in a discharge assigned to MS–DRG 469 or 470, we further believed that utilizing the hospital as the episode initiator is a straightforward approach for this model because the hospital furnishes the LEJR procedure. In addition, we noted our interest in testing a broad model in a number of hospitals under the CJR model in order to examine results from a more generalized payment model. Thus, we believed it is important that, in a model where hospital participation is not voluntary, all Medicare FFS LEJR episodes that begin at the participant hospital in a selected geographic area should be included in the model for beneficiaries that do not meet the exclusion criteria specified in section III.B.3. of this final rule and are not LEJR BPCI episodes that we are excluding as outlined in this section and also in section III.C.7 of this final rule. This is best achieved if the hospital is the episode initiator. Finally, as described in the following sections that present our proposed approach to geographic area selection, this geographic area selection approach relies upon our definition of hospitals as the entities that initiate episodes. We sought comment on our proposal to define the episode initiator as the hospital under CJR. However, commenters generally commented on our proposal to define the episode initiator as the hospital in tandem with comments regarding the proposal that the hospital also be the entity financially responsible for the episode of care under CJR. As such, comments regarding the proposed

episode initiator and the entity financially responsible for the episode of care are summarized in section III.A.2. of this final rule.

3. Financial Responsibility for the Episode of Care

BPCI Model 2 participants that have entered into agreements with CMS to bear financial responsibility for an episode of care include acute care hospitals paid under the IPPS, health systems, physician-hospital organizations, physician group practices (PGPs), and non-provider business entities that act as conveners by coordinating multiple health care providers' participation in the model. Thus, our evaluation of BPCI Model 2 will yield information about how results for LEJR episodes may differ based on differences in which party bears financial responsibility for the episode of care. For the CJR model, we proposed to make hospitals financially responsible for the episode of care.

Although we proposed that hospitals would bear the financial responsibility for LEJR episodes of care under CJR, because there are LEJR episodes currently being tested in BPCI Model 1, 2, 3 or 4, we believed that participation in CJR should not be required if it would disrupt testing of LEJR episodes already underway in BPCI models. Therefore, we proposed certain exceptions for instances where IPPS hospitals located in an area selected for the model are active participant hospitals or episode initiators for LEJR episodes as of July 1, 2015, and exceptions for LEJR episodes initiated by other providers or suppliers under certain BPCI models.

The following is a summary of the comments received and our responses.

Comment: Most commenters expressed overall support for the CJR model, with some commenters noting that the CJR model could help to transform care delivery through improved care coordination and financial accountability. Several commenters further expressed support for our proposal to designate hospitals as the episode initiators and the entity financially responsible for the episode of care under the CJR model. These commenters agreed that hospitals should bear the responsibility of implementing the CJR model and further agreed with being able to share this responsibility with ''collaborators'' through gainsharing agreements. The commenters noted that the themes surrounding responsibility and cost in conjunction with quality as presented in the proposed rule were encouraging and show a continued focus on bettering outcomes and patient engagement while lowering costs.

Response: We thank the commenters for their support. As noted in the proposed rule, the intent of the CJR model is to promote quality and financial accountability for episodes of care surrounding a lower-extremity joint replacement (LEJR) or reattachment of a lower extremity procedure. We anticipate the CJR model would benefit Medicare beneficiaries by improving the coordination and transition of care, improving the coordination of items and services paid for through Medicare FFS, encouraging more provider investment in infrastructure and redesigned care processes for higher quality and more efficient service delivery, and incentivizing higher value care across the inpatient and PAC spectrum spanning the episode of care (80 FR 41198).

Comment: Several commenters disagreed with the proposal for the CJR model to limit financial responsibility for the episode of care to only hospitals. Commenters advocated for PGPs or orthopedic surgeons to be financially responsible, while other commenters advocated for PAC entities to be financially responsibility for the episode of care. Commenters listed a variety of reasons why orthopedic physician groups and/or PAC providers should be financially responsible for the episode of care. Some commenters stated that the episode initiator for the CJR model should be a physician, as key clinical decisions about care within the episode are made by physicians, including determining what kind of follow-up care is needed. A few commenters stated that the episode initiator should be the PAC provider, similar to BPCI Model 3, since much of the reduction in CJR episode costs could occur through changes in PAC utilization. A few commenters stated that CMS should distribute program risk across all providers within the episode of care and not delegate that function to the hospital because during a CJR episode, ideal care and successful care coordination involve multiple providers across the care continuum and is especially dependent on PAC providers. Finally, several commenters stated that with gainsharing there is greater opportunity for the physician to participate in patient care redesign, but that unless the physician is also financially responsible, physician involvement in the full care redesign would be less than ideal.

Response: As noted in the proposed rule (80 FR 41204 through 41205), because the CJR model is testing a more generalizable model by including providers that might not participate in a voluntary model, we believe it is most appropriate to identify a single type of provider to bear financial responsibility for making repayment to CMS under the CJR model as one entity needs to be ultimately responsible for ensuring that care for CJR model beneficiaries is appropriately furnished and coordinated in order to avoid fragmented approaches that are often less effective and more costly. Hospitals play a central role in coordinating episode-related care and ensuring smooth transitions for beneficiaries undergoing LEJR procedures. Most hospitals already have some infrastructure in place related to patient and family education and health information technology as hospitals receive incentive payments for the adoption and meaningful use of interoperable health information technology (HIT) and qualified electronic health records (EHRs). In addition, hospitals are required by the hospital Conditions of Participation (CoPs) to have in effect a discharge planning process that applies to all patients (§ 482.43). As part of the discharge planning process, hospitals are required to arrange for the initial implementation of the discharge plan (§ 482.43(c)(3)), which includes coordinating with PAC providers, a function usually performed by hospital discharge planners or case managers. Thus hospitals can build upon already established infrastructure, practices, and procedures to achieve efficiencies under this episode payment model. Many hospitals also have recently heightened their focus on aligning their efforts with those of community providers to provide an improved continuum of care due to the incentives under other CMS models and programs, including ACO initiatives such as the Medicare Shared Savings Program, and the Hospital Readmissions Reduction Program (HRRP), establishing a base for augmenting these efforts under the CJR model. Hospitals are also more likely than other providers and suppliers to have an adequate number of episode cases to justify an investment in episode management for this model, have access to resources that would allow them to appropriately manage and coordinate care throughout the LEJR episode, and hospital staff is already involved in discharge planning and placement recommendations for Medicare beneficiaries, and more efficient PAC service delivery provides substantial opportunities for improving quality and reducing costs under CJR.

We considered requiring treating physicians (orthopedic surgeons or

others) or their associated PGPs, if applicable, to be financially responsible for the episode of care under the CJR Model. However, the services of providers and suppliers other than the hospital where the acute care hospitalization for the LEJR procedure occurs would not necessarily be furnished in every LEJR episode. For example, that physicians of different specialties play varying roles in managing patients during an acute care hospitalization for a surgical procedure and during the recovery period, depending on the hospital and community practice patterns and the clinical condition of the beneficiary and could not be assumed to be included in every LEJR episode. This variability would make requiring a particular physician or PGP to be financially responsible for a given episode very challenging. If we were to assign financial responsibility to the operating physician, it is likely that there would be significant variation in the number of relevant episodes that could be assigned to an individual person. Where the physician was included in a PGP, episodes could be aggregated to this group level but this would not be possible for all cases and would likely still have multiple instances with physicians with a very low volume of cases. We acknowledge that providers and suppliers with low volumes of cases may not find it in their financial interests to make systematic care redesigns or engage in an active way with the CJR model. We expect that low volume hospitals may achieve less savings compared to their target episode payments for the simple reason that they would not find the financial incentive present in the CJR sufficiently strong to cause them to shift their practice patterns. While this concern is present in low volume hospitals, it is much more likely to occur if physicians are financially responsible for episode costs because physicians typically do not have the case volume to justify an investment in the infrastructure needed to adequately provide the care coordination services required under the CJR model (such as dedicated support staff for case management), which leads us to believe that as a result, the model would be less likely to succeed.

Although the BPCI initiative allows a PGP and PAC providers to have financial responsibility for episodes of care, the physician groups and PAC providers electing to participate in BPCI have done so because their business structure supports care redesign and other infrastructure necessary to bear financial responsibility for episodes and is not necessarily representative of the typical group practice or PAC provider. Most of the PGPs in BPCI are not bearing financial responsibility, but are participating in BPCI as partners with convener organizations, which enter into agreements with CMS on behalf of health care providers, through which they accept financial responsibility for the episode of care. The PAC providers in BPCI are not at risk for episodes that include more than just the post-anchor hospital discharge period. The incentive to invest in the infrastructure necessary to accept financial responsibility for the entire CJR episode of care, starting at admission to an acute care hospital for an LEJR procedure that is paid under the IPPS MS–DRG 469 or 470 and ending 90 days after the date of discharge from the hospital, would not be present across all PGPs and PAC providers. Thus we do not believe it would be appropriate to designate PGPs or PAC providers to bear the financial responsibility for making repayments to CMS under the CJR model where participation is mandatory, rather than voluntary in nature, potentially causing this model to be less likely to succeed. We may consider, through future rulemaking, other episode of care models in which PGPs or PAC providers are financially responsible for the costs of care.

Comment: Several commenters suggested that conveners—non-provider business entities that coordinate multiple health care providers' participation in the model—should also be allowed to bear financial responsibility for episodes of care under the proposed CJR model. A commenter suggested that instead of making hospitals responsible for managing payments and costs, a management organization should be designated or created to manage the costs and payments.

Response: In the BPCI initiative, participants have entered into a variety of relationships with entities above the hospital level. Some of these relationships are ones where the financial responsibility is borne by an entity other than the hospital, such as a parent organization (known as awardee conveners). Other relationships between hospitals and other organizations (known as facilitator conveners) are more managerial or consultative where financial responsibility remains with the episode initiator (for example, the hospital). We acknowledge the important role that conveners play in the BPCI initiative with regard to providing infrastructure support to hospitals and other entities initiating episodes in BPCI. The convener relationship (where another entity assumes financial responsibility) may take numerous forms, including contractual (such as a separate for-profit company that agrees to take on a hospital's financial risk in the hopes of achieving financial gain through better management of the episodes) and through ownership (such as when financial responsibility is borne at a corporate level within a hospital chain). However, we proposed that for the CJR model we would hold only the participant hospitals financially responsible for the episode of care. This is consistent with the goal of evaluating the impact of bundled payment and care redesign across a broad spectrum of hospitals with varying levels of infrastructure and experience in entering into risk-based reimbursement arrangements. If conveners were included as participants in CJR, we may not gain the knowledge of how a variety of hospitals can succeed in relationship with CMS in which they bear financial risk for the episode of care.

While we proposed that the participant hospital be financially responsible for the episode of care under CJR, we agreed that effective care redesign for LEJR episodes requires meaningful collaboration among acute care hospitals, PAC providers, physicians, and other providers and suppliers within communities to achieve the highest value care for Medicare beneficiaries. We believe it may be essential for key providers and suppliers to be aligned and engaged, financially and otherwise, with the hospitals, with the potential to share financial responsibility with those hospitals. As such, CJR participant hospitals may enter into relationships with other entities in order to manage the episode of care or distribute risk. We refer readers to section III.C.10 of this final rule for further discussion of financial arrangements between participant hospitals and other providers and suppliers. Depending on a hospital's current degree of clinical integration, new and different contractual relationships among hospitals and other health care providers and suppliers may be important, although not necessarily required, for CJR model success in a community. We acknowledge that financial incentives for other providers and suppliers may be important aspects of the model in order for hospitals to partner with these providers and suppliers and incentivize certain strategies to improve episode efficiency.

As noted in the proposed rule (80 FR 41261), in addition to providers and

suppliers with which the participant hospital may want to enter into financial arrangements to share risks and rewards, we expect that participant hospitals may choose to engage with organizations that are neither providers nor suppliers to assist with matters such as: Episode data analysis; local provider and supplier engagement; care redesign planning and implementation; beneficiary outreach; CJR beneficiary care coordination and management; monitoring participant hospital compliance with the terms and conditions of the CJR model; or other model-related activities. These organizations may play important roles in a hospital's plans to implement the CJR model based on the experience these organizations may bring to the hospital's successful participation in the model, such as prior experience with bundled payment initiatives, care coordination expertise, familiarity with the local community, and knowledge of Medicare claims data. All relationships established between participant hospitals and these organizations for purposes of the CJR model would only be those permitted under existing law and regulation, meaning that gainsharing agreements between hospitals and organizations that are neither providers nor suppliers are not permitted. Hospital relationships with organizations other than providers and suppliers would be based solely on the ability of such organizations to directly support the participant hospitals' CJR model implementation.

Comment: Numerous commenters urged CMS to implement the CJR model on a voluntary basis, rather than requiring hospitals to participate. Commenters observed that the CJR model was unprecedented, unjustified, and risky for beneficiaries, because it was the first time CMS would require participation of providers who may not have the interest, experience, capability, or infrastructure to carry out what is necessary for an experiment whose outcomes are unknown. Other commenters claimed that some of the hospitals in the selected MSAs would not be prepared for model participation due to a lack of resources to better coordinate care, insufficient infrastructure, low patient volumes, and lack of negotiating power in their communities, among other reasons. A few commenters disagreed with designating hospitals as financially responsible for the episode of care under CJR if the hospital cannot withdraw its participation if it cannot thrive under the model. The commenters stated that absent readmissions, hospitals have limited influence over other, non-surgical costs associated with joint replacements, such as PAC, rehabilitation, home care, doctors' visits, and more. Conversely, a commenter wrote that there may be some hospitals not in the selected MSAs that would like to participate in CJR and would be precluded from doing so unless CMS opens the model to other hospitals who volunteered to participate. Several commenters requested that CMS continue to test voluntary payment models so that providers can continue to tailor bundled payment reforms to their particular patient populations, practice settings, markets, infrastructure, and administrative resources. A commenter stated that requiring participation in the CJR model may preclude testing of alternative, potentially more effective, approaches. Another commenter contended that requiring participation in this model for providers who may also be participating in a voluntary payment model could create confusion and competing incentives. Commenters further questioned the appropriateness of requiring participation in CJR, given that hospitals may not have contractual agreements with other providers and suppliers furnishing services during an episode. Finally, several commenters contended that the CJR model could result in beneficiary harm; a commenter stated that because participation in the CJR model is required, CMS should be held responsible for any harm to beneficiaries as a result of the model.

Response: We appreciate the views of the commenters on our proposal for required participation in the CJR model test of LEJR episode payment. We recognize that the CJR model represents the first time the Innovation Center will require hospital participation in a payment model being tested under section 1115A of the Act, and we have engaged in rulemaking to ensure robust opportunity for public notice and comment on the model and its design. This model will allow CMS to gain experience with making bundled payments to hospitals who have a variety of historic utilization patterns; different roles within their local markets; various volumes of services; different levels of access to financial, community, or other resources; and various levels of population and health provider density including local variations in the availability and use of different categories of PAC providers. We believe that by requiring the participation of a large number of hospitals with diverse characteristics, the CJR model will result in a robust data set for evaluation of this bundled payment approach, and will stimulate the rapid development of new evidence-based knowledge. Testing the model in this manner will also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize the improvement of quality for common LEJR procedure episodes. Finally, requiring participation removes selection bias and gives CMS a better, more accurate picture of the effects of the model for consideration of any potential expansion on a national scale.

We have multiple years of experience with several types of large voluntary episode payment models where we have successfully collaborated with participants on implementation of episode payment in a variety of settings for multiple clinical conditions. We believe the relatively narrow scope of the model (LEJR episodes only), the phasing in of full financial responsibility over multiple years of the model, and our plan to engage with hospitals to help them succeed under this model through the provision of claims data, will aid hospitals in succeeding under the CJR model. As discussed in section III.C.2. of this final rule, we are also finalizing that the model's first performance period will begin April 1, 2016, instead of on January 1, 2016 as originally proposed. The longer notice of the final model policies before implementation will provide hospitals with more time to prepare for participation by identifying care redesign opportunities, beginning to form financial and clinical partnerships with other providers and suppliers, and using data to assess financial opportunities under the model.

We acknowledge commenters' concern that some hospitals not in a selected MSA may desire to participate in the CJR model. We also note that CMS will continue to test voluntary bundled payment models, including those already undergoing testing through the BPCI initiative, which offered several open periods over the past few years where interested hospitals and other organizations could join. We expect that many providers will continue to engage in initiatives such as BPCI, and may also participate in other emerging models in the coming years. The coexistence of voluntary initiatives such as BPCI alongside new models in which providers are required to participate will provide CMS, providers, and beneficiaries with multiple opportunities to benefit from various care redesign and payment reform initiatives. We will also continue

to explore alternative approaches that may also prove effective in improving care for beneficiaries while reducing spending.

We disagree that requiring participation in the CJR model could create confusion and competing incentives for hospitals already participating in voluntary initiatives. We note that simultaneous testing of multiple bundled payment models is appropriate in many situations, depending on the care targeted under each model. Section III.C.7. of this final rule lays out our policies for accounting for overlap between models and contains discussion of the potential synergies and improved care coordination we expect will ensue through allowing for hospitals and beneficiaries to be engaged in more than one initiative simultaneously.

We appreciate that not all hospitals will have contractual arrangements with providers and suppliers furnishing services to beneficiaries during LEJR episodes. However, this final rule lays out the various financial arrangements that will be permitted under the CJR model, to allow hospitals the opportunity to engage with other providers and suppliers and to form clinical and financial partnerships. Section III.C.10. of this final rule details the requirements for these financial arrangements. Although hospitals will not be required to form financial relationships with other providers and suppliers, we expect many will do so in order to help align the clinical and financial incentives of key providers and suppliers caring for CJR model beneficiaries.

Finally, we do not see how participation in the CJR model, in and of itself, would lead to beneficiary harm and that if beneficiary harm were to occur, that CMS would be responsible. First, and most importantly, we note that under the model, providers and suppliers are still required to provide all medically necessary services, and beneficiaries are entitled to all benefits that they would receive in the absence of the model. Second, we note that we have employed many payment systems, such as IPPS, and payment models, such as BPCI and ACOs, that include similar economic incentives to promote efficiency, and we have not determined that beneficiaries have been harmed by those systems and models. Third, we note that CMS has numerous tools and monitoring plans which are both specific to this model and common to all FFS Medicare. These include audits, monitoring of utilization and outcomes within the model, and the availability of Quality Improvement Organization (QIOs) and 1–800–MEDICARE for reporting beneficiary concerns, among other protections. The CJR model includes monitoring to ensure beneficiary access, choice, and quality of care is maintained under the model. We refer readers to section III.F. of this final rule for discussion of beneficiary protections and monitoring under the CJR model. The model pricing structure, discussed in III.C. of this final rule, also includes features to protect against such potential harm, such as responsibility for post-episode spending increases, stop-gain policies that set a maximum threshold a hospital can earn for savings achieved during episodes, and other policies as detailed in that section. In summary, we note that this payment model does not constrain the practice of medicine and we do not expect clinical decisions to be made on the basis of the payment amount.

Comment: Several commenters stated that all states selected to participate in the proposed HHVBP should be exempted from having to participate in the CJR model. Commenters stated that forcing HHAs to participate in two mandatory models simultaneously is harsh and punitive and would likely skew the results of both models in areas of overlap.

Response: Only participant hospitals under the CJR model are financially responsible to CMS for the episode of care. HHAs will continue to be paid the FFS amount that they would otherwise receive for beneficiaries included in the CJR model. Therefore, there is no reason to exempt hospitals located in MSAs selected for participation in CJR that are also located in states selected for participation in the HHVBP model.

Comment: Many commenters expressed concern with the interaction between BPCI and the proposed joint replacement model due to instances where LEJR episodes excluded from CJR due to BPCI would cause a low volume issue for certain hospitals. Other commenters stated that the proposed CJR model penalizes providers that are voluntarily participating in the BPCI initiative and suggested that CMS allow hospitals in selected MSAs to be allowed to choose between participation in BPCI and the joint replacement model.

Response: Because there are LEJR episodes currently being tested in BPCI Models 1, 2, 3 and 4, we noted in the proposed rule that we believed that participation in CJR should not be required if it would disrupt testing of LEJR episodes already underway in BPCI models. Therefore, we proposed that IPPS hospitals located in an area selected for the model that are active Model 1 BPCI participant hospitals as of July 1, 2015, or episode initiators for LEJR episodes in the risk-bearing phase of Model 2 or 4 of BPCI as of July 1, 2015, would be excluded from participating in CJR during the time that their qualifying episodes are included in one of the BPCI models. We clarify that we will utilize current information on BPCI participation to determine whether a given hospital is included in CJR. For example, if a hospital elected to participate in the LEJR episode under BPCI Model 2 in September 2015, that hospital would not be included in CJR during the time that their qualifying episodes are included in BPCI. Likewise, we proposed that if the participant hospital is not an episode initiator for LEJR episodes under BPCI Model 2, then LEJR episodes initiated by other providers or suppliers under BPCI Model 2 or 3 (where the surgery takes place at the participant hospital) would be excluded from CJR. Otherwise qualifying LEJR episodes (that is, those that are not part of a Model 3 BPCI LEJR episode or a Model 2 PGP-initiated LEJR episode) at the participant hospital would be included in CJR. We are testing a model where participation is not voluntary; therefore, it would not be appropriate for hospitals in selected MSAs to be allowed to choose between participation in BPCI and the joint replacement model. If hospitals were allowed to voluntarily participate in the CJR model, this would introduce selection bias and hamper CMS' ability to analyze how such a payment model potentially would work on a national scale. In addition, a hospital interested in participating in a voluntary model had the opportunity under BPCI. In response to concerns regarding the interaction between BPCI and CJR and potential for too few LEJR episodes at a given hospital to remain under the CJR model, low volume concerns are discussed and addressed in section III.A.4.b of this final rule.

Comment: Some commenters requested CMS to allow hospitals participating in ACOs that achieved shared savings in recent performance periods, Shared Savings Program ACOs (Track 2 and Track 3), and full-risk ACOs (such as Next Generation ACO), to opt-out of participation in the CJR model.

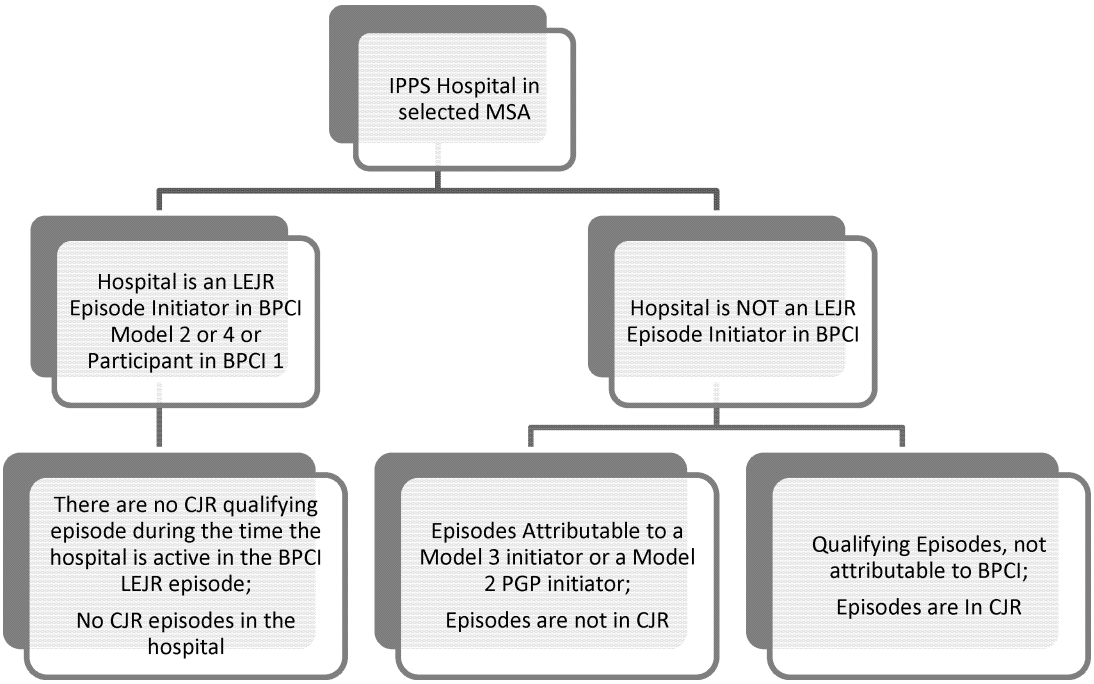
Response: As we previously noted and in the proposed rule, many hospitals have recently heightened their focus on aligning their efforts with those of community providers to provide an improved continuum of care due to the incentives under other CMS models and programs. Therefore, hospitals that are already involved in ACO initiatives and

the HRRP have already established a base for augmenting these efforts under the CJR model (80 FR 41205). Therefore, we see no compelling reason why hospitals participating in ACO initiatives and other efforts cannot be participant hospitals in the CJR model. However, adjustments to account for overlaps with other innovation center models and CMS programs are discussed in section III.C.7. of this final rule.

Comment: A commenter stated that a CMS Certification Number (CCN) can include multiple hospitals. The commenter inquired, if at least one hospital under the CCN is in a selected MSA, would the entire CCN be required to participate in the CJR model. The commenter also requested if some of the hospitals in the CCN are not eligible for the CJR program, would they be required to participate because they are under the same CCN.

Response: The proposed approach indicated that CMS would base selection on the physical location of the hospital. The manner in which CMS tracks and identifies hospitals is through the CCN. In keeping with this approach, the CJR model will administer model-related activities at the CCN level including the determination of physical location. The physical location associated with the CCN at the time of the model start will be used to determine whether that CCN is located in a selected MSA. For hospitals that share a CCN across various locations, all hospitals under that CCN would be required to participate in the CJR model if the physical address associated with the CCN is in the MSA, unless otherwise excluded. Similarly, all hospitals under the same CCN, even if some are physically located in the MSA selected for participation, would not participate in in the CJR model if the physical address associated with the CCN is not in the MSA. Our analysis of the hospitals in the selected MSAs indicates that this phenomenon is not present in the selected areas.

Final Decision: After consideration of the public comments we received, we are finalizing the proposal to designate IPPS hospitals as the episode initiators. The initiation of an episode is described in § 510.100. We are also finalizing our proposal to require IPPS hospitals physically located in an area selected for participation in the CJR model, according to the address associated with the CCN, to participate in the model and bear the financial responsibility for LEJR episodes of care under the CJR model. Finally, we are finalizing our proposal that hospitals selected for the model that are active Model 1 BPCI participant hospitals as of July 1, 2015, or episode initiators for LEJR episodes in the risk-bearing phase of Model 2 or 4 of BPCI as of October 1, 2015, are excluded from participating in CJR during the time that their qualifying episodes are included in one of the BPCI models. However, LEJR episodes initiated by other providers or suppliers under BPCI Model 2 or 3 (where the surgery takes place at the participant hospital) are excluded from CJR. Otherwise qualifying LEJR episodes (that is, those that are not part of a Model 3 BPCI LEJR episode or a Model 2 physician group practice-initiated LEJR episode) at the participant hospital are included in CJR. The definition of a ''participant hospital'' and ''CJR-regional hospital'' will be codified in § 510.2, exclusions to episodes being tested due to BPCI overlap will be codified in § 510.100(b). The following chart illustrates the inclusion of episodes in CJR relative to BPCI.



4. Geographic Unit of Selection and Exclusion of Selected Hospitals

In determining which hospitals to include in the CJR model, we considered whether the model should be limited to hospitals where a high volume of LEJRs are performed, which would result in a more narrow test on the effects of an episode-based payment, or whether to include all hospitals in particular geographic areas, which would result in testing the effects of an episode-based payment approach more broadly across an accountable care community seeking to coordinate care longitudinally across settings. Selecting certain hospitals where a high volume of LEJRs are performed may allow for fewer hospitals to be selected as model participants, but still result in a sufficient number of CJR episodes to

evaluate the success of the model. However, there would be more potential for behavioral changes that could include patient shifting and steering between hospitals in a given geographic area that could impact the test. Additionally, this approach would provide less information on testing episode payments for LEJR procedures across a wide variety of hospitals with different characteristics. Selecting geographic areas and including all IPPS hospitals in those areas not otherwise excluded due to BPCI overlap as previously described and in section III.C.7. of the proposed rule as model participants would help to minimize the risk of participant hospitals shifting higher cost cases out of the CJR model. Moreover, in selecting geographic areas we could choose certain characteristics, stratify geographic areas according to these characteristics, and randomly select geographic areas from within each stratum. Such a stratified random sampling method based on geographic area would allow us to observe the experiences of hospitals with various characteristics, such as variations in size, profit status, and episode utilization patterns, and examine whether these characteristics impact the effect of the model on patient outcomes and Medicare expenditures within episodes of care. Stratification would also substantially reduce the extent to which the selected hospitals will differ from non-selected hospitals on the characteristics used for stratification, which would improve the statistical power of the subsequent model evaluation, improving our ability to reach conclusions about the model's effects on episode costs and the quality of patient care. Therefore, given the authority in section 1115A(a)(5) of the Act, which allows the Secretary to elect to limit testing of a model to certain geographic areas, we proposed to use a stratified random sampling method to select geographic areas and require all hospitals paid under the IPPS in those areas to participate in the CJR model and be financially responsible for the cost of the episode, with certain exceptions as previously discussed and in sections III.B.3 and III.C.7. of the proposed rule.

a. Overview and Options for Geographic Area Selection

In determining the geographic unit for the geographic area selection for this model, we considered using a stratified random sampling methodology to select—(1) Certain counties based on their Core-Based Statistical Area (CBSA) status, (2) certain zip codes based on their Hospital Referral Regions (HRR) status; or (3) certain states. We address each geographic unit in turn.

We considered selecting certain counties based on their CBSA status. A CBSA is a core area containing a substantial population nucleus, together with adjacent communities having a high degree of economic and social integration within that core. Counties are designated as part of a CBSA when the county or counties or equivalent entities are associated with at least one core (urbanized area or urban cluster) of at least 10,000 in population, plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties with the counties associated with the core. There are 929 CBSAs currently used for geographic wage adjustment purposes across Medicare payment systems.[4] The 929 CBSAs include 388 MSAs, which have an urban core population of at least 50,000, and the 541 Micropolitan Statistical Areas (μSA), which have an urban core population of at least 10,000 but less than 50,000. CBSAs may be further combined into a Combined Statistical Area (CSA) which consists of two or more adjacent CBSAs (MSAs or μSAs or both) with substantial employment interchange. Counties not classified as a CBSA are typically categorized and examined at a state level.

The choice of a geographical unit based on CBSA status could mean selection of a CBSA, an MSA, or a CSA. We proposed basing the selection on an MSA, which we will discuss later in this section.

We proposed that counties not in an MSA would not be subject to the selection process. These counties not subject to selection would include the μSA counties and the counties without a core urban area of at least 10,000. These areas are largely rural areas and have a limited number of qualifying LEJR cases. Relatively few of these areas would be able to qualify for inclusion based on the minimum number of LEJR episodes in year requirement discussed later in this section.

We considered, but ultimately decided against, using CSA designation instead of MSAs as a potential unit of selection. Under this scenario, we would look at how OMB classifies counties. We would first assess whether a county has been identified as belonging to a CSA, a unit which consists of adjacent MSAs or μSAs or both. If the county was not in a CSA, we would determine if it was in an MSA that is not part of a larger CSA. Counties not associated with a CSA or an MSA would be unclassified and excluded from selection. These unclassified areas would include the counties in a state that were either not a CBSA (no core area of at least 10,000) or associated with a μSA (core area of between 10,000 and 50,000) but unaffiliated with a CSA.

Whether to select on the basis of CSA/MSAs or just on MSAs was influenced by a number of factors. We considered the following factors:

- CSAs, by definition, have a significantly lower degree of interchange between component parts than the interchange experienced within an MSA. Thus, we did not believe that using CSAs would be necessary in order to capture referral patterns. A case study examination of the geographic areas included in CSAs with respect to the health care markets of those areas and their respective parts helped to validate our conclusion.
- We assessed the anticipated degree to which LEJR patients would be willing to travel for their initial hospitalization.
- We assessed the extent to which surgeons are expected to have admitting privileges in multiple hospitals located in different MSAs.
- We considered the degree to which we desire to include hospitals within μSAs that are part of a larger CSA.

After examining these factors, we concluded that that the anticipated risk for patient shifting and steering between MSAs within a CSA was not severe enough to warrant selecting CSAs given CMS' preference for smaller geographic units. However, because MSAs are units with significant levels of social and commercial exchange and due to the mobility of patients and providers within MSAs, we believed that selecting complete MSAs is preferable to selecting metropolitan divisions of MSAs for inclusion in the CJR model. We use the metropolitan divisions to set wage indices for its prospective payment systems (PPSs). Of the 388 MSAs, there are 11 MSAs that contain multiple metropolitan divisions. For example, the Boston-Cambridge-Newton, MA–NH MSA is divided into the following metropolitan divisions:

- Boston, MA.
- Cambridge-Newton-Framingham, MA.
- Rockingham County-Strafford County, NH.

[4] As stated in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27552) and final rule (78 FR 50586), on February 28, 2013, OMB issued OMB Bulletin No.13–01, which established revised delineations for MSAs, μSA s, and CSAs, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf.*

The Seattle-Tacoma-Bellevue, WA MSA is divided into the following metropolitan divisions:

- Seattle-Bellevue-Everett, WA.
- Tacoma-Lakewood, WA.

We proposed selecting entire MSAs rather than sub-divisions within an MSA.

We next considered selecting HRRs. HRRs represent regional health care markets for tertiary medical care. There are 306 HRRs with at least one city where both major cardiovascular surgical procedures and neurosurgery are performed. HRRs are defined by determining where the majority of patients were referred for major cardiovascular surgical procedures and for neurosurgery.[5] Compared to MSAs, HRRs are classified based on where the majority of beneficiaries within a zip code receive their hospital services for selected tertiary types of care. The resulting HRRs represent the degree to which people travel for tertiary care that generally requires the services of a major referral center and not the size of the referral network for more routine services, such as knee and hip arthroplasty procedures. In addition, because HRRs are defined based on referrals for cardiovascular surgical procedures and neurosurgery, they may not reflect referrals for orthopedic procedures. Therefore, we believed that MSAs as a geographic unit are preferable over HRRs for this model.

We also considered selecting states for the CJR model. However, we concluded that MSAs as a geographic unit are preferable over states for the CJR model. As stated in section III.A.4.b. of the proposed rule, we anticipate that hospitals that would otherwise be required to participate in the CJR model would be excluded from the model because their relevant LEJR episodes are already being tested in BPCI. If we were to select states as the geographic unit, there is a potential that an entire state would need to be excluded because a large proportion of hospitals in that state are episode initiators of LEJR episodes in BPCI. In contrast, if we excluded a specific MSA due to BPCI participation, as discussed in the next section, we could still select another MSA within that same state. Likewise, if we chose states as the geographic unit, we would automatically include hospitals in all rural areas within the state selected. If MSAs are selected for the geographic unit, we anticipate that fewer small rural hospitals would be included in the model. Using a unit of selection smaller than a state would allow for a more deliberate choice about the extent of inclusion of rural or small population areas. Selecting states rather than MSAs would also greatly reduce the number of independent geographic areas subject to selection under the model, which would decrease the statistical power of the model evaluation. Finally, MSAs straddle state lines where providers and Medicare beneficiaries can easily cross these boundaries for health care. Choosing states as the geographic unit would potentially divide a hospital market and set up a greater potential for patient shifting and steering to different hospitals under the model. The decision that the MSA-level analysis was more analytically appropriate was based on the specifics of this model and is not meant to imply that other levels of selection would not be appropriate in a different model such as the proposed HHVBP model.

For the reasons previously discussed, we proposed to require all IPPS hospitals to participate in the CJR model (with limited exceptions as previously discussed in section III.A.2. of the proposed rule) if located in an MSA selected through a stratified random sampling methodology (outlined in section III.A.3.b. of the proposed rule) to test and evaluate the effects of an episode-based payment approach for an LEJR episodes. We proposed to determine that a hospital is located in an area selected if the hospital is physically located within the boundary of any of the counties in that MSA where the counties are determined by the definition of the MSA as of the date the selection is made. In response to comments, we are clarifying that we will determine physical location using the address associated with the CCN of the hospital. Although MSAs are revised periodically, with additional counties added or removed from certain MSAs, we proposed to maintain the same cohort of selected hospitals throughout the 5 performance years of the model with limited exceptions as described later in this section. Thus, we proposed that, if after the start of the model, new counties are added to one of the selected MSAs or counties are removed from one of the selected MSAs, those re-assigned counties would retain the same CJR status they had at the beginning of the initiative. We believed that this approach will best maintain the consistency of the participants in the model, which is crucial for our ability to evaluate the results of the model. We retain the possibility of adding a hospital that is opened or incorporated within one of the selected counties after the selection is made and during the period of performance. (See section III.C.4. of the proposed rule for discussion of how target prices will be determined for such hospitals.) Hospitals in selected counties that do not have any LEJR cases that qualify for CJR, due to their participation in the BPCI initiative as a hospital initiator in an LEJR episode, will become subject to CJR at the time their participation in BPCI ends and their episodes become eligible for CJR. Although we considered including hospitals in a given MSA based on whether the hospitals were classified into the MSA for IPPS wage index purposes, this process would be more complicated, and we could not find any compelling reasons favoring this approach. For example, we assign hospitals to metro divisions of MSAs when those divisions exist. See our previous discussion of this issue. In addition, there is the IPPS process of geographic reclassification by which a hospital's wage index value or standardized payment amount is based on a county other than the one where the hospital is located. For the purpose of this model, it is simpler and more straightforward to use the hospital's physical location as the basis of assignment to a geographic unit. This decision would have no impact on a hospital's payment under the IPPS. We sought comment on our proposal to include participant hospitals for the CJR model based on the physical location of the hospital in one of the counties included in a selected MSA.

The following is a summary of the comments received and our responses.

Comment: Commenters generally supported MSAs as the unit of geographic selection. However, several had concerns regarding the particular circumstances of their MSAs. Some commenters stated that MSAs were too large and preferred the use of metropolitan regions for large urban areas such as New York City, while others expressed concern with the inclusion of rural portions of the MSA counties. Commenters addressing the rural providers within the selected MSAs questioned whether the inclusion of rural hospitals in the model was deliberate or whether CMS believed hospitals in rural areas should not be included in the CJR model. Other commenters expressed concern that MSAs were a smaller than ideal unit of selection and that selecting MSAs for the model would encourage practices such as funneling patients to hospitals outside a selected MSA for surgery in order to avoid inclusion in the model. Conversely, a commenter asserted that

[5] The Dartmouth Atlas of Healthcare, *http://www.dartmouthatlas.org/data/region/*. Accessed on April 9, 2015.

participation in the model would result in a competitive advantage for hospitals in a selected MSA through the use of gainsharing to recruit physicians to move referrals into a selected market. Some commenters were also concerned about patient shifting in or out of a selected MSA in areas where the MSA was part of a larger CSA, such as in the Atlanta CSA in which some, but not all, component MSAs were selected for participation in the CJR model.

Response: We first address the issue of the inclusion of the entirety of an MSA as the unit of selection rather than just the core urban area. This was a deliberate choice reflecting the fact that we seek to examine the performance of hospitals under CJR that could be considered rural, low volume, or outside the urban core. Inclusion of such hospitals in the model will give us insight on how the model functions in these areas and increase the potential generalizability of the model. The proposed rule proposed additional protections to selected classes of hospitals such as SCHs, Medicare-Dependent Hospitals (MDHs), and RCHs because we wanted to further protect these federally-recognized categories of vulnerable hospitals while including them in the model.

We chose MSAs as the unit of selection to balance the following considerations: The scope for shifting patients in or out of selected areas, our ability to observe the impact of the model in a variety of circumstances, and our preference to not use a geographic unit larger than strictly necessary to evaluate the model. We acknowledge that there are inevitably tradeoffs among these criteria. With respect to the choice of CSA versus MSA, a far greater number of commenters were concerned with the inclusion of rural providers than were concerned with their or their competitor's markets crossing the borders of MSAs within a CSA. By definition, CSAs have a lesser degree of the employment interchange than an MSA and basing the geographic unit of selection on a CSA would entail the possibility of selecting μSAs within CSAs. On balance, we believe it is appropriate to limit the extent of rural participation in CJR by confining it to rural areas within MSAs. We are sympathetic to concerns related to the experience of hospitals that are located near the borders between MSAs, but believed that those concerns did not outweigh these other considerations. In contrast, the density of populations and providers at the borders of these markets was one of the reasons that we decided to not proceed with allowing selection to be done based on metropolitan divisions for those 11 MSAs that were so sub-divided. Metropolitan divisions are very likely to have hospitals whose referral markets straddle divisions and their use as a unit would have had been problematic. After weighing the comments we continue to believe that MSAs are the most appropriate compromise position for the choice of geographic unit of selection.

Finally, we note that separate commenters stated that a hospital in a CJR selected county could be either at both a competitive advantage (for example, by providing an opportunity to attract physicians through gainsharing), or a competitive disadvantage (for example, by causing physicians to shift patients to nearby hospitals). We believe that both phenomena may occur and that the ability of a hospital to use the opportunities presented to it under the CJR model to strengthen its relationship with other providers and potentially achieve savings will vary by the hospital's specific circumstances and capabilities. We do not see a strong argument for why these types of effects necessitate a change to the geographic unit used for this model.

Comment: Some commenters contended that the CJR model has inadequate participation by small and rural providers due to the elimination of non-CBSA and μSAs from the possibility of selection for this model. The commenters wrote that CMS should include more rural providers in order to foster a model that is not overly tailored to large providers and urban areas. A commenter stated that inclusion in the model would result in rural providers being more prepared to adapt to future payment and delivery reforms. Another stated that it was important to include more small volume hospitals, and urged CMS to reconsider the implications of this exclusion and to broaden the definition of geographic areas.

Response: We appreciate commenters' input on how to incorporate rural providers in the CJR model and acknowledge commenters' concerns related to the ability of small and rural providers to effectively participate and succeed in the model. Our proposed approach to including low-volume and non-urban providers within the selected MSAs but removing from the possibility of selection counties that are not in an MSA or in an MSA with less than 400 qualifying LEJR cases is an appropriate strategy that allows for inclusion of rural providers in the model, while not oversampling such providers.

Comments related to requests for exclusion of particular hospitals are addressed in the next section, MSA Selection Methodology. Financial protections for hospitals are addressed later in section III.C.8. of this final rule.

Final Decision: After consideration of the public comments we received, we are finalizing the proposal, without modification, to utilize MSAs as the unit of selection for the model.

b. MSA Selection Methodology

We proposed to select the MSAs to include in the CJR model by stratifying all of the MSAs nationwide according to certain characteristics.

(1) Exclusion of Certain MSAs

Prior to assigning an MSA to a selection stratum, we examined whether the MSA met specific proposed exclusion criteria. MSAs were evaluated sequentially using the following 4 exclusion criteria: First, MSAs in which fewer than 400 LEJR episodes (determined as discussed in section III.B.2. of this final rule) occurred from July 1, 2013 through June 30, 2014 were removed from possible selection. The use of the 400 LEJR cases in a year was based on a simple one-sided power calculation to assess the number of episodes that would be needed to detect a 5 percent reduction in episode expenditures. Cases in hospitals paid under either the critical access hospital (CAH) methodology or the Maryland All-Payer Model are not included in the count of eligible episodes. This criterion removed 156 MSAs from possible selection.

Second, MSAs were removed from possible selection if there were fewer than 400 non-BPCI LEJR episodes in the MSA in the reference year. For the purposes of this exclusion, the number of BPCI episodes was estimated as the number of potentially eligible cases during the reference year that occurred in acute care hospitals participating in BPCI Model 1, or in phase 2 of BPCI Models 2 or 4 as of July 1, 2015 and the number of LEJRs in the reference year associated with these hospitals was examined. This criterion removed an additional 24 MSAs from potential selection.

Third, MSAs were also excluded from possible selection if the MSA was dominated by BPCI Models 1, 2, 3, or 4 episodes to such a degree that it would impair the ability of participants in either the CJR model or the BPCI models to succeed in the objectives of the initiative or impair the ability to set accurate and fair prices. We anticipate that some degree of overlap in the two models will be mutually helpful for both models. There are two steps to this exclusion. First, we looked at the number of LEJR episodes at BPCI Model 1, 2 or 4 initiating hospitals and second,

the number of LEJR episodes among BPCI Model 3 SNF and Home Health Agency (HHA) episode initiators. First, we excluded MSAs if more than 50 percent of otherwise qualifying proposed CJR episodes were in Phase 2 of BPCI Model 2 or 4 with hospital initiators. Second, we excluded MSAs if either SNF or HHA BPCI Model 3 initiating providers accounted for more than 50 percent of LEJR referrals to that provider type. As a result of this third criterion, 4 additional MSAs were removed from possible selection. No MSAs were excluded based on SNF or HHA participation in Model 3.

Finally, MSAs were removed if, after applying the previous three criteria they remained eligible for selection, but more than 50 percent of estimated eligible episodes during the reference year were not paid under the IPPS system. The purpose of this rule was to assess the appropriateness of MSAs that contained both Maryland and non-Maryland counties. No MSAs were eliminated on the basis of this rule. Please refer to the appendix for this final rule for the status of each MSA based on these exclusion criteria, available at *http://innovation.cms.gov/initiatives/cjr/.* After applying these four exclusions, 196 MSAs remained to be stratified for purposes of our proposed selection methodology.

The following is a summary of the comments received and our responses.

Comment: Many commenters requested that we exclude additional MSAs from the selection process. Commenters supported our exclusion of MSAs with less than a minimum number of eligible LEJR episodes and a high rate of BPCI LEJR penetration, but were concerned that the list of BPCI participating providers used in making the exclusion determination did not reflect providers entering BPCI as of October 1, 2015. Such commenters recommended that CMS recalculate BPCI participation in LEJR episodes in each MSA based on both hospital- and physician-led participants and adjust the MSA selection accordingly. Commenters also suggested adding additional selection criteria based on the overall percent of LEJR episodes associated with a BPCI episode, the percent of LEJR episodes associated with a PGP initiated BPCI episode, and the percent of LEJR episodes associated with an ACO.

Response: In response to the comments, we re-examined the exclusion rules based on an updated list of providers participating in the BPCI initiative for LEJR episodes. We also examined the potential impact on selection of MSAs that incorporating an updated list of BPCI participants would have. For the purposes of the re-examination of exclusion rule 2, which eliminates MSAs with less than 400 CJR eligible, non-BPCI episodes, we estimated the BPCI LEJR episode count as the number of potentially eligible cases during the reference year that (1) occurred in an acute care hospital participating in BPCI Model 1 that would still be active as of April 1, 2016; (2) occurred in an acute care hospital in a Phase 2 LEJR episode for BPCI Models 2 or 4 as of October 1, 2015; or (3) were associated with an operating or admitting physician on the hospital claim assigned to a PGP with an LEJR episode in Phase 2 of BPCI Model 2 as of October 1, 2015. October 1, 2015 is the final quarter for which participants in Phase 1 of BPCI could transition any episode into Phase 2. This represents a change to the exclusion rule articulated in the proposed rule, in that it updates the list of BPCI participants and also takes into account episodes associated with Model 2 PGP episode initiators. As we did for exclusion rule 2, we used the October 2015 list of BPCI participants to reassess exclusion rule 3. Rule 3 removes an MSA if more than 50 percent of patients were treated in a BPCI initiating hospital or if more than 50 percent of LEJR patients treated in a PAC setting of that type were treated in a BPCI initiating HHA or SNF.

After we made the previously stated changes, some MSAs previously eligible for selection would now be considered excluded. Additionally, two of the MSAs previously excluded would now be eligible for selection due to hospitals withdrawing from BPCI and the MSAs now having more than 400 eligible cases. Eight MSAs that were selected in the proposed rule would be classified as excluded on the basis of these updated exclusion rules.

We considered a variety of alternative approaches to address the changes in the eligibility of MSAs. First, we considered proceeding with the list of 75 MSAs as initially selected and using the exclusion rules as initially proposed. Second, we considered removing the 8 selected MSAs that would now be excluded on the basis of the updated BPCI participation numbers. Third, we considered replacing the 8 MSAs by randomly selecting new MSAs from the remaining MSAs in the relevant strata. However, we believed that it would preferable, although not required, to give the selected MSAs a consistent period of time between selection and the start of the model. Fourth, we contemplated creating a revised list of eligible MSAs and randomly selecting a new group of 75 MSAs. Given the concern of many commenters about the start date of the model, we were reluctant to create a completely new list of selected MSAs. We believe that making a new selection would be regarded unfavorably by impacted MSAs and hospitals and should be avoided if possible. In order to be responsive to concerns regarding the growth of BPCI after the publication of the proposed rule and the increase in PGP participation in BPCI, we are proceeding with the second option.

The function of the stratification approach was to ensure that our selection of MSAs covered a range of efficiency levels and population sizes and allowed us to target our sampling percentages so as to oversample in the less efficient areas. Regarding the selected MSAs now eliminated, they are distributed fairly evenly throughout the distribution of average episode payments. From the least expensive to the most expensive quartiles, the number selected and now eliminated are, in order, 2/15 (13 percent), 2/19 (11 percent), 3/30 (15 percent), and 1/22 (5 percent). We also believe that the removal of these 8 MSAs from the model will not preclude us from undertaking a rigorous statistical evaluation of the model.

Given the aforementioned information, we believe that the relatively minor reduction in statistical power due to not re-selecting MSAs is outweighed by the desire to give affected participant hospitals equal time to prepare for the model. We are removing the 8 MSAs as noted in Table 1.

TABLE 1—MSAS THAT WERE PREVIOUSLY SELECTED THAT ARE NO LONGER INCLUDED IN CJR

CBSA title	Revised exclusion rule 2 status	Revised exclusion rule 3 status
Colorado Springs, CO	Fail	Pass.
Evansville, IN–KY	Fail	Pass.
Fort Collins, CO	Fail	Pass.
Las Vegas-Henderson–Paradise, NV	Fail	Fail.

TABLE 1—MSAs THAT WERE PREVIOUSLY SELECTED THAT ARE NO LONGER INCLUDED IN CJR—Continued

CBSA title	Revised exclusion rule 2 status	Revised exclusion rule 3 status
Medford, OR	Fail	Pass.
Richmond, VA	Fail	Pass.
Rockford, IL	Fail	Pass.
Virginia Beach-Norfolk-Newport News, VA–NC	Pass	Fail.

We next contemplated whether to apply additional MSA-level exclusion rules. We investigated a potential new rule whereby an MSA would be excluded based on the percent of the MSA's qualifying LEJR episodes associated with Phase 2 Model 2 PGP initiators. We did not believe that there was as strong of an argument for excluding MSAs on the basis of the percent of patients treated by a BPCI physician given that the hospital is the financially accountable entity in CJR. We examined two possible cut off points (>65 percent and >50 percent) to assess which MSAs would be eliminated if we were to exclude MSAs where a specific percent of an MSA's otherwise qualifying LEJR cases was attributable to a BPCI PGP. At 65 percent, no selected MSAs not otherwise excluded were impacted. 8 MSAs that were previously selected had more than 50 percent of their LEJRs performed by BPCI PGPs. Five of these 8 MSAs are already eliminated due to the revised exclusion rule 2. For markets with more than 400 non-BPCI cases but more than 50 percent BPCI PGP penetration, the number of the CJR eligible patients was between 556 and 1834 indicating that there was a sizable number of cases. Consequently, we did not find this new exclusion rule necessary.

Comment: Commenters requested modifications to the proposed exclusions of specific categories of hospitals within an MSA. While commenters stated a variety of concerns, many of them were related to the request that CMS exclude low volume hospitals from the model. Commenters made requests around specific categories of hospitals including Medicare Dependent Hospitals (MDHs), Sole Community Hospitals (SCHs), Rural Referral Centers (RRCs), hospitals that are reclassified as rural, hospitals perceived of as rural or outside of a core urban area, and larger hospitals with a low potential CJR LEJR volume due to the exclusion of their patients because their LEJR episodes were initiated by a PGP BPCI LEJR episode initiator.

Commenters provided a variety of rationales for why they believed it was undesirable or unfair to include low volume providers in the model. These reasons include, but are not limited to, observations that—

- Low-volume providers are less likely to be proficient at taking care of these patients in an efficient cost-effective manner and they will be less likely to achieve savings;
- Low-volume hospitals will be disproportionately impacted by outlier cases and will have less predictable cost and quality outcomes making it difficult for them to manage the model effectively. In addition, low volume providers are likely to see a greater proportion of hip fractures and non-planned procedures;
- Low-volume hospitals will have less control over and ability to impact the behavior of other providers. The pool of collaborating providers such as orthopedic surgeons in most rural communities may be limited and small hospitals may not have the market position to successfully influence others' behavior;
- Hospitals with a limited number of Medicare hip and knee procedures may not have sufficient incentive to invest the time and resources necessary to develop the infrastructure and partnerships required to effectively manage these episodes of care and may not find the opportunity to improve patient outcomes significant enough to engage referring physicians and PAC partners for redesign;
- Low volume providers may be more financially vulnerable and with fewer resources to design and carry out initiatives or make effective responses to the financial incentives in the model. A commenter noted concerns with hospital margins, and the possibility for the reductions in revenue as a result of the loss of volume or loss of margin under CJR could result in additional hospital closures.

Due to these concerns, commenters requested a variety of solutions including (1) the exclusion of hospitals based on a volume cut off variously defined by volume of eligible LEJR cases, LEJR cases within specific MS–DRGs and total hospital volume, (2) making the model voluntary for low volume providers, (3) extending the protections afforded to SCH, MDH and RRC to additional categories of hospitals including hospitals electing to be treated as rural under § 412.103, and (4) the provision of additional protections or payment adjustments beyond what was included in the proposed rule.

Response: We acknowledge the fact that hospitals, particularly low volume hospitals, are concerned and would like to increase their probability of receiving reconciliation payments under CJR while minimizing the possibility of reduction in revenue. We refer readers to the following sections of this final rule: Section III.C.8. for a discussion of hospital financial protections, III.C.4. for a discussion of how we will determine target prices for hospitals with low volume, and section III.C.4. for a discussion of target prices for hip fracture patients. We believe that the modification of the treatment of hip fractures in the payment methodology should allay many concerns of small and rural providers. This change may disproportionately impact them since emergency surgeries, such as hip fractures, have a higher probability of being performed in low volume settings.

As stated in relation to comments requesting that CJR operate as a voluntary model, the inclusion of low volume hospitals in the CJR model is consistent with the goal of evaluating the impact of bundled payment and care redesign across a broad spectrum of hospitals with varying levels of infrastructure, care redesign experience, market position, and other considerations and circumstances. The design of the CJR model and the inclusion of low volume providers within the model reflects our interest in testing and evaluating the impact of a bundled payment approach for LEJR procedures in a variety of circumstances, especially among those hospitals that may not otherwise participate in such a test. The inclusion of these providers allows CMS to better appreciate and understand how the model operates as a general payment approach and its impact on a wide range of hospitals. Many LEJR surgeries are performed in low volume settings, thus, the impact of the CJR model on low volume hospitals is of great interest to the evaluation of this initiative.

We acknowledge that providers with low volumes of cases may not find it in their financial interests to make

systematic care redesigns or engage in an active way with the CJR model. We expect that low volume providers may decide that their resources are better targeted to other efforts because they do not find the financial incentive present in the CJR sufficiently strong to cause them to shift their practice patterns. We acknowledge that low volume hospitals may achieve less savings because they did not or could not make the necessary changes to the treatment of their qualifying beneficiary population. We believe this choice is similar in nature to that made as hospitals decide their overall business strategies and where to focus their attentions.

Comment: Many commenters requested that CMS exclude hospitals where more than 50 percent of the eligible LEJRs performed at a hospital would be attributed to a PGP initiated BPCI episode and would thus not be in CJR. The majority of these commenters were concerned about low volumes of patients, which is addressed in the previous comment and response. Some were concerned about the operational complexity of identifying, tracking, and managing patients treated in CJR versus BPCI.

Response: We will not exclude IPPS hospitals in selected MSAs other than as already specified or allow IPPS hospitals to opt out of participation in CJR. As previously noted in the discussion on low volume hospitals, we consider the inclusion of low volume providers a core feature of the model that will aid us in understanding the impact of a variety of providers in various circumstances. Similarly, we do not believe it is necessary or appropriate to exclude hospitals on the basis of some of the surgeons in their hospitals being associated with a BPCI PGP. Like with more traditional low volume providers, the extent to which a hospital alters its behavior in response to the CJR model will likely be the result of a variety of factors including but not limited to the anticipated number of cases. It should be noted that the revised exclusion rule that resulted in the elimination of 8 MSAs was based on failing to meet a minimum MSA number of LEJRs and not based on either the number of LEJRs at a particular hospital or the portion of PGPs at any level of analysis. If an IPPS hospital in a selected area has some of their LEJR cases qualify as CJR episodes and some that do not due to BPCI participation, Medicare Advantage status or any other reason, the fact that CJR cases are not their full caseload will not be considered a reason for exclusion of the hospital.

With respect to challenges that hospitals may experience related to identifying eligible patients and following them over the course of their episodes, we acknowledge that concern. However, we consider the improved tracking and communication with other providers and suppliers that is likely to occur as a result of hospital efforts in CJR to be a benefit of the model that will improve the coordination of patient care and possibly improve patient outcomes.

Comment: Two commenters raised the issue of hospital systems spanning more than one MSA. They requested that CMS either allow all of the hospitals in the system to be included in CJR or allow all of the hospitals to be excluded. Commenters stated that the additional administrative burden associated with two concurrent Medicare payment methodologies would be unduly burdensome. Additionally, commenters stated that CMS should develop criteria under which all providers in health systems with a significant number of BPCI participants would be excluded from the CJR model due to operational challenges to managing the BPCI and CJR models simultaneously within a health care system.

Response: With respect to the request that all members within a health system be allowed to have all of their hospitals participate in BPCI because operating under two systems is too onerous, if a health system made the choice to enter some but not all of their locations into BPCI, they have already made the business decision to operate partly under one incentive structure and partly under another. We do not believe that the existence of CJR model as proposed should change the timelines for transitioning to Phase 2 of BPCI. We will not exclude hospitals from the model on the basis that some of the hospitals in its health system are participating in BPCI or some of the hospitals in its health system have CCNs with addresses located in a non-selected MSA.

The CJR model will require hospitals within selected geographic areas to participate (unless otherwise excluded as set forth in this final rule). The inclusion of additional voluntarily participating hospitals outside of these selected areas would constitute a major change to the model that was not considered in the proposed rule. Providers who wished to participate in a voluntary episode model had the opportunity under the BPCI initiative.

Final Decision: After consideration of the public comments we received, we are modifying the MSA exclusion rules used in determining which MSAs are eligible for selection. The following is a description of the MSA exclusion criteria used in this final rule:

In determining if an MSA was eligible for selection, we first examined whether the MSA met any of the four exclusion criteria as formulated in the proposed rule. This process resulted in a pool of 196 MSA from which we then selected 75 for inclusion in CJR via stratified random selection.

In this final rule, we revised the exclusion rules as defined later in this section, with the purpose of assessing whether any of the 75 selected MSAs would be considered not eligible for selection based on applying the new criteria.

Specifically, the second exclusion rule, which eliminates MSAs with fewer than 400 non-BPCI CJR eligible cases, is modified with the following additions (1) the determination of the count of patients associated with a BPCI Phase 2 initiating hospital is based on the participation in BPCI as of October 1, 2015 rather than July 1, 2015 and (2) the count of BPCI episodes to be removed from the count of eligible episodes takes into consideration patients who would have been attributed to a BPCI Model 2 initiating PGP in Phase 2 for an LEJR episode as of October 1, 2015. The third exclusion rule, wherein MSAs were excluded based on the percent of the MSA's LEJR population associated with either a BPCI hospital, SNF or HHA in an MSA, was changed to be based on episodes associated with participation in BPCI as of October 1, 2015 rather than July 1, 2015.

As a result of updating the list of BPCI participants to those entering the model in October 2015 and including Phase 2 PGPs in the calculation of the number of cases in the MSA, 8 MSAs out of the 75 MSAs that were previously selected are now deemed not eligible for selection and are consequently no longer required to participate in CJR. These previously selected and now excluded MSAs are shown in Table 1. The remaining 67 MSAs selected in the proposed rule will be required to participate in CJR.

(2) Selection Strata

Numerous variables were considered as potential strata for classifying MSAs included in the model. However, our proposal was intended to give priority to transparency and understandability of the strata. We proposed creating selection strata based on the following two dimensions: MSA average wage-adjusted historic LEJR episode payments and MSA population size.

(a) MSA Average Wage-Adjusted Historic LEJR Episode Payments

We were interested in being able to classify and divide MSAs according to their typical patterns of care associated with LEJR episodes. As a straightforward measure of LEJR patterns of care, we selected the mean MSA episode payment, as defined in the proposed rule. MSAs vary in their average episode payments. The average episode payments in an area may vary for a variety of reasons including—(1) In response to the MS–DRG case mix and thus the presence of complicating conditions; (2) readmission rates; (3) practice patterns associated with type of PAC provider(s) treating beneficiaries; (4) variations of payments within those PAC providers, and (5) the presence of any outlier payments.

The measure of both mean episode payments and median episode payments within the MSA was considered. We proposed to stratify by mean because it would provide more information on the variation in episode payments at the high end of the range of payments. We are interested in the lower payment areas for the purpose of informing decisions about potential future model expansion. However, the CJR model is expected to have the greatest impact in areas with higher average episode payments.

The average episode payments used in this analysis were calculated based on the proposed episode definition for CJR using Medicare claims accessed through the Chronic Conditions Warehouse for 3 years with admission dates from July 1, 2011 through June 30, 2014. Episode payments were wage-adjusted using the FY 2014 hospital wage index contained in the FY 2014 IPPS Final Rule, downloaded at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY-2014-IPPS-Final-Rule-Home-Page-Items/FY-2014-IPPS-Final-Rule-CMS-1599-F-Data-Files.html*. The adjusted payment was calculated by dividing the unadjusted payment by a factor equal to the sum of 0.3 plus the multiplicative product of 0.7 and the wage index value of the hospital where the LEJR was performed. We truncated the episode payment at the 99.9th percentile of the distribution ($135,000) to limit the impact of extreme outliers.

(b) MSA Population Size

The second dimension proposed for the CJR selection strata is the number of persons in the MSA. In deciding how best to incorporate the dimensions of urban density and availability of medical resources, a variety of measures were considered, including overall population in the included counties, overall population in the core area of the MSA, population over the age of 65 in the MSA, the number of hospital beds and the number of Medicare FFS LEJR procedures in a year. The reason we decided to include this dimension in the strata definition is that these factors are believed to be associated with the availability of resources and variations in practice and referral patterns by the size of the healthcare market. When examined, these alternative measures were all very highly correlated with one another, which allowed the use of one of these measures to be able to substitute for the others in the definition of the stratum. From these alternative approaches, we choose to use MSA population. In operationalizing this measure, MSAs were classified according to their 2010 census population.

(c) Analysis of Strata

The two proposed domains, MSA population and MSA historic LEJR episode spending, were examined using a K-Means factor analysis. The purpose of this factor analysis was to inform the process of which cut points most meaningfully classify MSAs. Factor analysis attempts to identify and isolate the underlying factors that explain the data using a matrix of associations. Factor analysis is an interdependence technique. Essentially, variables are entered into the model and the factors (or clusters) are identified based on how the input variables correlate to one another. The resulting clusters of MSAs produced by this methodology suggested natural cut points for average episode payments at $25,000 and $28,500. While not intentional, these divisions correspond roughly to the 25th and 75th percentiles of the MSA distribution. Cut points based on these percentiles seemed reasonable from statistical and face validity perspectives in the sense that they created groups that included an adequate number of MSAs and a meaningful range of costs.

As a result of this analysis, we classified MSAs according to their average LEJR episode payment into four categories based the on the 25th, 50th and 75th percentiles of the distribution of the 196 potentially selectable MSAs as determined in the exclusion rules as applied in the proposed rule (80 FR 41198). This approach ranks the MSAs relative to one another and creates four equally sized groups of 49. The population distribution was divided at the median point for the MSAs eligible for potential selection as determined and defined in the proposed rule. This resulted in MSAs being divided into two equal groups of 98. The characteristics of the resulting strata are shown in Table 2.

TABLE 2—SUMMARY POPULATION AND EPISODE PAYMENT STATISTICS BY MSA GROUP

	Payment in lowest quarter	Payment in 2nd lowest quarter	Payment in 3rd lowest quarter	Payment in highest quarter	Total eligible
MSAs deemed eligible in the proposed rule (80 FR 41198) with population less than median:					
Number of Eligible MSAs	33	19	22	24	98
Average of Population	251,899	238,562	268,331	254,154	253,554
Minimum MSA Population	96,275	55,274	106,331	96,024	55,274
Maximum MSA Population	425,790	416,257	424,858	428,185	428,185
Average Episode Payments ($)	$22,994	$25,723	$27,725	$30,444	$26,410
Minimum Episode Payments	$18,440	$24,898	$26,764	$29,091	$18,440
Maximum Episode Payments	$24,846	$26,505	$28,679	$32,544	$32,544
MSAs deemed eligible in the proposed rule (80 FR 41198) with population more than median:					
Number of Eligible MSAs	16	30	27	25	98
Average of Population	1,530,083	1,597,870	1,732,525	2,883,966	1,951,987
Minimum MSA Population	464,036	436,712	434,972	439,811	434,972
Maximum MSA Population	4,335,391	5,286,728	12,828,837	19,567,410	19,567,410
Average Episode Payments ($)	$23,192	$25,933	$27,694	$30,291	$27,082

TABLE 2—SUMMARY POPULATION AND EPISODE PAYMENT STATISTICS BY MSA GROUP—Continued

	Payment in lowest quarter	Payment in 2nd lowest quarter	Payment in 3rd lowest quarter	Payment in highest quarter	Total eligible
Minimum Episode Payments	$16,504	$25,091	$26,880	$28,724	$16,504
Maximum Episode Payments	$24,819	$26,754	$28,659	$33,072	$33,072
Total Eligible MSAs	49	49	49	49	

Note: Population and episode payment means are unweighted averages of the MSA values within each of the eight MSA groups.

Please refer to the addenda for this final rule for information on the non-excluded MSAs, their wage adjusted average LEJR episode spending, their population and their resultant group assignment at: *http://innovation.cms.gov/initiatives/cjr/*.

(3) Factors Considered But Not Used in Creating Proposed Strata

In addition to the two dimensions we proposed to use for the selection groups previously discussed, a variety of possible alternative measures and dimensions were considered. Many of these variables are considered to be important but it was believed that it was important to have a fairly straightforward and easily understandable stratum definition. Simplicity, by definition, required that only the most important variables would be used. If a market characteristic under consideration was correlated with one of the chosen dimensions or it was believed that variations in the characteristic could be adequately captured by random selection within the strata, is was not prioritized for inclusion.

Some of the factors considered that we did not propose as dimensions are—

- Measures associated with variation in practice patterns associated with LEJR episodes. In considering how to operationalize this measure, a number of alternatives were considered including total PAC LEJR payments in an MSA, percent of LEJR episodes with a SNF claim in an MSA, percent of LEJR episodes with an initial discharge to HHA, percent of LEJR episodes with an Inpatient rehabilitation facility (IRF) claim, and percent of LEJR episodes with claims for two or more types of PAC providers;
- Measures associated with relative market share of providers with respect to LEJR episodes;
- Healthcare supply measures of providers and suppliers in the MSA including counts of IRF beds, SNF beds, hospital beds, and number of orthopedic surgeons;
- MSA level demographic measures such as; average income, distributions of population by age, gender or race, percent dually eligible, percent of population with specific health conditions or other demographic composition measures; and
- Measures associated with the degree to which a market might be more capable or ready to implement care redesign activities. Examples of market level characteristics that might be associated with anticipated ease of implementation include the MSA-level EHR meaningful use levels, managed care penetration, ACO penetration and experience with other bundling efforts.

It should be noted that, while these measures were not proposed to be part of the selection strata, we acknowledge that these and other market-level factors may be important to the proper understanding of the evaluation of the impact of CJR. It is the intention that these and other measures will be considered in determining which MSAs are appropriate comparison markets for the evaluation as well as considered for possible subgroup analysis or risk adjustment purposes. The evaluation will include beneficiary, provider, and market level characteristics in how it examines the performance of this proposed model.

(4) Sample Size Calculations and the Number of Selected MSAs

Analyses of the necessary sample size to facilitate a robust statistical analysis of CJR's effects led us to conclude that we needed to include between 50 and 100 MSAs of the 384 MSAs with eligible LEJR episodes to participate in CJR and we proposed to select 75 MSAs. As previously discussed, the proposed revision of the MSA exclusion rules resulted in 8 of the previously selected MSAs now being considered excluded, leading to their removal from the model. The resulting number of selected MSAs, 67, is still within the acceptable range for an MSA count as determined by our analysis. The number and method of selection of these original 75 MSAs from the 8 proposed groups is addressed in the following section. In finalizing this approach, we are undertaking a test in as few markets as possible while still allowing us to be confident in our results and to be able to generalize from the model to the larger national context. We discuss the assumptions and modeling that went into our proposal later in this section.

In calculating the necessary size of the model, a key consideration was ensuring that the model would have sufficient power to be able to detect the desired size impact. The larger the anticipated size of the impact, the fewer MSAs we would have to sample in order to observe it. However, a model sized to be able to only detect large impacts runs the risk of not being able to draw conclusions if the size of the change is less than anticipated. The measure of interest used in estimating sample size requirements for the CJR model was wage-adjusted total episode spending. To measure wage-adjusted total episode spending, we used the 3 year data pull also used for the average regional episode spending estimation that covers LEJR episodes with admission dates from July 1, 2011 through June 30, 2014. For the purposes of the sample size calculation the impact estimate assumed we wanted to be able to detect a 2 percent reduction in wage adjusted episode spending after 1 year of experience. This amount was chosen because it is the anticipated amount of the discount we proposed to apply to target prices in CJR.

The next consideration in calculating the necessary sample size is the degree of certainty we will need for the statistical tests that will be performed. In selecting the right sample size, there are two types of errors that need to be considered ''false negatives'' and ''false positives''. A false positive occurs if a statistical test concludes that the model was successful when it was, in fact, not. A false negative occurs if a statistical test fails to find statistically significant evidence that the model was successful, but it was, in fact, successful. In considering the minimum sample size needs of a model, a standard guideline in the statistical literature suggests calibrating statistical tests to generate no more than a 5 percent chance of a false positive and selecting the sample size to ensure no more than a 20 percent

chance of a false negative. In contrast, the proposed sample size for this project was based on a 20 percent chance of a false positive and a 30 percent chance of a false negative after one year of episodes in order to be as conservative as was practicable. A greater degree of certainty will be available with additional years of data.

A third consideration in the sample size calculation was the appropriate unit of selection and whether it is necessary to base the calculation on the number of MSAs, the number of hospitals, or the number of episodes. As discussed later in this section, we are proposing to base the sample size calculation at the MSA level.

The CJR model is a nested comparative study, which has two key features. First, the unit of assignment (to treatment and comparison groups) is an identifiable group; such groups are not formed at random, but rather through some physical, social, geographic, or other connection among their members. Second, the units of observation are members of those groups. In such designs, the major analytic problem is that there is an expectation for a positive correlation (intra-class correlation (ICC)) among observations of members of the same group (MSA). The ICC reflects an extra component of variance attributable to the group above and beyond the variance attributable to its members. This extra variation will increase the variance of any aggregate statistic beyond what would be expected with random assignment of beneficiaries or hospitals to the treatment group.

In determining the necessary sample size, we need to take into consideration the degrees of freedom. As part of this process, we examined the number of beneficiaries, the number of hospitals, and the number of MSAs and the level of correlation in episode payments between each level. For example, while each beneficiary has their own episode expenditure level, there are commonalities between those expenditure amounts at the hospital level, based on hospital-specific practice and referral patterns. The number of degrees of freedom needed for any aggregate statistic is related to the number of groups (MSAs or hospitals), not the number of observations (beneficiary episodes). If we were to base the determination of the size of the model on beneficiary episodes where correlation exists, we would have an inflated false positive error rate and would overstate the impact of the model. We empirically examined the level of correlation between beneficiaries and hospitals and between hospitals and MSAs and determined that the correlation was high enough to be of concern and necessitate an MSA level unit of selection.

Using the previous assumptions, a power calculation was run which indicated we would need between 50 and 150 treatment MSAs to be able to reliably detect a 2 percent reduction in payments after 1 year. The lower end of this range assumed that our evaluation approach could substantially reduce variation through regression adjustment and other types of statistical modeling. We anticipated that we would have adequate statistical power based on prior research results, but wanted to ensure that we did not have to achieve the ''best possible'' results from such modeling in order to draw conclusions. In order to allow for some degree of flexibility we proposed the selection of 75 MSAs. We narrowed the acceptable range to between 50 and 100 MSAs rather than 50 to 150 MSAs, based on the assumption that we will be able to substantially improve our estimates through modeling, and then chose a number near the middle of this reduced range. Due to the revised exclusion rules, we are proceeding with 67 MSAs, which we believe will provide adequate statistical power.

In assessing to what degree regression adjustment and other statistical adjustments could reduce the number of MSAs needed to generate statistically reliable results, it should be noted that calculations are based on the actual Medicare payments associated with episodes. Thus, the variation in payments associated with MS–DRG case mix, or other reasons are already captured in the methodology.

(5) Method of Selecting MSA

As previously discussed, we selected 75 MSAs from our proposed 8 selection groups and subsequently reduced this number to 67. In performing the initial MSA selection, we examined and considered a number of possible approaches including equal selection in each of the eight groups, equal selection in the four payment groups, selection proportionate to the number of MSAs in each group, and a number of approaches that differentially weighted the payment categories.

After consideration, we proposed a methodology that proportionally under-weighted more efficient MSAs and over-weighted more expensive MSAs was the most appropriate approach to fulfilling the overall priorities of this model to increase efficiencies and savings for LEJR cases while maintaining or improving the overall quality of care. This approach made MSAs in the lowest spending category less likely to be selected for inclusion. We thought this appropriate because the MSAs in the lowest expenditure areas have the least room for possible improvement and are already performing relatively efficiently compared to other geographic areas, which means that experience with the model in these areas may be relatively less valuable for evaluation purposes. At the same time, we believed it was important to include some MSAs in this group in order to assess the performance of this model in this type of circumstance. We also believed it was appropriate for higher payment areas to be disproportionately included because they are most likely to have significant room for improvement in creating efficiencies. We expect more variation in practice patterns among the more expensive areas. There are multiple ways an MSA can be more relatively expensive, including through outlier cases, higher readmission rates, greater utilization of physician services, or through PAC referral patterns. A larger sample of MSAs within the higher payment areas will allow for us to observe the impact of the CJR model on areas with these various practice patterns in the baseline period.

The method of disproportionate selection between the strata used was to choose 30 percent of the MSAs in the two groups in the bottom quarter percentile of the payment distribution, 35 percent of the MSAs in the two groups in the second lowest quartile, 40 percent in the third quartile, and 45 percent in the highest episode payment quartile. This proportion resulted in the selection of the 75 originally selected MSAs out of the 196 eligible. The number of MSAs originally chosen as well as the final selection counts within the eight selection groups is shown in Table 3.

TABLE 3—NUMBER OF MSAS TO BE CHOSEN FROM THE EIGHT SELECTION GROUPS

	Payment in lowest quarter	Payment in 2nd lowest quarter	Payment in 3rd lowest quarter	Payment in highest quarter	Total eligible MSAs
Selection Proportion	30%	35%	40%	45%	
Less Than Median Population (Group #)	(1)	(2)	(3)	(4)	
Number Eligible MSAs per Proposed Rule (80 FR 41198)	33	19	22	24	98
Proportion x Number	9.9	6.65	8.8	10.8	
Number initially selected from group	10	7	9	11	37
Number finally selected from group	8	6	8	11	33
More Than Median Population (Group #)	(5)	(6)	(7)	(8)	
Number Eligible MSAs per NPRM	16	30	27	25	98
Proportion x Number	4.8	10.5	10.8	11.25	
Number initially selected from group	5	11	11	11	38
Number finally selected from group	5	10	9	10	34
Total Eligible MSAs per Proposed Rule (80 FR 41198)	49	49	49	49	196
Number initially selected	15	18	20	22	75
Number finally selected from group	13	16	17	21	67

We selected the proposed MSAs for the CJR model through random selection. In the proposed method of selection, each MSA was assigned to one of the eight selection groups previously identified. Based on this sampling methodology, SAS Enterprise Guide 7.1 software was used to run a computer algorithm designed to randomly select MSAs from each strata. SAS Enterprise Guide 7.1 and the computer algorithm used to conduct selection represents an industry standard for generating advanced analytics and provides a rigorous, standardized tool by which to satisfy the requirements of randomized selection. The key SAS commands employed include a ''PROC SURVEYSELECT'' statement coupled with the ''METHOD=SRS'' option used to specify simple random sampling as the sample selection method. A random number seed was generated for each of the eight strata by using eight number seeds corresponding to birthdates and anniversary dates of parties present in the room. The random seeds for stratum one through eight were as follows: 907, 414, 525, 621, 1223, 827, 428, 524. Note that no additional stratification was used in any of the eight groupings so as to produce an equal probability of selection within each of the eight groups. For more information on this procedure and the underlying statistical methodology, please reference SAS support documentation at: *http://support.sas.com/documentation/cdl/en/statug/63033/HTML/default/viewer.htm#statug_surveyselect_sect003.htm/* We also considered a potential alternative approach to this random selection in which we would generate a starting number within SAS and then choose every third MSA within a group starting at this point until the relevant number of MSAs were chosen. We opted to not utilize this feature for simplicity's sake and alignment with other randomization methodologies used for CMS models.

The selection of an MSA means that all hospitals are included whose address associated with their CCN is physically located anywhere within the counties that make up the MSA. By definition, the entire county is included in an MSA and hospitals that are in the relevant counties will be impacted even if they are not part of the core urban area.

We stated in the proposed rule, should the methodology we propose in this rule change as a result of comments received during the rulemaking process, it could result in different areas being selected for the model. In such an event, we would apply the final methodology and announce the selected MSAs in the final rule. Therefore we sought comment from all interested parties in every MSA on the randomized selection methodology proposed in this section.

The following is a summary of the comments received and our responses.

Comment: Two commenters raised concerns regarding the number of MSAs selected for inclusion in the model. One noted that, given the range between 50 and 150 treatment MSAs to be able to reliably detect a 2 percent reduction in payments, CMS could drop some of the 75 selected MSAs without jeopardizing the ability to produce generalizable results from the CJR model. Another commenter suggested that the approach to the model should focus on an intense analysis within fewer markets prior to expansion into a larger representative sample.

Response: As discussed in the proposed rule, a variety of considerations were made in the determination of what would be an appropriate sample size. The initially proposed 75 MSAs represented the 25 percentage points of the acceptable range of MSAs to be included as determined by sample size calculations. We believe that using a number near the bottom of the range would represent an unnecessary risk to our ability to draw conclusions from the model in a timely manner. While we would prefer to have 75 MSAs in the model in order to increase the likelihood of being able to make definitive statements about the impact of the model at an earlier date, we believe the loss of the 8 MSAs now deemed not eligible for selection constitutes an acceptable risk.

With respect to the request to test the model in a limited pool of MSAs prior to testing it in the full set of selected MSAs, we believe that the testing of this model broadly is crucial to achieving the model's desired objectives and does not believe that proceeding in a few test MSAs prior to testing it in a broader set of MSAs would yield the same degree of information in the same time period.

Comment: A commenter was concerned that the selection strata used did not use MSA-level demographic measures in its selection process, including distributions of population by age, gender, or race; percent of population dually-eligible; percent of population with specific health conditions or other demographic composition measures. They believed these areas associated with more at-risk populations should be represented less in the selection. Another commenter did not question the selection strata but contended that the random selection happened to choose fewer areas with lower income and minority Medicare beneficiaries than they thought desirable. They specifically inquired

after the lack of inclusion of MSAs in Alabama and Georgia.

Response: We considered but ultimately decided against including the dimension based on the demographic characteristics of an MSA incorporated in the selection strata. If we were to have done so, the purpose would have been to ensure an adequate representation along the range of these demographic considerations rather than to eliminate them from possible selection. While these factors are not explicitly part of the selection strata used, the resulting selected MSAs provide an adequate representation of a variety of circumstances including the experiences of areas with a higher degree of non-white populations, MSAs with a range in average income level, and other key characteristics. With regards to the specific concerns regarding under-representation in the MSAs selected from specific states, we note that Alabama, which has relatively high episode costs, had three of its seven eligible MSAs selected while Georgia, whose MSAs had episode payments that indicated relatively more efficient patterns of care, had two of its six eligible MSAs selected. As such, we believe that the experiences of these states and MSAs that are similar in nature to them are adequately represented in the selected MSAs.

Comment: A commenter requested clarification regarding how to interpret which MSAs are included in the model.

Response: We refer readers to Table 4 for a final list of the MSAs that are in the CJR model.

Final Decision: After consideration of the public comments we received, we are finalizing the proposal, with modification to include 67 of the originally selected 75 MSAs. We used updated BPCI participation level information in the application of the MSA exclusion rules for this final rule, resulting in the exclusion of an additional 8 MSAs that were previously selected. We note that we are posting the list of the participant hospitals in the selected MSAs on the CJR Web site at *http://innovation.cms.gov/initiatives/CJR/*. This list will be updated throughout the model, to account for circumstances such as hospital mergers, BPCI termination, and new hospitals within the selected MSAs.

We set forth this final policy in § 510.100 and § 510.105.

TABLE 4—MSAS INCLUDED IN THE CJR MODEL

MSA	MSA Name
10420	Akron, OH
10740	Albuquerque, NM
11700	Asheville, NC
12020	Athens-Clarke County, GA
12420	Austin-Round Rock, TX
13140	Beaumont-Port Arthur, TX
13900	Bismarck, ND
14500	Boulder, CO
15380	Buffalo-Cheektowaga-Niagara Falls, NY
16020	Cape Girardeau, MO-IL
16180	Carson City, NV
16740	Charlotte-Concord-Gastonia, NC-SC
17140	Cincinnati, OH-KY-IN
17860	Columbia, MO
18580	Corpus Christi, TX
19500	Decatur, IL
19740	Denver-Aurora-Lakewood, CO
20020	Dothan, AL
20500	Durham-Chapel Hill, NC
22420	Flint, MI
22500	Florence, SC
23540	Gainesville, FL
23580	Gainesville, GA
24780	Greenville, NC
25420	Harrisburg-Carlisle, PA
26300	Hot Springs, AR
26900	Indianapolis-Carmel-Anderson, IN
28140	Kansas City, MO-KS
28660	Killeen-Temple, TX
30700	Lincoln, NE
31080	Los Angeles-Long Beach-Anaheim, CA
31180	Lubbock, TX
31540	Madison, WI
32820	Memphis, TN-MS-AR
33100	Miami-Fort Lauderdale-West Palm Beach, FL
33340	Milwaukee-Waukesha-West Allis, WI
33700	Modesto, CA
33740	Monroe, LA
33860	Montgomery, AL
34940	Naples-Immokalee-Marco Island, FL
34980	Nashville-Davidson–Murfreesboro–Franklin, TN
35300	New Haven-Milford, CT
35380	New Orleans-Metairie, LA
35620	New York-Newark-Jersey City, NY-NJ-PA
35980	Norwich-New London, CT
36260	Ogden-Clearfield, UT
36420	Oklahoma City, OK
36740	Orlando-Kissimmee-Sanford, FL
37860	Pensacola-Ferry Pass-Brent, FL
38300	Pittsburgh, PA
38940	Port St. Lucie, FL
38900	Portland-Vancouver-Hillsboro, OR-WA
39340	Provo-Orem, UT
39740	Reading, PA
40980	Saginaw, MI
41860	San Francisco-Oakland-Hayward, CA
42660	Seattle-Tacoma-Bellevue, WA
42680	Sebastian-Vero Beach, FL
43780	South Bend-Mishawaka, IN-MI
41180	St. Louis, MO-IL
44420	Staunton-Waynesboro, VA
45300	Tampa-St. Petersburg-Clearwater, FL
45780	Toledo, OH
45820	Topeka, KS
46220	Tuscaloosa, AL
46340	Tyler, TX
48620	Wichita, KS

B. Episode Definition for the CJR Model

1. Background

CJR model is an episode payment model, focused on incentivizing health care providers to improve the efficiency and quality of care for an episode of care as experienced by a Medicare beneficiary by bundling payment for services furnished to the beneficiary for an episode of care for a specific clinical condition over a defined period of time. Key policies of such a model include the definition of episodes of care. Episodes of care have two significant dimensions—(1) A clinical dimension that describes what clinical conditions and associated services comprise the episode; and (2) a time dimension that describes the beginning, middle, and end of an episode. We present our proposals, summarize public comments and provide our responses, and finalize the policies for these two dimensions of CJR episodes in this section.

2. Clinical Dimension of Episodes of Care

a. Definition of the Clinical Conditions Included in the Episode

As discussed previously in section I.A. of this final rule, we identified LEJR episodes, primarily hip and knee replacements, as the focus of this model. In the proposed rule, we stated our belief that a straightforward approach for hospitals and other providers to identify Medicare beneficiaries in this payment model is important for the care redesign that is required for model success, as well as to operationalize the proposed payment and other model policies.

The vast majority of LEJRs are furnished in the inpatient hospital setting, with a small fraction of partial knee replacements occurring in the hospital outpatient department (HOPD) setting. Most of the Current Procedural Terminology (CPT) codes that physicians report for LEJR are on the hospital OPPS inpatient only list. The CY 2015 OPPS inpatient only list is Addendum E of the CY 2015 Hospital Outpatient Prospective Payment—Final Rule with Comment Period, which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-*

1613-FC.html. Thus, under current FFS payment policy, Medicare pays hospitals for the facility services required for most LEJR procedures only when those procedures are furnished in the inpatient hospital setting. Therefore, in our proposal we stated our belief that an episode payment model most appropriately focuses around an inpatient hospitalization for these major surgical procedures, as there is little opportunity for shifting the procedures under this model to the outpatient setting.

We noted further that LEJRs are paid for under the IPPS through the following two Medicare Severity-Diagnosis Related Groups (MS–DRGs):

- MS–DRG 469 (Major joint replacement or reattachment of lower extremity with Major Complications or Comorbidities (MCC)).
- MS–DRG 470 (Major joint replacement or reattachment of lower extremity without MCC).

Multiple International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) procedure codes that describe LEJR procedures and other less common lower extremity procedures group to these MS–DRGs, with their percentage distribution within the IPPS MS–DRGs 469 and 470 for the past 4 years outlined in Table 5.

TABLE 5—DISTRIBUTION OF HOSPITAL CLAIMS FOR ICD–9–CM PROCEDURE CODES MAPPING TO MS–DRGS 469 AND 470

ICD–9–CM procedure code	Code descriptor	FY 2014 (%)	FY 2013 (%)	FY 2012 (%)	FY 2011 (%)
81.54	Total knee replacement	57	58	58	58
81.51	Total hip replacement	30	29	29	28
81.52	Partial hip replacement	12	13	13	14
81.56	Total ankle replacement	0	0	0	0
00.85	Resurfacing hip, total, acetabulum and femoral head	0	0	0	0
00.86	Resurfacing hip, partial, femoral head	0	0	0	0
00.87	Resurfacing hip, partial, acetabulum	0	0	0	0
84.27	Lower leg or ankle reattachment	0	N/A	N/A	N/A
84.28	Thigh reattachment	N/A	N/A	N/A	0

Note: Percentages or claim counts with "N/A" had no claims. Percentages of 0% represent less than 0.5% of total claims.

Additionally, we noted that there are various types of claims-based information available to CMS, hospitals, and other providers, that could be used to identify beneficiaries in the model who receive LEJRs, including the MS–DRGs for the acute care hospitalization for the procedure, the ICD–9–CM procedure code on the hospital claim, or the CPT code(s) reported by the orthopedic surgeon who furnishes the surgical procedure. While we could utilize ICD–9–CM procedure codes or CPT codes to identify beneficiaries included in the model, over 85 percent of procedures that group to MS–DRGs 469 and 470 are hip or knee replacements. Additionally, the hospitals that would be participating in this model receive payment under the IPPS, which is not determined by CPT codes and is based on clinical conditions and procedures that group to MS–DRGs. Finally, our review of the other low volume procedures that group to these same MS–DRGs, aside from total or partial hip and knee replacements, did not suggest that there is significant clinical or financial heterogeneity within these two MS–DRGs such that we would need to define care for included beneficiaries by ICD–9–CM procedure codes.

Therefore, we proposed that an episode of care in the CJR model would be triggered by an admission to an acute care hospital stay (hereinafter ''the anchor hospitalization'') paid under MS–DRG 469 or 470 under the IPPS during the model performance period. This approach offers operational simplicity, for providers and CMS, and is consistent with the approach taken by the BPCI initiative to identify beneficiaries whose care is included in the LEJR episode for that model. We sought public comments on this proposal to define the clinical conditions that are the target of CJR.

The following is a summary of the comments received and our responses.

Comment: Some commenters expressed support for CMS' proposal to define the clinical conditions included in the CJR model episode by discharge from an anchor hospitalization that is paid under MS–DRG 469 or 470 under the IPPS, although a commenter claimed that the cases within each MS–DRG are too heterogeneous to form the basis of a single target price as CMS proposed. The commenter added that risk adjustment could take the form of case exclusions, stratifying cases within each MS–DRG to create separate target prices, or adjusting the target prices based on principal procedure and patient characteristics. Most commenters recommended that CMS limit the model to a subset of beneficiaries that were discharged from these two MS–DRGs, effectively excluding certain cases as form of risk adjustment to reduce the heterogeneity of the cases in the model. The commenters asserted that CMS' proposal, which did not include risk adjustment beyond setting different target prices for episodes based on discharges from the two different MS–DRGs, failed to take into consideration the variability of service needs of beneficiaries discharged from these two MS–DRGs related to the specific procedure performed, the elective or urgent/emergent nature of the procedure, and the beneficiary's clinical and demographic characteristics, including underlying medical conditions and age. Several commenters recommended that CMS define the clinical conditions included in the model by discharges only from MS–DRG 470, claiming that these beneficiaries represented a more homogeneous group that had less complex health care needs. Some commenters urged CMS to define the clinical conditions in the model based on specific MS–DRG and ICD–9–CM procedure code combinations for hip and knee arthroplasty, and stated that CMS should exclude low volume procedures that also map to MS–DRGs 469 and 470 including ankle replacement; lower leg, ankle, and thigh reattachment; and hip resurfacing procedures. The commenters stated that these uncommon procedures display substantial heterogeneity in the clinical characteristics and needs of the beneficiary, as well as the associated Medicare payment for services throughout an episode. They contended that the rationale for CMS' proposal addressed hip and knee replacement in

detail but failed to consider the different PAC patterns of other beneficiaries discharged from the same MS–DRGs but who had different surgical procedures. A commenter recommended that CMS specifically exclude episodes for conversion total joint arthroplasty procedures, which require removal of previously placed hardware followed by THA or TKA in the same operative session, arguing that these beneficiaries had more complex needs.

Many commenters recommended that CMS define the clinical conditions in the model as episodes specific to elective total hip arthroplasty (THA) and total knee arthroplasty (TKA) procedures. The commenters stated that this group of beneficiaries is more homogeneous than beneficiaries undergoing emergent joint replacement procedures for hip fractures or undergoing the other low volume procedures that map to the MS–DRGs. Given that CMS did not propose risk adjustment under the model based on procedure or patient characteristics, the commenters contended that limiting the model to these clinical conditions, that represent about 85 percent of beneficiaries discharged for the two MS–DRGs, would provide a sufficient number of cases to test LEJR episode payment and allow hospitals to create efficient, effective clinical pathways for these beneficiaries. The commenters also observed that CMS' quality measures, specifically the THA/TKA readmissions and complications measures, as well as the voluntary data collection for patient-reported outcomes, would represent only the quality of care for beneficiaries undergoing elective THA and TKA procedures. Several commenters recommended that CMS only include episodes in the model for beneficiaries discharged from MS–DRG 469 or 470 whose data would be used to determine the model's quality measures for the participant hospital.

The commenters suggested several different approaches to defining the clinical conditions included in the model as elective THA or TKA. One approach would be to eliminate from the model beneficiaries with reported ICD–9–CM procedure codes other than THA or TKA, and then further exclude some remaining beneficiaries with ICD–9–CM codes for hip fracture on their claim for the anchor hospitalization. Other commenters asserted that CMS should exclude the beneficiaries receiving the low volume procedures as well as those receiving partial hip arthroplasty (PHA) procedures. The commenters pointed out that almost all of the beneficiaries receiving PHA would have hip fractures and observed that the average Medicare episode payment for beneficiaries undergoing PHA was similar to beneficiaries discharged from MS–DRG 469 or 470 with hip fracture diagnoses, almost twice the payment for beneficiaries undergoing elective THA and TKA. Several commenters presented analyses that demonstrated that beneficiaries with hip fracture, regardless of their discharge from MS–DRG 469 or 470, when compared to beneficiaries with elective procedures, experience twice as high readmissions and PAC utilization rates, as well as higher morbidity and mortality.

The commenters in favor of excluding clinical conditions involving hip fractures from the model stated that the number of hip fracture cases treated by individual hospitals can vary significantly on an annual basis, both due to random variation and practice or population changes. Moreover, different hospitals provide care for different percentages of beneficiaries with hip fracture and, according to some commenters, academic medical centers and small hospitals care for disproportionate percentages of these cases for reasons of medical complexity and the urgent nature of the procedure, respectively, because beneficiaries who fall and experience a hip fracture are commonly transported to their local hospital for emergent treatment. Furthermore, in addition to the variation a hospital itself may experience regarding the percentage of hip fracture cases, which could lead to the hospital-specific historical data used for a portion of the target price to not be reflective of the health care needs of the hospital's episode population in a given performance year, some commenters observed that the increasing percentage of the target price contributed by regional data exacerbated their concerns. Hospitals in a region that care for a disproportionately high percentage of hip fracture patients compared to the regional average would be disadvantaged due to the more intense service needs of hip fracture patients, whereas hospitals caring for a disproportionately low percentage of hip fracture patients compared to the regional average would be advantaged. The commenters contended that excluding clinical conditions involving hip fractures from the CJR model would ensure homogeneity in the beneficiaries in the model such that hospitals would be treated fairly with respect to episode pricing based on the hospital-specific and regional historical CJR episode data for only those beneficiaries undergoing elective THA and TKA.

Response: We appreciate the analyses and suggestions provided by the commenters regarding the most appropriate approach to defining the clinical conditions included in the CJR model. As discussed in section III.C.4.b. of this final rule, we have decided to risk stratify the target price for each MS–DRG-anchored episode based on a beneficiary's hip fracture status. This policy allows us to maintain beneficiaries who receive LEJR procedures due to hip fractures in the CJR model, while acknowledging their typically greater health care needs by providing a target price that is based on payment for services furnished in the historical CJR episode data for Medicare beneficiaries with hip fractures in order to account for a significant amount of beneficiary-driven episode expenditure variation. While beneficiaries with hip fractures may present a more costly population due to greater health care needs, and CJR participant hospitals may vary in their percentages of such beneficiaries, we believe that beneficiaries with hip fracture have the potential to benefit substantially from the care pathways and improved care coordination among providers and suppliers that is incentivized by an episode payment model. In addition, we believe there are opportunities for increased efficiency in the care of beneficiaries with hip fracture who receive LEJR procedures with respect to appropriate PAC utilization and care coordination and management of chronic conditions that may be affected by the LEJR procedure or post-surgical care. Thus, we are finalizing our proposal to include LEJR procedures that result from hip fracture treatment in the clinical conditions that are part of the CJR model episodes, rather than limiting the model conditions to only elective THA and TKA.

We are also finalizing our proposal to include clinical conditions represented by discharge from both MS–DRG 469 and 470 in the CJR model. We believe that providing separate prices for episodes anchored by the two different MS–DRGs accounts for the differences in typical health care needs of the two groups of beneficiaries, specifically the higher IPPS payment for the anchor hospitalization for beneficiaries discharged under MS–DRG 469, as well as the pattern of service utilization for this group of beneficiaries in the 90 days following discharge.

Additionally, we are finalizing our proposal to include any lower extremity joint procedure that results in discharge from MS–DRG 469 or 470 in the CJR

model, including ankle replacement; lower leg, ankle, and thigh reattachment; and hip resurfacing procedures. While the model beneficiaries with these less common clinical conditions are likely to be a small number at any specific participant hospital, they too may benefit from care redesign resulting in improved care coordination and quality that are goals of the CJR model. These beneficiaries share the experience of undergoing major surgical procedures involving the lower extremity with the majority of CJR model beneficiaries undergoing THA or TKA, and they too are likely to require PAC services and care coordination and management of chronic medical conditions to optimize their return to function. We expect that the Medicare actual episode payments for these clinical conditions may be highly variable given the small numbers and variable clinical characteristics of these beneficiaries such that historical episode data may have little predictive power regarding the actual episode payment for the beneficiaries in a model performance year. We do not believe this small number of beneficiaries will put participant hospitals at undue financial risk and further note that our payment policies as discussed in section III.C.3.c. and III.C.8. of this final rule provide a pricing adjustment for high payment episodes and limit hospital financial responsibilities to provide participant hospitals with additional protections.

We note that our final policy to include all clinical conditions that result in a discharge from MS–DRGs 469 or 470 in the CJR model allows us to continue to rely on MS–DRGs to define the clinical conditions included in the LEJR episode being widely tested under the CJR model, consistent with the BPCI methodology to define clinical conditions included in 48 different episodes based on the MS–DRGs for the anchor hospitalization. This approach provides greater certainty from the perspective of participant hospitals or CMS regarding the clinical conditions included in episodes, since the discharge MS–DRG is the defining parameter, and includes the greatest number of beneficiaries with similar clinical conditions in the CJR model test.

Comment: Several commenters urged CMS to include in the CJR model LEJR procedures where the procedure that would result in a beneficiary's discharge from MS–DRG 469 or 470 if furnished in the inpatient hospital setting is furnished in the HOPD, ambulatory surgical center (ASC), or other dedicated facility that is not an acute care facility. The commenters explained that elective procedures are commonly furnished in the HOPD, ASC, or other dedicated facilities that are not acute care facilities for certain beneficiaries covered by commercial insurance, while Medicare covers and pays for the procedures only when they are furnished in the inpatient hospital settings. The commenters disputed CMS' assertion in the proposed rule that there is little opportunity for shifting these procedures to the outpatient setting. They urged CMS to permit these LEJR procedures to be furnished to Medicare beneficiaries in other settings under the CJR model to improve episode efficiency. The commenters contended that physicians should be able to select the most appropriate inpatient hospital or outpatient setting based on the beneficiary's clinical condition.

Response: We appreciate the interest of the commenters in providing LEJR procedures under the CJR model to Medicare beneficiaries in alternative outpatient settings as a further opportunity to test strategies to provide high quality, efficient episode care for beneficiaries undergoing LEJR procedures. As we discussed in the proposed rule, the vast majority of LEJR procedures are furnished to Medicare beneficiaries in the inpatient hospital setting, with a small fraction of partial knee replacements occurring in the hospital outpatient department (HOPD). Most of the CPT codes that physicians report for LEJR procedures are on the hospital OPPS inpatient only list. Thus, under current Medicare program policy, Medicare generally pays hospitals for the facility services required for LEJR only when those procedures are furnished in the inpatient hospital setting. When we stated our belief in the proposed rule that an episode payment model such as the CJR model most appropriately focuses around an inpatient hospitalization for these major surgical procedures, as there is little opportunity for shifting the procedures under the model to the outpatient setting, we meant that this would be true under current Medicare policy. Because Medicare generally does not pay hospitals if procedures that would be assigned to MS–DRG 469 or 470 when furnished to inpatients are performed on hospital outpatients, these procedures would not be able to be shifted under the CJR model to the outpatient setting.

Because most LEJR procedures are on the OPPS inpatient list and CMS has, therefore, determined that Medicare beneficiaries require an inpatient hospitalization for payment of these procedures to hospitals, we are not changing the current inpatient only list designation of these LEJR procedures for the CJR model. CJR is an episode payment model, not a model designed to test different sites of services for procedures that CMS has thus far determined may not be safely performed on Medicare beneficiaries in the outpatient setting. Therefore, we are finalizing our proposal that the CJR model will continue to focus around an inpatient hospitalization for these major surgical procedures that result in a discharge from MS–DRG 469 or 470, and a procedure furnished in the outpatient setting will not be included in the model.

Comment: Several commenters maintained that because the procedures that result in discharge from MS–DRG 469 and 470 that define the clinical conditions included in the CJR model are on the OPPS inpatient only list, CMS should commit to keeping these procedures on the inpatient only list for the 5-year performance period of the model. The commenters pointed out that CMS has previously proposed, but not finalized, the removal of TKA procedures from the inpatient only list. The commenters stated that if any additional procedures that would otherwise result in discharge from one of the two MS–DRGs in the CJR model were to be removed from the inpatient only list during a year when the CJR model is being tested, the beneficiaries who would be included in the model performance year due to a procedure in the inpatient hospital setting would be sicker and more complex than those included in the historical CJR episodes used to set target prices. Therefore, the commenters reasoned that in order to establish target prices that reflect the health care needs and medical complexity of the CJR model beneficiaries in a model performance year, CMS should not remove any LEJR procedures from the OPPS inpatient only list until after the CJR model ends.

Response: We share the commenters' interest in ensuring that the historical CJR episodes that are used to set the target prices for CJR model episodes during a performance year reflect the health care needs and medical complexity of beneficiaries who are comparable to those actually included in the CJR model. If we were to remove an LEJR procedure from the OPPS inpatient only list at any point during the 5-year model test, we agree with the commenters that we would need to consider the effects of such a change on the CJR model pricing methodology, taking into consideration the characteristics of the beneficiaries expected to be in the model due to a

procedure furnished in the inpatient hospital setting after the change to the inpatient only list. If we concluded that changes in our pricing methodology were necessary because the beneficiaries in the historical CJR episodes used to set target prices would no longer be similar to those in the model performance year, we would propose such changes through notice and comment rulemaking.

Comment: Several commenters claimed that different states were testing different LEJR episode payment models. A commenter provided the example of Tennessee mandatory Medicaid bundles that utilize a different episode definition than proposed for the CJR model. The commenters encouraged CMS to move toward standard episode definitions for mandatory models, noting that each of the inconsistent mandatory models is being tested under the Innovation Center's statutory authority. The commenters contended that different episode payment models lead to excessive burden and greater cost for health care providers.

Response: We appreciate the perspective of the commenters on the challenges related to testing mandatory bundled payments with different episode definitions in the same community. We note, however, that the CJR model and various state episode payment models are all in various stages of testing and have used different strategies to arrive at the episode definitions for each model. By definition, models being tested have not yet produced evidence of improved quality and/or cost savings, so we lack the necessary evaluation results from various approaches to consider standardizing episode definitions. We believe there is value in testing different episode definitions given the current state of knowledge about bundled payment. We also believe that, regardless of the specific definitions for episodes that address the same clinical conditions in various different payment models, episode payment models share a common focus on improving the quality of care and increasing the efficiency of care through a variety of well-established strategies, such as increased communication among health care providers along the continuum of acute and PAC and improved care coordination and care management to promote beneficiary engagement that leads to adherence to treatment plans and, correspondingly, reductions in hospital readmissions and complications. As we gain more experience with episode payment models and examine their results, we will consider the potential benefits of standardizing episode definitions to the extent possible.

Summary of Final Decisions: After consideration of the public comments we received, we are finalizing our proposal to define the clinical conditions included in the CJR model by admission to an IPPS hospital that results in a discharge from MS–DRG 469 or 470.

The final policies for defining the clinical conditions are set forth in § 510.100 and § 510.200.

b. Definition of Related Services Included in the Episode

For purposes of this model, as in BPCI, given the frequent comorbidities experienced by Medicare beneficiaries and the generally elective nature of LEJR, we are interested in testing inclusive episodes to incentivize comprehensive, coordinated patient-centered care for the beneficiary throughout the episode. We proposed to exclude only those Medicare items and services furnished during the episode that are unrelated to LEJR procedures based on clinical justification. During our experience with BPCI implementation, we reviewed a number of narrow episode definitions for LEJR episodes that were recommended by BPCI participants and other interested parties during the design phase for this project. We concluded that these narrow definitions commonly exclude many services that may be linked to the LEJR, as LEJR beneficiaries, on average, are at higher risk for more clinical problems than Medicare beneficiaries who have not recently undergone such procedures.

Therefore, we proposed that all CJR episodes, beginning with the admission for the anchor hospitalization under MS–DRG 469 or 470 through the end of the proposed episode, include all items and services paid under Medicare Part A or Part B with the exception of certain exclusions that would be excluded because they are unrelated to the episode. The items and services ultimately included in the episode after the exclusions are applied are called related items and services. As discussed in sections III.C.4. and III.C.6. of this final rule, Medicare spending for related items and services would be included in the historical data used to set target prices, as well as in the calculation of actual episode spending that would be compared against the target price to assess the performance of participant hospitals. In contrast, Medicare spending for unrelated items and services (excluded from the episode definition) would not be included in the historical data used to set target prices or in the calculation of actual episode spending.

We proposed that related items and services included in CJR episodes would be the following items and services paid under Medicare Part A or Part B, after the exclusions are applied:

- Physicians' services.
- Inpatient hospital services (including readmissions), with certain exceptions discussed later in this section.
- Inpatient psychiatric facility (IPF) services.
- Long Term Care Hospital (LTCH) services.
- IRF services.
- SNF services.
- HHA services.
- Hospital outpatient services.
- Independent outpatient therapy services.
- Clinical laboratory services.
- Durable medical equipment (DME).
- Part B drugs.
- Hospice.

We noted that under our proposed definition of related services included in the episode, the episode could include certain per-member-per-month model payments, as discussed in section III.C.7.d. of this final rule.

We proposed to exclude from CJR drugs that are paid outside of the MS–DRG, specifically hemophilia clotting factors (§ 412.115), identified through HCPCS code, diagnosis code, and revenue center on IPPS claims. Hemophilia clotting factors, in contrast to other drugs that are administered during an inpatient hospitalization and paid through the MS–DRG, are paid separately by Medicare in recognition that clotting factors are costly and essential to appropriate care for certain beneficiaries. Thus, in the proposed rule we stated our belief that there are no efficiencies to be gained in the variable use of these high cost drugs when particular beneficiaries receive LEJR procedures who have significantly different medical needs for clotting factors under an episode payment model, so we proposed to exclude these high cost drugs from the actual historical episode expenditure data used to set target prices and from the hospital's actual episode spending that is reconciled to the target price. Similarly, we proposed to exclude IPPS new technology add-on payments for drugs, technologies, and services from CJR episodes, excluding them from both the actual historical episode expenditure data used to set target prices and from the hospital's actual episode spending that is reconciled to the target price. This proposal would apply to both the anchor hospitalization

and any related readmissions during the episode. New technology add-on payments are made separately and in addition to the MS–DRG payment under the IPPS for specific new drugs, technologies, and services that substantially improve the diagnosis or treatment of Medicare beneficiaries and would be inadequately paid otherwise under the MS–DRG system. Medicare pays a marginal cost factor of 50 percent for the costs to hospitals of the new drugs, technologies, or services. We did not believe it would be appropriate for the CJR model to potentially hamper beneficiaries' access to new technologies that are receiving new technology add-on payments or to burden hospitals who choose to use these new drugs, technologies, or services with concern about these payments counting toward actual episode expenditures. In addition, because new drugs, technologies, or services approved for the add-on payments vary unpredictably over time in their application to specific clinical conditions, in the proposed rule we stated our belief that we should exclude IPPS new technology add-on payments from CJR episodes.

We followed a number of general principles in determining other proposed excluded services from the CJR episodes in order to promote coordinated, high-quality, patient-centered care. Based on the broad nature of these episodes, we proposed to identify excluded (unrelated) services rather than included (related) services based on the rationale that all Part A and Part B services furnished during the episode are related to the episode, unless they are unrelated based on clinical justification as described in more detail later in this section. In developing our proposals for exclusions for this model, we stated our belief that no Part A services, other than certain excluded hospital readmissions during the episode as described in this section, furnished post-hospital discharge during the episode should be excluded, as post-hospital discharge Part A services are typically intended to be comprehensive in nature. We also stated our belief that no claims for services with diagnosis codes that are directly related to the LEJR procedure itself (for example, loosening of the joint prosthesis) based on clinical judgment, and taking into consideration coding guidelines, should be excluded. Furthermore, we stated our belief that no claims for diagnoses that are related to the quality and safety of care furnished during the episode, especially the anchor hospitalization under MS–DRG 469 or 470, should be excluded, such as direct complications of post-surgical care during the anchor hospitalization. Examples of diagnoses that would not be excluded on this basis include surgical site infection and venous thromboembolism. Finally, in the proposed rule we stated our belief that no claims for services for diagnoses that are related to preexisting chronic conditions such as diabetes, which may be affected by care furnished during the episode, should be excluded. However, severe exacerbations of chronic conditions (for example, some surgical readmissions) that are unlikely to be affected by care furnished during the episode should be excluded; thus, when a beneficiary is admitted to the hospital during the episode for these circumstances, we would not consider it to be a related readmission for purposes of CJR. We also stated our belief that services for clinical conditions that represent acute clinical conditions not arising from an existing chronic clinical condition or complication of LEJR surgery occurring during an episode of care, which would not be covered by the previous principles about included services, should be excluded.

To operationalize these principles for CJR, we proposed to exclude unrelated inpatient hospital admissions during the episode by identifying MS–DRGs for exclusion. We proposed to exclude unrelated Part B services based on the ICD–9–CM diagnosis code (or their International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) equivalents when ICD–10–CM codes are implemented) that is the principal diagnosis code reported on claims for services furnished during the episode. More specifically, we proposed to exclude specific inpatient hospital admissions and services consistent with the LEJR episode definition (also triggered by MS–DRGs 469 and 470) that is currently used in BPCI Model 2. We note that the list of exclusions was initially developed over 2 years ago for BPCI through a collaborative effort of CMS staff, including physicians from medical and surgical specialties, coding experts, claims processing experts, and health services researchers. The list has been shared with thousands of entities and individuals participating in one or more phases of BPCI, and has undergone refinement over that time in response to stakeholder input about specific diagnoses or MS–DRGs for exclusion, resulting in only minimal changes over the last 2 years. Thus, the BPCI list of exclusions for LEJR procedures has been vetted broadly in the health care community; refined based on input from a wide variety of providers, researchers and other stakeholders; and successfully operationalized in the BPCI models. We proposed its use in CJR based on our confidence related to our several of years of experience that this definition is reasonable and workable for LEJR episodes, for both providers and CMS.

With respect to the proposed inpatient hospital admission exclusions for this model, we proposed that all medical MS–DRGs for readmissions be included in CJR episodes as related services, with the exception of oncology and trauma medical MS–DRGs. We proposed that admissions for oncology and trauma medical MS–DRGs be excluded from CJR episodes. Readmissions for medical MS–DRGs are generally linked to the hospitalization for the LEJR procedure as a complication of the illness that led to the surgery, a complication of treatment or interactions with the health care system, or a chronic illness that may have been affected by the course of care. We refer readers to section III.D. of this final rule for background and discussion of the complication rate measure proposed for CJR that includes common medical complications resulting from the previously stated circumstances following LEJR procedures and that may result in related hospital readmissions. For readmissions for medical MS–DRGs, the selection of the primary diagnosis code is not clear-cut, so in the proposed rule we stated our belief that all should be included because providers should focus on comprehensive care for beneficiaries during episodes. We proposed to include all disease-related surgical MS–DRGs for readmissions, such as hip/knee revision, in CJR episodes. We also proposed to include readmissions for all body system-related surgical MS–DRGs as they are generally related to complications of the LEJR procedures. An example of a readmission of this type would be for an inferior vena cava filter placement for treatment of thromboembolic complications of the LEJR. We proposed to exclude hospital admissions for chronic disease surgical MS–DRGs, such as prostatectomy (removal of the prostate gland), as they are unrelated to the clinical condition that led to the LEJR and they would not have been precipitated by the LEJR. Finally, we proposed that hospital admissions for acute disease surgical MS–DRGs, such as appendectomy, be excluded because they are highly unlikely to be related to, or precipitated by, LEJR procedures and would not be affected by LEJR episode care redesign.

With respect to the LEJR proposed diagnosis code exclusions for Part B services for this model, we proposed that ICD–9–CM codes be excluded or included as a category and as identified by code ranges. We proposed that disease-related diagnoses, such as osteoarthritis of the hip or knee, are included. We also proposed that body system-related diagnoses are included because they relate to complications that may arise from interactions with the health care system. An example of this would be pressure pre-ulcer skin changes. Additionally, we proposed that all common symptom diagnoses are included because providers have significant discretion to select these as principal diagnosis codes. We proposed that acute disease diagnoses, such as severe head injury, are excluded. Finally, we proposed that chronic disease diagnoses be included or excluded based on specific clinical and coding judgment as described previously with respect to the original development of the exclusions for LEJR episodes under BPCI, taking into consideration whether the condition was likely to have been affected by the LEJR procedure and recovery period and whether substantial services were likely to have been provided for the chronic condition during the episode. Thus, chronic kidney disease and cirrhosis would be included in the episode, but glaucoma and chemotherapy would be excluded.

Proposed exclusions from CJR episodes were based on care for unrelated clinical conditions represented by MS–DRGs for readmissions during the episode and ICD–9 CM codes for Part B services furnished during the episode after discharge from the anchor hospitalization. The complete lists of proposed excluded MS–DRGs for readmissions and proposed excluded ICD–9–CM codes for Part B services are posted on the CMS Web site at *http://innovation.cms.gov/initiatives/cjr/*.

In the proposed rule, we noted that as CMS moves to implement ICD–10–CM we would make the CJR exclusions that would map to the final ICD–9–CM exclusions for CJR available in the ICD–10–CM format as well. We proposed that all Part A and B-covered items and services that would not be excluded based on the exclusions list are included in the episode. Furthermore, we proposed to update the exclusions list without rulemaking on an annual basis, at a minimum, to reflect annual changes to ICD–CM coding and annual changes to the MS–DRGs under the IPPS, as well as to address any other issues that are brought to our attention by the public throughout the course of the model test.

We would first develop potential exclusions list revisions of MS–DRGs for readmissions and ICD–9–CM (or ICD–10–CM, as applicable) diagnosis codes for Part B services based on our assessment against the following standards:

- We would not exclude any items or services that are—

++ Directly related to the LEJR procedure itself (such as loosening of the joint prosthesis) or the quality or safety of LEJR care (such as post-surgical wound infection or venous thromboembolism); and

++ For chronic conditions that may be affected by the LEJR procedure or post-surgical care (such as diabetes). By this we mean that where a beneficiary's underlying chronic condition would be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care must be managed differently as a result of the chronic condition, then those items and services would be related and would be included in the episode.

- We would exclude items and services for—

++ Chronic conditions that are generally not affected by the LEJR procedure or post-surgical care (such as removal of the prostate). By this we mean that where a beneficiary's underlying chronic condition would not be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care need not be managed differently as a result of the chronic condition, then those items and services would not be related and would not be included in the episode; and

++ Acute clinical conditions not arising from existing episode-related chronic clinical conditions or complications of LEJR surgery from the episode (such as appendectomy).

We proposed to post the potential revised exclusions, which could include additions to or deletions from the exclusions list, to the CMS Web site to allow for public input on our planned application of these standards, and then adopt changes to the exclusions list with posting to the CMS Web site of the final revised exclusions list after our consideration of the public input.

We sought comment on our proposals for identifying excluded readmissions and Part B-covered items and services, as well as our proposed process for updating the exclusions list.

The following is a summary of the comments received and our responses.

Comment: Several commenters recommended that CMS clarify the proposal that named ''independent outpatient therapy services'' in the episode definition list of related Part A and Part B services included in the episode. The commenters pointed out that while this list specified ''independent outpatient therapy services,'' which would appear to only represent services furnished by therapists in private practices included in CMS data under certain supplier specialty codes, the commenters believe that CMS should refer to the services as outpatient therapy services in order to include all outpatient physical therapy, occupational therapy, and speech-language pathology therapy services in the definition of related Part A and Part B services included in the episode. The commenters noted that in the proposed rule discussion of CJR collaborators CMS referred to financial arrangements with outpatient therapy providers, a category of providers that was not defined in the proposed rule and has not otherwise been previously defined in the Medicare program. Therefore, the commenters recommended that CMS define outpatient therapy providers in regulation in the CJR final rule as a physician, supplier, or provider furnishing outpatient physician therapy services, outpatient occupational therapy services, or outpatient speech-language pathology services. The commenters suggested that CMS should then clarify that services furnished by these outpatient therapy providers (outpatient therapy services) would be included in the episode definition, thereby including these payments in the CJR historical episode data used to set target prices and in the calculation of actual episode spending that would be compared against the target price.

Response: We agree with the commenters' suggestion that we define outpatient therapy providers in regulation to ensure consistent and accurate reference to certain providers and services under the CJR model, and that we should include services furnished by outpatient therapy providers as related services in the CJR model after the exclusions are applied. Therefore, we are adding the following new definition to § 510.2: *Provider of outpatient therapy services* means a provider or supplier furnishing—(1) Outpatient physical therapy services as defined in 410.60 of this chapter, or (2) outpatient occupational therapy services as defined in 410.59 of this chapter, or (3) outpatient speech-language pathology services as defined in 410.62 of this chapter. We are also revising § 510.200(b)(10) to remove the word ''independent'' preceding outpatient therapy services.

Comment: Several commenters recommended that CMS add to the list of related services included in CJR model episodes drugs covered under Medicare Part D. The commenters asserted that Part D-covered drugs make important contributions to beneficiary health, especially for beneficiaries with chronic medical conditions and, therefore, should be included in a broadly defined episode payment model such as the CJR model to provide opportunities for improved quality and efficiency of care for beneficiaries.

Response: We appreciate the interest expressed by the commenters in including drugs covered under Part D in the LEJR episode definition used for the CJR model. However, while we agree with the commenters that the appropriate use of Part D-covered drugs can play an important role in improving a beneficiary's health, we will not be expanding our list of Part A and Part B items and services related to the episode to add Part D-covered drugs. We proposed to require all beneficiaries included in the CJR model to have both Part A and Part B coverage throughout the duration of the episode in order to ensure we had comprehensive episode payment data to calculate actual episode spending to be compared against the target price. However, enrollment in Part D is voluntary and a substantial percentage of Medicare beneficiaries do not have Part D coverage, so we would lack comprehensive payment information for all beneficiaries in the model in order to determine an episode target price and calculate actual episode spending. In addition, beneficiary-specific information about Part D drug spending that could be attributed to episodes would not be available in a timeframe consistent with the time periods for claims used to set target prices and the timeline for reconciliation where actual episode spending is aggregated and compared against the target price. Finally, given that the CJR model is testing LEJR episodes, we believe there is limited opportunity to shift spending from Part B to Part D to reduce actual episode spending, even though we have not included Part D payments in the episode definition. Most beneficiaries with chronic conditions would be taking similar drugs before and during the episode, and, other than pain medications, Part D-covered drugs are not commonly used to manage the direct post-surgical and PAC rehabilitation needs of most LEJR beneficiaries, who rarely experience significant complications from the surgery. Therefore, we are finalizing our proposal to not include all Part D-covered drugs from the list of related items and services included in CJR episodes.

Comment: Several commenters recommended that CMS exclude Inpatient Psychiatric Facility (IPF) services from CJR episodes because they would be unlikely to be related to the LEJR procedure. The commenters suggested that the services are always medically necessary with no opportunities for efficiency and would be more likely to be associated with injury that led to the need for LEJR procedure, rather than related to the surgical procedure or recovery. Several commenters stated that CMS should exclude these services from the episode definition because they were excluded under LEJR episodes in BPCI. Another commenter suggested that CMS exclude IPF services furnished more than 14 days after surgery because after than point, the commenter believes these services would be unlikely to be related to the surgery or recovery.

Response: We are clarifying that under BPCI, IPF services furnished following discharge from the LEJR episode anchor hospitalization but during the episode are included in the LEJR episode definition, unless they fall into one of the excluded MS–DRGs. Thus, we include inpatient psychiatric services whether paid under the IPPS or the IPF PPS in LEJR episodes under BPCI according to the same policy that would exclude readmissions paid under either payment system based on the same exclusion list. We see no reason under the CJR model not to apply the standard we proposed to define related and unrelated Part A and Part B services with respect to CJR episodes. Therefore, we believe the list of excluded MS–DRGs identifies those IPF admissions during the episode that would be clinically unrelated to the LEJR episode so we exclude them from the episode definition, whereas IPF services any time during a CJR episode that result in discharge from an MS–DRG that is not excluded would be related and included in the CJR model episode definition. We disagree with the commenter that all IPF services furnished more than 14 days after surgery are unlikely to be related to the LEJR procedure or complications of the procedure or to a chronic condition that must be managed differently as a result of the procedure. Regardless of the time IPF services are furnished following discharge from the anchor hospitalization, we believe the MS–DRG exclusions identify those circumstances when IPF services are unrelated to the CJR model episode. Therefore, consistent with the BPCI policy, we are finalizing our proposal to include IPF services in the CJR model episode definition when they are assigned to an MS–DRG that is not excluded from episode definition.

Comment: Several commenters commended CMS for proposing to include hospice services in the episode definition for the CJR model, which provides recognition of hospice services as an essential element of the health care continuum. They stated that they looked forward to CMS sharing data resulting from the model that provides insight into the impact of incorporating hospice as part of a bundled care model and coordinated approach to post-hospital care. However, the commenters asserted that generally hospice services would be unrelated to the LEJR episode because they would most commonly address a serious and unanticipated complication of surgery or the hospitalization, discovery during or immediately after the surgery of a previously undetected terminal prognosis, or an unrelated accident following the procedure. While acknowledging that some hospice services would be related to the LEJR episode under uncommon circumstances, the commenters encouraged CMS to include in the final rule the process that would be used to identify included and excluded hospice services from CJR episodes. The commenters urged CMS to further describe its rationale for including hospice services in the episode definition, and supply data that relates to hospice services and the CJR model. Finally the commenters recommended that CMS establish a data acquisition system on hospice use in the final model. Some commenters expressed confusion about CMS' proposal to include hospice services in the episode definition and inquired about whether CMS intended to include all hospice services or to exclude certain hospice services as unrelated to the LEJR episode according to the beneficiary's diagnosis.

A number of other commenters recommended that CMS exclude all hospice services from the CJR episode definition, except for the post-episode spending calculation that analyzes all Part A and Part B spending for model beneficiaries, both for consistency with BPCI and to ensure no incentives for underutilization of the hospice benefit were created by the CJR model. The commenters asserted that all hospice services were unrelated to the LEJR episode, and encouraged CMS to exclude hospice services in order to ensure timely access to hospice for CJR model beneficiaries.

Response: We appreciate the interest of the commenters in ensuring continuing beneficiary access to hospice services under the CJR model. We note that while we exclude all hospice services under BPCI, our proposal for the CJR model would exclude no hospice services. Specifically, we proposed no exclusions of Part A services furnished during the 90 day period after discharge from the anchor hospitalization other than certain hospital readmissions identified by excluded MS–DRGs. We understand that CJR model beneficiaries could receive hospice services during an episode under several different types of clinical circumstances. For example, the beneficiary could be enrolled in hospice prior to the LEJR episode, experience a pathologic hip fracture, and require THA to stabilize the beneficiary's hip. Alternatively, the beneficiary could have an LEJR procedure and enter into hospice at some point during the episode in the 90 days following discharge from the anchor hospitalization, either after experiencing a surgical complication leading to a terminal prognosis or based on a new diagnosis of a terminal stage of an illness. We note that given the pre-surgical screening that patients must undergo before an LEJR procedure, it would be rare for a new diagnosis that would render the patient terminally ill to occur within 3 months after the LEJR procedure that was not already identified during the pre-surgical screening process.

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. As referenced in § 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. When an individual is terminally ill, many health problems are brought on by underlying condition(s), as bodily systems are interdependent. Section 1861(dd)(1) of the Act establishes the services that are to be rendered by a Medicare certified hospice program and those 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 biologics); medical appliances; counseling services (including dietary counseling); short-term inpatient care (including both respite care and care necessary for pain control and acute or chronic symptom management) in a hospital, nursing facility, or hospice inpatient facility; 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. The services offered under the Medicare hospice benefit must be available, as needed, to beneficiaries 24 hours a day, 7 days a week (section 1861(dd)(2)(A)(i) of the Act).

The regulations at § 418.54(c) stipulate that the comprehensive hospice assessment must identify the patient's physical, psychosocial, emotional, and spiritual needs related to the terminal illness and related conditions, and address those needs in order to promote the hospice patient's well-being, comfort, and dignity. 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)). Additionally, the hospice 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. In the December 16, 1983 Hospice final rule (48 FR 56010 through 56011), 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.''

Thus, hospice services furnished to CJR model beneficiaries should be included in the episode definition for the CJR model, regardless of the specific diagnosis of the beneficiary, because hospices are to provide virtually all care that is needed by terminally ill patients. If a CJR beneficiary was receiving hospice services during an episode, either because the beneficiary was enrolled in hospice prior to surgery and continued in hospice following surgery or the beneficiary enrolled in hospice following surgery that initiated the CJR model episode, we believe that hospice services would encompass care related to the LEJR episode and should, therefore, be included in the episode definition. As previously noted, given the comprehensive nature of the hospice benefit and the fact that body systems are interdependent at end of life, virtually all care needed by the terminally-ill individual would be related to the terminal prognosis and thus the responsibility of the hospice. As previously noted, hospices are required, per the Hospice CoPs at § 418.56(c), to provide all reasonable and necessary services for the palliation and management of the terminal illness, related conditions, and interventions to manage pain and symptoms. For patients that underwent LEJR procedures as part of the CJR model that have also elected the Medicare hospice benefit, hospice services would need to adapt and respond to the care needs of the CJR beneficiary following surgery. As in the case of other medically necessary services that would improve a beneficiary's quality of care and quality of life, we expect that CJR model beneficiaries will receive clinically appropriate referrals to hospice in a timely manner. Furthermore, we also believe hospice services could contribute to episode efficiency through improved comprehensive care coordination and management for CJR model beneficiaries that have a terminal prognosis. As previously stated, hospices are required to provide comprehensive care coordination and management per the hospice CoPs at 418.56. As discussed in sections III.F.3. and 5. of this final rule, we will be monitoring for access to care and delayed care and will take actions as described if problems are found. Therefore, we are finalizing our proposal to include hospice services in the CJR model episode definition.

With regard to the commenters' request for data regarding hospice use and the CJR model, we note that the evaluation approach described in IV.D. of this final rule will yield utilization information on CJR beneficiaries' episodes for specific types of providers and services. As discussed in section IV.E. of this final rule, we plan to evaluate the CJR model on an annual basis and release internal periodic summaries to offer useful insight, with

a final analysis after the end of the 5-year performance period. Finally, we plan to make available to participant hospitals upon their request periodic summary claims data reports or raw claims data, including payment information, using type of service categories that including hospice. We refer readers to section III.E.2. of this final rule for a more detailed discussion of the plans for sharing data under the CJR model.

Comment: Several commenters requested that CMS exclude prosthetic limbs, orthopedic braces, and customized durable medical equipment (DME) from the related services included in CJR model episodes. The commenters stated that these uncommonly furnished items were at risk of not being provided to CJR model beneficiaries, and provided historical example of access problems during implementation of the SNF PPS that eventually resulted in some HCPCS codes for these items being exempted from SNF consolidated billing. Another commenter requested clarification about included services with respect to the definition of DME. The commenter expressed its belief that there would be no need for verification by CMS or its contractors about coverage of DME as CMS would be making a single episode payment to hospitals. The commenter sought clarification that devices that would usually be paid for under the MS–DRG payment should be able to be used in the CJR beneficiary's home.

Response: While some commenters recommended that we exclude altogether certain prosthetics, braces, and customized DME from the episode definition under the CJR model, we believe that our Part B ICD–9–CM (or equivalent ICD–10–CM) diagnosis code exclusions will allow these items to be excluded when they are unrelated to the episode., both in determining historical CJR episode payments used to set the target price and in calculating actual episode spending during the model performance years Just as for other Part B services, when the primary ICD–9–CM (or equivalent ICD–10–CM) diagnosis code on the claim for the item is not excluded, the prosthetics, orthopedic braces, and customized DME will be included in the CJR episode. Because we will identify unrelated items when they are furnished, and the Medicare payment for those items will not be included in calculating the actual episode spending, we believe that CJR model beneficiaries will continue to have access to these items when they are furnished for unrelated diagnoses on the Part B ICD–10–CM diagnosis code exclusions list. With regard to the commenter who discussed a single payment by CMS to hospitals for the episode, we want to emphasize that this is a retrospective payment model and, thus, payments for all covered items and services will continue to be made under the usual Medicare program rules to all providers and suppliers furnishing services to CJR model beneficiaries, unless we have specifically waived certain Medicare program rules under the CJR model. We refer readers to section III.C.11. of this final rule for further discussion of waivers of Medicare program rules, but note that we have waived no existing requirements or conditions about DME. All existing program rules for coverage and payment of DME continue to apply. Therefore, we are finalizing our proposal to include DME in the CJR model episode definition, after application of the exclusions.

Comment: A number of commenters commended CMS on the proposal to exclude IPPS new technology add-on payments from the CJR model episode definition, as well as hemophilia clotting agents furnished to hospital inpatients. The commenters believe these policies will ensure access to these important treatments for CJR model beneficiaries who would benefit from them. Several commenters suggested that CMS also exclude from the CJR model episode definition OPPS transitional pass-through payments for devices, which are paid separately for a limited period of time based on their increased cost over existing technologies and evidence that they are a substantial clinical improvement, for consistency with CMS' proposed treatment of IPPS new technology add-on payments which accomplish the same objective for hospital inpatients. Other commenters recommended that CMS exclude other innovative technologies from the episode definition by establishing a review process to see if their cost should be removed from CJR episode spending to ensure that the financial incentives under the CJR episode payment model did not discourage appropriate use of new technologies for CJR model beneficiaries who would benefit from them. These commenters stated that such a policy would ensure that beneficiaries in the CJR model have access to beneficial new technologies that otherwise might be limited because of participant hospitals' concerns over providing items and services that would increase actual episode spending. A commenter, arguing in support of CMS' proposal to exclude IPPS new technology add-on payments from the episode definition, suggested that CMS analyze Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) data to see if customized joints correlated with HCAHPS scores under the model.

Response: We agree with the commenters that CJR model beneficiaries should have access to beneficial new technologies while they are in CJR episodes. We do not believe it would be appropriate for the CJR model to potentially hamper beneficiaries' access to new technologies that are receiving IPPS new technology add-on payments or to burden hospitals who choose to use these new drugs, technologies, or services with concern about these payments counting toward actual episode expenditures. We also agree with the commenters' recommendation that we should exclude OPPS pass-through payments for medical devices from the episode definition for the same reasons we proposed to exclude IPPS new technology add-on payments. In both of these cases, through the established OPPS and IPPS review processes, we have determined that these technologies have a substantial cost but also lead to substantial clinical improvement for beneficiaries. Therefore, we are finalizing our proposal to exclude from the CJR episode definition IPPS new technology add-on payments and hemophilia clotting factors paid separately during an inpatient hospitalization. In addition, we are modifying our proposal and will exclude OPPS transitional pass-through payments for medical devices from the CJR model episode definition and price determinations.

We will not establish a new process to review innovative technologies and make individual determinations regarding their exclusion from the CJR model episode definition, as recommended by some commenters. Because the CJR model is a retrospective reconciliation model that pays all providers and suppliers under the regular Medicare program throughout the episode of care, we believe it is more appropriate to rely on the existing processes under the Medicare program to make determinations about separate payment for new technology items and services. If those existing processes identify new technologies that would qualify for add-on payments under the IPPS or transitional pass-through payment under the OPPS, we will exclude them from the CJR model episode definition to ensure that access to new technology items and services for beneficiaries is not influenced by their care being include in the CJR model. We note that the evaluation

approach for the model as discussed in section IV. of this final rule will analyze a variety of information about the model to draw conclusions about its effects on quality and cost but is not designed to examine patient experience as related to specific items or services furnished during the episode.

Comment: Most commenters expressed support for CMS' proposed episode definition that would exclude certain readmissions based on a list of MS–DRGs, as well as certain Part B services based on the principal diagnosis on the claim, consistent with the episode definition for LEJR episodes under BPCI that has been used for several years. The commenters acknowledged that most services would be included in the episode definition under the proposal, thus creating broadly defined episodes that should lead to comprehensive care for beneficiaries following LEJR procedures. A number of commenters characterized the proposed episode definition as clinically reasonable and agreed with the proposed lists of services that would be excluded. A commenter claimed that the proposed episode definition would encourage the integration of post-fracture care coordination, such as could be provided through a fracture liaison service, with acute care for CJR model beneficiaries with hip fractures, leading to improved outcomes. However, some commenters expressed general concern about CMS' proposal to hold participant hospitals financially accountable for these broadly defined episodes, especially as CMS did not propose to risk adjust target prices for the episodes to reflect beneficiaries' chronic conditions.

Several commenters suggested that CMS adopt an episode definition for the CJR model that is flexible and condition-specific. A commenter questioned the role of the beneficiary's health care provider in evaluating relatedness to the episode under the proposal and recommended that CMS permit the beneficiary's health care provider to make determinations of relatedness of services to the episode on a case-by case basis specific to a beneficiary's unique clinical condition. A few commenters suggested that CMS' proposed episode definition was more consistent with a total cost of care model by including beneficiaries with chronic conditions and excluding so few services. These commenters stated that if CMS finalizes such a broad definition, risk adjustment would be necessary in order to ensure fair payment to participant hospitals. Some commenters contended that CMS should include in the episode definition only services that are directly related to the procedure and complications for which the hospital could be held accountable. In the view of some commenters, CMS should exclude all chronic conditions from the episode definition, especially when the LEJR episode is unavoidable, such as in trauma cases. Examples provided by commenters of chronic conditions that should be excluded include diabetes and renal failure. Other commenters recommended that CMS only exclude care for unrelated chronic conditions and acute medical conditions such as urinary tract infection and dehydration occurring later than 30 days following discharge from the anchor hospitalization or otherwise shorten the episode duration of the model to 30 days. They claimed that holding the participant hospital accountable through the episode definition for chronic conditions two months after surgery is unfair. A commenter recommended that CMS include all readmissions for the first 30 days following discharge from the anchor hospitalization and thereafter only those hospital readmissions for the subsequent 60 days that are directly related to the LEJR procedures. Overall, a number of commenters expressed concern that unless CMS narrowed the proposed CJR model episode definition to exclude more services or diagnoses or shortened the episode duration, hospitals may be more cautious about treating patients with complex medical status, especially if CMS also does not risk adjust the target prices for the episode based on beneficiary characteristics and specific procedures.

A commenter stated that the proposed episode definition was not sufficiently broad for frail patients, especially those with multiple illnesses who may have had a hip fracture. The commenter contended that providers should be paid to provide comprehensive care and treat the whole person, who can have many different types of interrelated health care needs when he or she is acutely ill due to a hip fracture in the face of serious underlying chronic conditions. The commenter stated that the CJR model would contribute to the fracturing of comprehensive care for vulnerable beneficiaries by excluding some services from the episode definition, even if those services are for clinical conditions that appear to be clinically unrelated to the LEJR episode, and claimed that the solution to this challenge is moving people with complex medical needs into a patient-centered medical home or comprehensive ACO. The commenter stressed that any existing medical home or ACO arrangements that apply to CJR model beneficiaries should be respected by the participant hospital managing the CJR episode, so as to not disrupt or otherwise interfere with comprehensive care for beneficiaries with complex medical needs.

Response: We appreciate the support of many commenters for our proposed overall approach of identifying excluded services by MS–DRGs for hospital readmissions and ICD–9–CM (or equivalent ICD–10–CM) diagnosis codes for Part B services for LEJR episodes that are broadly inclusive of related services. Because the methodology for setting episode prices as discussed in section III.C. of this final rule requires the construction of historical CJR episodes upon which to base target prices that are then compared with actual episode payment during each performance year of the model, we must use a standard episode definition for the CJR model to ensure comparability of services included in the episode in the historical CJR episode data and the model performance year. Thus, we are unable to adopt the suggestions of commenters that the CJR model episode definition be flexible or that health care providers make service-by-service determinations of relatedness for individual beneficiaries.

As discussed in the proposed rule and confirmed by the commenters, beneficiaries undergoing LEJR procedures have frequent comorbidities where their management may be affected by the surgery and post-operative recovery period. We do not believe it would be appropriate given the frequent comorbidities experienced by Medicare beneficiaries and the generally elective nature of LEJR to utilize a narrow episode definition for CJR that includes only those services directly related to the LEJR procedure or the quality or safety of the LEJR care, as we are interested in testing inclusive episodes to incentivize comprehensive, coordinated patient-centered care for the beneficiary throughout the episode. The care for many chronic conditions and the development of acute medical conditions may be affected by the LEJR procedure or post-surgical care throughout the post-surgical recovery period that extends significantly beyond 30 days following hospital discharge, a point in time where beneficiaries are usually still receiving PAC services, often including SNF services, and have not returned to their level of presurgical function. Therefore, we do not believe it would be appropriate to define services for chronic conditions and acute medical conditions as related to the CJR

model episode for 30 days post-discharge from the anchor hospitalization, and unrelated for the remaining 60 days in the episode. We believe that care for chronic medical conditions affected by the LEJR procedure or post-surgical care is related to the episode for the full episode duration because the care for these conditions is likely to be affected by the procedure and associated recovery for 90 days post-hospital discharge or even longer as the beneficiary recovers function over the course of the episode and returns to the community. We note that we have finalized several waivers of Medicare program rules as discussed in section III.C.11. of this final rule specifically to assist participant hospitals in efficient and effective care coordination and care management for CJR beneficiaries with significant, ongoing health needs, including chronic medical conditions whose care may be affected by the LEJR procedure and post-surgical recovery. Thus, we will exclude only those Medicare Part A and B-covered items and services furnished during the episode that are unrelated to LEJR procedures based on clinical justification, and the exclusions will apply throughout the episode duration. Finally, we believe that the payment policies of the model as described in sections III.C.3.c. and III.C.8. of this final rule to adjust pricing for high payment episodes and to provide stop-loss limits provide sufficient protections for participant hospitals from excessive financial responsibility for high payment cases that may result from the broad episode definition adopted for the model. We expect that participant hospitals, with responsibility for the quality and cost performance of CJR model episodes, will work closely with all providers, suppliers, and organizations engaged in the care of model beneficiaries, in order to ensure that efficient, coordinated care is furnished to the beneficiary.

We appreciate the concerns expressed by commenters about holding participant hospitals financially responsible for broad LEJR episodes extending 90 days post-discharge from the anchor hospitalization. We note that we are finalizing 90 days post-discharge from the anchor hospitalization as we proposed for the reasons discussed later in this section. Additionally, we refer readers to section III.C.4.b. of this final rule for the final policy that will risk stratify the target prices based on the presence or absence of a hip fracture for CJR model beneficiaries. We believe that this risk stratification policy addresses the commenters' concerns that beneficiaries with chronic conditions are likely to need more costly care throughout the CJR model episode that would have been inadequately paid under our proposal because these beneficiaries are those most likely to be present in the population receiving LEJR procedures emergently due to a hip fracture. Beneficiaries with chronic conditions are more likely to initiate CJR episodes due to hip fracture than beneficiaries without chronic condition who more likely undergo elective THA or TKA, so the typically higher historical spending for chronically ill beneficiaries will be reflected in the historical CJR episodes used to risk stratify target prices for hip fracture patients. In contrast, beneficiaries undergoing elective THA or TKA are less likely to have chronic conditions, so their typically lower historical spending will be reflected in the historical CJR episodes used to risk stratify target prices for LEJR patients without hip fracture. Thus, risk stratification of target prices based on a beneficiary's hip fracture status should account for patient-specific expenditure variation both directly resulting from more intense care due to the hip fracture itself, as well as indirectly resulting from the higher prevalence of chronic conditions that must be treated and managed in beneficiaries with hip fracture. We also believe that risk stratification based on a model beneficiary's hip fracture status will help to ensure that participant hospitals continue to treat these medically complex patients because target prices for these episodes will reflect the more costly care that these beneficiaries are likely to require based on historical experience.

Additionally, while we agree with the commenter that the ongoing and acute health care needs of medically complex beneficiaries may be addressed through a patient-centered medical home or ACO, many of these vulnerable beneficiaries currently are not included in such models or programs. In the case of other beneficiaries who are included in medical home or ACO models or programs, they may have specific, new care management needs arising from an LEJR procedure that may be best managed by the participant hospital that has substantial expertise in coordinating and managing care throughout LEJR episodes because of the hospital's participation in the CJR model, while the ACO or patient-centered medical home may have less specific expertise in managing beneficiaries recovering from major orthopedic surgery. We expect that participant hospitals, accountable for LEJR episode quality and cost performance under this model, will work closely with all providers and other organizations with which a model beneficiary has established relationships, toward the mutual goal of high quality, well-coordinated care that maximizes the rate of a beneficiary's return of function following surgery.

We are finalizing our proposal to include all Medicare Part A and B items and services in the CJR model episode definition, except for excluded services identified by the CJR model exclusions list, with modification to additionally exclude OPPS transitional pass-through payments for devices.

Comment: Many commenters expressed support for CMS' proposed approach to identifying excluded services by MS–DRGs for readmissions and ICD–9–CM diagnosis codes on Part B claims. Some commenters suggested that CMS consider additional coding sources beyond ICD–9–CM diagnosis codes to identify exclusions by adding ICD–9–CM procedure codes and HCPCS and/or CPT codes to the list of Part B exclusions.

Response: We appreciate the commenters' support for our proposal. We note that we have successfully used our current approach to identify excluded services for 48 clinical episodes under BPCI Models 2, 3, and 4 for several years. We will consider whether supplementing our current approach to identifying excluded services with additional coding strategies could help us more accurately identify unrelated services as we review future stakeholder input about the CJR model episode definition. We would need to also take into consideration the current coding requirements for different Part A and Part B services in assessing the potential benefit of supplementing our existing approaches to identifying excluded services. We would address any changes to the current CJR model approach to identifying excluded services through rulemaking. Therefore, we are finalizing our proposal to identify CJR model excluded services by MS–DRGs for readmissions and ICD–9–CM (or equivalent ICD–10–CM) diagnosis codes for Part B services.

Comment: A number of commenters provided their perspective on certain specific proposed related services and exclusion. Several commenters expressed support for CMS' proposal to exclude readmissions for trauma medical and oncology MS–DRGs from the CJR episode definition. The commenters agreed with CMS that readmissions during LEJR episodes for

the clinical conditions that would result in discharge from trauma medical or oncology MS–DRGs would be clinically unrelated to the LEJR episode. A commenter recommended that CMS exclude rheumatoid arthritis care from the LEJR episode definition. While the commenter pointed out that rheumatoid arthritis can result in the need for LEJR procedures, the commenter observed that including treatment for rheumatoid arthritis in the episode would result in the accompanying high payments for this care being included in actual episode spending. The commenter stated that the high costs of treatment could either affect a beneficiary's treatment for rheumatoid arthritis during the CJR model episode or reduce the beneficiary's access to a medically necessary joint replacement. Several commenters recommended that CMS exclude services for which beneficiary claims data are not made available, specifically those subject to the regulations governing the confidentiality of alcohol and drug abuse patient records (42 Code of Federal Regulations (CFR) part 2). Other commenters suggested that CMS exclude elective surgery during the CJR model episode, providing examples of cataract surgery, hernia repair, gallbladder procedures, and transurethral resection of the prostate. A commenter requested that CMS add the ICD–9–CM procedure code for chemotherapy administration to the Part B exclusions list, because CMS proposed to consider chemotherapy to be unrelated and, therefore, excluded from the CJR episode definition.

Several commenters requested further justification of CMS's proposals to include all body system-related surgical MS–DRGs and medical MS–DRGs except oncology and trauma medical MS–DRGs in the CJR episode definition. Several commenters requested further rationale for CMS' proposal to include all PAC services in the episode following an excluded readmission. Another commenter requested clarification on the inclusion of communication, cognitive, and swallowing-related diagnoses in the LEJR episode and CMS' intent in bundling services the commenter believes to be unrelated. The commenter also requested information about how providers could submit clinical justification when an exclusion of therapy services from the CJR model episode is needed. Finally, several commenters expressed support for excluding patients from the model with acute disease diagnoses such as head injury, based on their conclusion that CMS proposed to exclude these beneficiaries due to CMS' proposed exclusion of Part B claims reporting acute disease diagnoses, such as severe head injury.

Response: We appreciate the specific requests by the commenters for clarification and modification of our proposed list of exclusions from the CJR model episode definition. We agree with the commenters who supported our proposal to exclude readmissions resulting in discharges from oncology and trauma medical MS–DRGs. While we believe that readmissions for medical MS–DRGs are generally linked to the hospitalization for the LEJR procedure as a complication of the illness that led to the surgery, a complication of treatment or interactions with the health care system, or a chronic illness that may have been affected by the course of care, we agree with the commenters that hospitalizations resulting in discharge from oncology and trauma medical MS–DRGs are not related to the hospitalization for the LEJR procedure.

We do not believe that Part B claims including ICD–9–CM diagnosis codes for rheumatoid arthritis should be excluded from CJR model episodes. This chronic condition is likely to be affected by care during the procedure and recovery period and, therefore, we would consider claims reporting these diagnoses codes to be related to the LEJR episode. With regard to the commenter's concerns about delays in timely treatment as a result of high treatment costs and reduced access to joint replacement procedures for beneficiaries with rheumatoid arthritis, we refer readers to sections III.F.3. and 5. of this final rule for discussion of our plans to monitor for access to care and delayed care due to the potential of the CJR model to direct patients away from more expensive services at the expense of outcomes and quality. We will also not exclude claims for substance abuse and mental health services that are not available in beneficiary claims data because these services are clinically related to LEJR episodes. Claims for substance abuse and mental health services include care for clinical conditions that are related to the CJR episode because these conditions may be affected by the LEJR procedure or post-surgical care. With regard to the commenters' requests that we exclude elective procedures such as cataract surgery, hernia repair, gallbladder procedures, and transurethral resection of the prostate from the CJR model episode definition, while we believe these procedures will be uncommon during the post-surgical recovery period for CJR model beneficiaries that extends 90 days following discharge from the anchor hospitalization, we will not exclude them as unrelated because all of the procedures may be related to care furnished during the post-surgical recovery period. Our exclusion methodology does not allow us to identify those procedures that are truly elective; that is, the condition was present and surgery was planned prior to the LEJR procedure and scheduled during the 90-cay post-hospital discharge period.

While we agree with the commenter that chemotherapy services should be excluded from the CJR model episode, our exclusion methodology for Part B services does not rely upon ICD–9–CM procedure codes but instead upon ICD–9–CM (or equivalent ICD–10–CM) diagnosis codes reported on Part B claims. We note that the Part B payment systems, including those for physicians' services, Part B drugs, and institutional services, reject claims that do not report valid ICD–9–CM diagnosis codes. Therefore, we believe that our proposal to base Part B exclusions only on ICD–9 diagnosis codes and not additionally upon ICD–9 procedure codes should allow us to identify and exclude from the CJR episodes all Part B claims for chemotherapy administration services. Providers and suppliers do not report ICD–9–CM (or equivalent ICD–10–CM) procedure codes on Part B claims because they are paid for their chemotherapy and other services on the basis of the CPT or HCPCS codes that describe those services. However, these Part B claims must also include ICD–9–CM (or equivalent ICD–10–CM) diagnosis codes. CMS requires ICD–9–CM (or equivalent ICD–10–CM) procedure codes to be reported only on Part A claims, which are excluded from the CJR model on the basis of readmission MS–DRG rather than ICD–9 (or equivalent ICD–10) codes, so adding ICD–9–CM (or equivalent ICD–10–CM) procedure codes to the Part B exclusions list is not necessary.

As we stated in the proposed rule, for readmissions to medical MS–DRGs the selection of the primary diagnosis code is not clear-cut so we believe they should all be included in the episode definition so that providers focus on comprehensive care to beneficiaries in episodes. We reiterate our belief that readmissions to medical MS–DRGs are generally linked to the hospitalization for the procedure as a complication of the illness that led to the surgery, a complication of treatment or interactions with the health care system, or a chronic illness that may have been affected by the course of care. Moreover,

we believe that all body-system related surgical MS–DRGs for readmissions are also related to the LEJR episode because these readmissions are generally related to complications of the LEJR procedure. Such surgeries result from the treatment of systemic conditions that arise from the LEJR procedure or its complications. Examples include placement of an inferior vena cava filer or a percutaneous coronary intervention for treatment of thromboembolic complications of the LEJR procedure.

We did not propose to exclude any PAC services in the 90-day post-hospital discharge period, even when those PAC services follow an excluded readmission. As Part A services are generally intended to be comprehensive in nature and because the beneficiary in a CJR model episode would still be in the post-operative recovery period following LEJR surgery, we believe any PAC services provided during the episode would be related to the LEJR procedure. Regardless of the reason for the hospitalization immediately preceding the initiation of PAC services, the PAC provider would need to address the beneficiary's post-surgical recovery from the LEJR procedure, even if the PAC services immediately followed an unrelated readmission to the hospital.

We did not propose to exclude claims for Part B services for communication, cognitive, or swallowing-related diagnoses from the CJR model episode definition because we believe these diagnoses are due either to chronic conditions whose care may be affected by the LEJR procedure or post-surgical care or to complications of the procedure, such as stroke, that result in these diagnoses. Therefore, we consider all Part B claims reporting these diagnoses in the principal diagnosis field to be related to the CJR episode. Providers are unable to submit clinical justification or other special requests for services to be designated as unrelated to the episode if one of these diagnoses is in the principal diagnosis field on claims. The CJR model is testing LEJR episode payment and we need consistency in the scope of the episode for the model. We will include all related Part A and Part B services as identified in this final rule in the calculation of episode target prices based on historical CJR episode data and in the calculation of actual episode spending for a model performance year.

Finally, in response to the commenters who supported the exclusion of beneficiaries with acute disease diagnoses, such as head injury, from the CJR model, we want to clarify that we did not propose to exclude these beneficiaries from the model. Instead, we proposed to exclude Part B claims reporting acute disease diagnoses from the episode because we consider these services to be unrelated under the episode definition. Therefore, we will not include claims for Part B services reporting excluded acute disease ICD–9–CM (or equivalent ICD–10–CM) diagnosis codes in calculating target prices based on historical CJR episodes or in calculating actual episode spending that will be compared to the episode's target price in the CJR model.

We are finalizing our proposal to exclude the specific list of MS–DRGs for readmissions and ICD–9–CM (or equivalent ICD–10–CM) diagnosis codes that is posted on the CMS Web site at: *http://innovation.cms.gov/initiatives/cjr/.*

Comment: A commenter requested that CMS clarify how it will address hospital-acquired conditions that should never occur, when these conditions are part of CMS' Hospital-Acquired Condition Reduction Program and experienced by CJR model beneficiaries. The commenter explained that under current Medicare program policy, Medicare will not pay the higher MS–DRG arising from a specified list of non-reimbursable hospital-acquired conditions. The commenter pointed out that CMS proposed to not exclude claims for diagnoses related to the quality and safety of care furnished during the episode in the CJR model episode definition, but CMS' list of non-reimbursable hospital-acquired conditions includes surgical site infections after certain orthopedic procedures. In addition to clarifying how never events will be addressed in setting payments under the CJR model, the commenter recommended that CMS incorporate an analysis of never events and their incidence into the reconciliation process and review whether to expand the list of never events for elective surgeries.

Another commenter recommended that the CJR episode include a warranty for complications associated with surgery and other treatment, that is, if complications occur, they should be treated at no additional cost to the patient or Medicare.

Response: We appreciate the commenter's request for clarification about treatment of IPPS claims that include hospital-acquired conditions under the CJR model. Our model policy as discussed in section III.C.4. of this final rule bases the CJR target prices on historical CJR episodes that reflect discharge MS–DRGs and paid claim amounts for those beneficiaries who would have begun episodes by admission to an IPPS hospital that resulted in a discharge from MS–DRG 469 and 470. To the extent that Medicare does not pay the higher MS–DRG amount due to a hospital-acquired condition that was not present on admission, the lower payment for the hospitalization due to the hospital-acquired condition would be used in setting the episode target price for the MS–DRG that anchored the episode. This same would hold true for related readmissions during the episode. When calculating actual episode spending during a performance year, we would use, once again, the paid claim amount that, in the case of a hospital-acquired condition that was not present on admission, would be at the level of the lower paying MS–DRG for the anchor hospitalization or related readmission, as applicable. We further note that if a CJR beneficiary experiences a hospital-acquired condition that was not present on admission during an anchor hospitalization and has no other comorbid conditions other than the HAC that would result in assignment of MS–DRG 469, the beneficiary's episode would be considered an MS–DRG 470-anchored episode (initiated by the MS–DRG for LEJR procedures without complications). Therefore, the hospital-acquired condition penalty would not itself inflate the target price such that CMS would pay back the hospital-acquired condition penalty through a reconciliation payment.

Our proposal not to exclude claims for diagnoses related to the quality and safety of care during the episode is the basis for our excluded list of MS–DRGs for readmissions and ICD–9–CM (or equivalent ICD–10–CM) diagnosis codes for Part B services and, therefore, this list would not apply to the anchor hospitalization itself where hospital-acquired conditions that were not present on admission could be reported.

As discussed in sections III.C.5. and 6. of this final rule, the model evaluation will examine changes in utilization, as well as outcomes and quality, in order to assess the impact of the CJR model on the aims of improved care quality and efficiency as well as well as reduced health care costs. We refer readers to section IV. of this final rule for further information on the planned evaluation. We have an ongoing process to review claims data regarding potential candidates for additions to the list of hospital-acquired conditions, so we do not believe there is a need to specifically identify CJR episodes for analysis because the IPPS claims included in CJR episodes would already be considered in the ongoing process used by CMS in the Hospital-Acquired Condition Reduction Program.

In response to the commenter who recommended for the CJR model that if complications due the LEJR procedure occur, they should be treated at no additional cost to the patient or Medicare, we note that because the CJR model uses a retrospective payment approach, we will rely on the existing Medicare program policies under the Hospital-Acquired Condition Reduction Program that define the specific circumstances in which Medicare will not make additional payment for a condition occurring after surgery. When these circumstances occur for CJR model beneficiaries in episodes, the existing Medicare program policies apply and Medicare would not provide additional payment. We do not believe it would be appropriate to establish policies specific to the CJR model regarding Medicare nonpayment for other complications, and we further note that some complications may not be preventable. The final pay-for-performance methodology for the CJR model as discussed in section III.C.5. of this final rule provides strong financial incentives for participant hospitals to coordinate and manage care to reduce complications, as the THA/TKA Complications measure (NQF #1550) contributes half of the available points for the hospital's composite quality score that determines the hospital's eligibility for reconciliation payments and quality incentive payments.

Comment: Several commenters opposed CMS' proposal to make changes to CJR model exclusions through an annual, at a minimum, update outside of rulemaking. Most commenters recommended that CMS update the exclusions annually through rulemaking, at least for routine annual updates. Other commenters stated that they did see value in CMS making possible additions and deletion to the exclusions list on a quarterly basis, especially early in the model. If following a quarterly process outside of rulemaking, these commenters urged CMS to seek stakeholder comment and input on candidate revisions through the CMS Web site and list serves to ensure broad input. The commenters encouraged CMS to adopt a transparent process for revisions to the episode definition in considering other exclusions. A number of commenters recommended that CMS explore other exclusions for the future, such as those inpatient hospital admissions or outpatient procedures planned for the beneficiary prior to the episode, ongoing care for patients' chronic conditions, and PAC following an excluded hospital readmission.

Response: We appreciate the interest of the commenters' in ensuring that any changes to the CJR model episode definition involve a transparent process with opportunity for broad stakeholder input. We continue to believe that updating the exclusions annually, at a minimum, outside of rulemaking, is most appropriate for this 5-year model, allowing for more frequent updates than through rulemaking as necessary to accommodate timely ICD–CM annual coding changes and the transition to ICD–10–CM and annual IPPS MS–DRG changes, as well as to address significant issues raised by participant hospitals and other stakeholders.

Commenters who supported an exclusions list update process outside of rulemaking did not suggest specific revisions to our proposed criteria for updating the exclusions, namely that:

- We would not exclude any items or services that are—

++ Directly related to the LEJR procedure itself (such as loosening of the joint prosthesis) or the quality or safety of LEJR care (such as post-surgical wound infection or venous thromboembolism); and

++ For chronic conditions that may be affected by the LEJR procedure or post-surgical care (such as diabetes). By this we mean that where a beneficiary's underlying chronic condition would be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care must be managed differently as a result of the chronic condition, then those items and services would be related and would be included in the episode.

- We would exclude items and services for—

++ Chronic conditions that are generally not affected by the LEJR procedure or post-surgical care (such as removal of the prostate). By this we mean that where a beneficiary's underlying chronic condition would not be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care need not be managed differently as a result of the chronic condition, then those items and services would not be related and would not be included in the episode; and

++ Acute clinical conditions not arising from existing episode-related chronic clinical conditions or complications of LEJR surgery from the episode (such as appendectomy).

Thus, we continue to believe these criteria provide the appropriate clinical review framework for updates to the CJR model exclusions. Finally, we believe that our proposed process to post the potential revised exclusions, which could include additions to or deletions from the exclusions list, to the CMS Web site to allow for public input on our planned application of these standards, and then adopt changes to the exclusions list with posting to the CMS Web site of the final revised exclusions list after our consideration of the public input, is consistent with the recommendation of commenters that we use a transparent process reflective of robust opportunity for public input. Conducting this update process outside of rulemaking based on the criteria set forth in this final rule will allow us the greatest flexibility to update the exclusions as changes to the MS–DRGs and ICD diagnosis codes, upon which our exclusions rely, are released. This process will also allow us to respond quickly to any episode definition issues that arise during implementation of the model across the broad array of participant hospitals in the selected MSAs. We would widely publicize the opportunity for review and public input through the CMS Web site and listservs. We also note that any changes to our overall approach to identifying excluded services or to our criteria for evaluating services for exclusion would be addressed through rulemaking. Therefore, we are finalizing our proposal to update the exclusions list annually, at a minimum, using the process as described.

Comment: Several commenters referred to the impending change from ICD–9–CM to ICD–10–CM coding on claims and identified that this change would have implications for the Part B exclusions list. A commenters stated that CMS would need to define the excluded ICD–10–CM codes prior to implementation of the CJR model and recommended that CMS also provide the ICD–10–CM diagnosis code list that would identify included Part B services.

Response: We appreciate the commenters' interest in the list of CJR model exclusions that are identified based on ICD–10–CM codes. In the proposed rule, we stated that as we move to implement ICD–10–CM we would develop the CJR exclusions that would map to the final ICD–9–CM exclusions for CJR available in the ICD–10–CM format as well.

With ICD–10–CM implementation beginning in October 2015, we are making available the final CJR model Part B exclusions list in ICD–10–CM format as additional worksheet tabs to the final exclusions list posted on the CMS Web site at: *http://innovation.cms.gov/initiatives/cjr/.* This is the same list of exclusions that will be used for LEJR episodes under BPCI. This list will be applied to claims for services furnished on or after October 1, 2015 and that

report ICD–10–CM codes. For ease of understanding by the public, our objective was to present the ICD–10–CM excluded codes as ranges of excluded ICD–10–CM categories, just as we present the ICD–9–CM excluded codes as ICD–9–CM ranges.

To develop the ICD–10–CM exclusions list, we began with the list of final CJR ICD–9–CM code ranges. From that list of ranges, we generated an expanded list of all excluded ICD–9–CM codes. We then compared the list of excluded ICD–9–CM codes against both the ICD–9–CM-to-ICD–10–CM and ICD–10–CM-to-ICD–9–CM General Equivalence Mappings (GEMs) available at: *https://www.cms.gov/Medicare/Coding/ICD10/2015-ICD-10-CM-and-GEMs.html.* Comparing against both GEM files was necessary because there were matches in the ICD–9–CM-to-ICD–10–CM GEM that did not appear in the ICD–10–CM-to-ICD–9–CM GEM and vice versa. For example —

- In the ICD–9–CM-to-ICD–10–CM GEM file, ICD–9–CM code 85110 (Cortex (cerebral) contusion with open intracranial wound, unspecified state of consciousness) maps to ICD–10–CM code S0190XA (Unspecified open wound of unspecified part of head, initial encounter), but there is not a corresponding map from S019XA to 85110 in the ICD–10–CM-to-ICD–9–CM GEM.
- In the ICD–10–CM-to-ICD–9–CM GEM file, ICD–10–CM code A0101 (Typhoid meningitis) maps to ICD–9–CM code 020 (Typhoid), but there is not a corresponding map from 020 to A0101 in the ICD–9–CM to-ICD–10–CM GEM.

After compiling the results from both GEM files, we created a list of every billable ICD–10–CM code and whether each billable ICD–10–CM code matched to an excluded ICD–9–CM code. We then moved from the list of individual codes to a list of ICD–10–CM three-digit categories (for example, ICD–10–CM code A0101 (Typhoid meningitis) is in ICD–10–CM category A01 (Typhoid and paratyphoid fevers)) to present the final CJR exclusions. We excluded ICD–10–CM categories in which 100 percent of billable ICD–10–CM codes matched to an excluded ICD–9–CM code. There are 574 such categories, and we consider these CD–10–CM categories excluded based on a direct mapping from ICD–9–CM (see the ''Excluded Part B ICD10 Direct'' worksheet tab in the final exclusions list file). We did not exclude ICD–10–CM categories in which no billable ICD–10–CM codes matched to an excluded ICD–9–CM code. There are 1,258 categories, and we consider these categories not excluded based on a direct mapping from ICD–9–CM. For those 71 categories in which only some billable ICD–10–CM codes in the category matched to an excluded ICD–9–CM code after mapping, we excluded 48 ICD–10–CM categories where all of the ICD–10–CM codes in the category met one or more of our two final criteria for updating the excluded codes on the exclusions list as described previously in this section (see the ''Excluded Part B ICD10 Medical'' worksheet tab in the final exclusions list file). Specifically, the 48 ICD–10–CM categories that are excluded on this basis include ICD–10–CM codes that meet one or more of the following two criteria:

- Chronic conditions that are generally not affected by the LEJR procedure or post-surgical care (such as removal of the prostate). By this we mean that where a beneficiary's underlying chronic condition would not be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care need not be managed differently as a result of the chronic condition, then those items and services would not be related and would not be included in the episode.
- Acute clinical conditions not arising from existing episode-related chronic clinical conditions or complications of LEJR surgery from the episode (such as appendectomy).

We did not exclude the 23 other ICD–10–CM categories in which only some billable ICD–10–CM codes in the category matched to an excluded ICD–9–CM code after mapping because the ICD–10–CM codes in these categories met one or more of the following criteria:

- Directly related to the LEJR procedure itself (such as loosening of the joint prosthesis) or the quality or safety of LEJR care (such as post-surgical wound infection or venous thromboembolism).
- For chronic conditions that may be affected by the LEJR procedure or post-surgical care (such as diabetes). By this we mean that where a beneficiary's underlying chronic condition would be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care must be managed differently as a result of the chronic condition, then those items and services would be related and would be included in the episode.

When constructing prices for CJR, we will exclude Part B services from target prices and from performance year episodes based on the final excluded ICD–9–CM code ranges and final excluded ICD–10–CM code categories as appropriate, based on the applicable version of ICD diagnosis coding at the time the services was furnished.

In addition, we have addressed changes to the CJR model exclusion list that result from revisions for the FY 2016 IPPS. From FY 2015 to FY 2016, there were few changes to IPPS MS–DRGs that appear on the MS–DRG excluded readmissions list for the CJR model. Specifically, the FY 2016 IPPS update contains changes to existing MS–DRGs 237 and 238, Major Cardiovascular Procedures with MCC and without MCC, respectively, which are on the exclusions list for CJR episodes. For discharges after October 1, 2015, inpatient stays that previously would have been assigned to MS–DRG 237 or 238 will be assigned to one of the following MS–DRGs:

- 268 Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC.
- 269 Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC.
- 270 Other Major Cardiovascular Procedures with MCC.
- 271 Other Major Cardiovascular Procedures with CC.
- 272 Other Major Cardiovascular Procedures without CC/MCC.

We also note that the list of excluded readmissions posted with the proposed rule inadvertently omitted MS–DRGs 490 and 491, which were eliminated in the FY 2015 IPPS Final Rule and from which MS–DRGs 518, 519, and 520 were created in FY 2015. We are adding MS–DRGs 490 and 491 to the list of excluded readmissions posted with this final rule as we will exclude readmissions in MS–DRGs 490 and 491 for the purposes of calculating CJR target prices.

Additional information on the new MS–DRGs is provided in the FY 2016 IPPS final rule (80 FR 49371 through 49390, available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page.html*). When constructing prices for CJR, we will exclude readmissions for MS–DRGs 237 and 238 in historical data. We will also exclude readmissions for MS–DRGs 268, 269, 270, 271, and 272 from performance year episodes.

Summary of Final Decisions: After consideration of the public comments we received, we are adding the following new definition for the CJR model: ''Provider of outpatient therapy services'' means a provider or supplier furnishing—(1) Outpatient physical therapy services as defined in § 410.60 of this chapter, or (2) outpatient occupational therapy services as defined in § 410.59 of this chapter, or (3) outpatient speech-language pathology

services as defined in § 410.62 of this chapter.

We are finalizing our proposal, with modification to remove the term ''independent'' preceding outpatient therapy services, that related items and services included in CJR episodes, defined by all of the clinical conditions requiring an admission to an IPPS hospital that results in a discharge from MS–DRG 469 or 470 would be the following items and services paid under Medicare Part A or Part B, after the final exclusions are applied:

- Physicians' services.
- Inpatient hospital services (including readmissions), with certain exceptions, as discussed later in this section.
- IPF services.
- LTCH services.
- IRF services.
- SNF services.
- HHA services.
- Hospital outpatient services.
- Outpatient therapy services.
- Clinical laboratory services.
- DME.
- Part B drugs.
- Hospice.

Medicare spending for related items and services will be included in the historical data used to set episode target prices, as well as in the calculation of actual episode spending that would be compared against the target price to assess the performance of participant hospitals. In contrast, Medicare spending for unrelated items and services (excluded from the episode definition) will not be included in the historical data used to set target prices or in the calculation of actual episode spending.

Additionally, we are finalizing our proposal to exclude inpatient hospital readmissions based on the list of excluded MS–DRGs and Part B services that report an excluded ICD–9–CM (or equivalent ICD–10–CM) diagnosis code as the principal diagnosis based on the list posted on the CMS Web site at: *http://innovation.cms.gov/initiatives/cjr/.* As we proposed, we will exclude IPPS new technology add-on payments for drugs, technology, and services and hemophilia clotting factors paid separately during an inpatient hospitalization from the CJR model episode definition. We are modifying our proposal and, under our final policy, we will also exclude OPPS transitional pass-through payments for devices. We are also finalizing our proposal to update the exclusions list without rulemaking on an annual basis, at a minimum, to reflect annual changes to ICD–CM coding and annual changes to the MS–DRGs under the IPPS, as well as to address any other issues that are brought to our attention by the public throughout the course of the model test.

We will first develop potential exclusions list revisions of MS–DRGs for readmissions and ICD–9–CM (or equivalent ICD–10–CM) diagnosis codes for Part B services based on our assessment against the following standards:

- We would not exclude any items or services that are—

++ Directly related to the LEJR procedure itself (such as loosening of the joint prosthesis) or the quality or safety of LEJR care (such as post-surgical wound infection or venous thromboembolism); and

++ For chronic conditions that may be affected by the LEJR procedure or post-surgical care (such as diabetes). By this we mean that where a beneficiary's underlying chronic condition would be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care must be managed differently as a result of the chronic condition, then those items and services would be related and would be included in the episode.

- We would exclude items and services for—

++ Chronic conditions that are generally not affected by the LEJR procedure or post-surgical care (such as removal of the prostate). By this we mean that where a beneficiary's underlying chronic condition would not be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care need not be managed differently as a result of the chronic condition, then those items and services would not be related and would not be included in the episode; and

++ Acute clinical conditions not arising from existing episode-related chronic clinical conditions or complications of LEJR surgery from the episode (such as appendectomy).

We will post the potential revised exclusions, which could include additions to or deletions from the exclusions list, to the CMS Web site to allow for public input on our planned application of these standards, and then adopt changes to the exclusions list with posting to the CMS Web site of the final revised exclusions list after our consideration of the public input. Through the process for public input on potential revised exclusions and then posting of the final revised exclusions, we will also provide information to the public about when the revisions would take effect and to which episodes they would apply. These parameters could vary, depending on the relationship of exclusion list changes to annual ICD–CM or MS–DRG changes or to other issues brought to our attention by the public. While these revised exclusions may correspond to the time when we provide new target prices for a performance year, depending on the timing of when they would take effect and to which episodes they would apply, we would recalculate target prices as necessary.

The final definitions are set forth in § 510.2 which has been revised to remove proposed (b)(3) for inpatient hospital readmission services because hospital readmissions are already referenced in (b)(2). The remaining provisions under § 510.2(b) have been renumbered accordingly. The final policies for included services, excluded services, and updating the lists of excluded services are set forth in § 510.200(b), (d), and (e). We note that § 510.200(d)(3) has been renumbered to § 510.200(d)(4) and § 510.200(d)(3) added to state, ''Transitional pass-through payments for medical devices as defined in § 419.66 of this chapter.'' In addition, § 510.200(b)(10) has been modified to read ''Outpatient therapy services.''

3. Duration of Episodes of Care

a. Beginning the Episode and Beneficiary Care Inclusion Criteria

While we proposed to identify LEJR episodes by an acute care hospitalization for MS–DRG 469 and 470, we recognize that the beneficiary's care for an underlying chronic condition, such as osteoarthritis, which ultimately leads to the surgical procedure, typically begins months to years prior to the surgical procedure. Because of the clinical variability leading up to the joint replacement surgery and the challenge of identifying unrelated services given the multiple chronic conditions experienced by many beneficiaries, we did not propose to begin the episode prior to the anchor hospitalization (that is, the admission that results in a discharge under MS–DRG 469 or 470). In the proposed rule, we stated our belief that the opportunities for care redesign and improved efficiency prior to the inpatient hospitalization are limited for an episode payment model of this type that focuses on a surgical procedure and the associated recovery once the decision to pursue surgery has been made, rather than an episode model that focuses on decision-making and management of a clinical condition itself (such as osteoarthritis).

We proposed to begin the episode with an inpatient anchor hospitalization for MS–DRG 469 or MS–DRG 470 in

accordance with the methodology described. This proposal to begin the episode upon admission for the anchor hospitalization is consistent with LEJR episode initiation under Model 2 of BPCI. While we did not propose to begin the episode prior to the inpatient hospital admission, we noted that our proposed episode definition includes all services that are already included in the IPPS payment based on established Medicare policies, such as diagnostic services (including clinical diagnostic laboratory tests) and nondiagnostic outpatient services related to a beneficiary's hospital admission provided to a beneficiary by the admitting hospital, or by an entity wholly owned or wholly operated by the admitting hospital (or by another entity under arrangements with the admitting hospital), within 3 days prior to and including the date of the beneficiary's admission. For more information on the 3-Day Payment Window payment policies, see CMS Pub. 100–04, Chapter 3, section 40.3 and Chapter 4, section 10.12.

We proposed that the defined population of Medicare beneficiaries whose care will be included in CJR meet the following criteria upon admission to the anchor hospitalization. We noted that these criteria are also consistent with Model 2 of BPCI, as well as most other Innovation Center models that do not target a specific subpopulation of beneficiaries. We proposed that the LEJR episodes for all beneficiaries in the defined population will be included in CJR (although we proposed that certain episodes may be canceled for purposes of determining actual episode payments for reasons discussed later in this final rule), and we refer readers to section III.F.2. of this final rule for further discussion of beneficiary notification and a beneficiary's ongoing right under CJR to obtain health services from any individual or organization qualified to participate in the Medicare program.

- The beneficiary is enrolled in Medicare Part A and Part B throughout the duration of the episode.
- The beneficiary's eligibility for Medicare is not on the basis of End Stage Renal Disease (ESRD).
- The beneficiary must not be enrolled in any managed care plan (for example, Medicare Advantage, Health Care Prepayment Plans, cost-based health maintenance organizations).
- The beneficiary must not be covered under a United Mine Workers of America health plan, which provides healthcare benefits for retired mine workers.
- Medicare must be the primary payer.

Our proposal for inclusion of beneficiaries in CJR is as broad as feasible, representing all those LEJR episodes for which we believe we have comprehensive historical Medicare payment data that allow us to appropriately include Medicare payment for all related services during the episode in order to set appropriate episode target prices. For beneficiaries whose care we proposed to exclude from the model, we are unable to capture or appropriately attribute to the episode the related Medicare payments because of Medicare's payment methodology. For example, if a beneficiary is enrolled in a Medicare Advantage plan, Medicare makes capitated payments (and providers do not submit complete claims data to CMS), so we would not have a way to identify and attribute the portion of those payments related to an LEJR episode. More information on setting bundled payment target prices for episodes under CJR is available in section III.C.4.b. of this final rule. Including the broadest feasible array of Medicare beneficiaries' admissions in the model would provide CMS with the most robust information about the effects of this model on expenditures and quality for beneficiaries of the widest variety of ages and comorbidities, and allow the participant hospitals the greatest opportunity to benefit financially from systematic episode care redesign because most Medicare beneficiaries undergoing an LEJR procedure will be included in the model and, therefore, subject to the policies we proposed.

We sought comment on our proposal on when to begin the CJR episode, as well as to identify the care included for beneficiaries.

The following is a summary of the comments received and our responses.

Comment: Most commenters agreed that the episode should begin with the hospital admission for the LEJR procedure. Some of these commenters noted that it would not be appropriate to include the period prior to the hospital admission as it could include unrelated care and introduce variability.

Several orthopedic surgeons commented that physician treatment and care management begin prior to surgery, with the physician continuing to manage care during surgery, following surgery, and throughout the entire PAC period. These commenters were concerned that beginning the episode with the hospital admission would result in beneficiaries choosing and initiating care plans designed with their treating physicians and later, when hospitalized, the beneficiaries would receive conflicting care plans and, ultimately, experience adverse outcomes.

Many commenters recommended starting the episode earlier than the hospital admission. Some commenters recommended starting the episode once the decision to pursue surgery is made, and some recommended specific timeframes that ranged between four to eight weeks prior to the surgery. Some commenters provided examples of presurgical services that they have found improve patient outcome and satisfaction, improve care quality, and reduce costs, such as comprehensive patient evaluations to assess a beneficiary's overall condition and chronic comorbid conditions; pre-surgical counseling for non-medical pain management; home safety reviews; post-discharge planning; patient and caregiver education; weight loss programs; and physical therapy. Some commenters requested that CMS consider additional program rule waivers for the CJR model, beyond those specifically proposed, to facilitate the provision of various preoperative services and incentives that are not allowed or payable under current Medicare rules.

A few commenters were concerned that starting the episode with the hospital admission may lead to participants shifting costs to just prior to the start of the episode to receive payments for those services in addition to the bundle. To minimize gaming, they recommended starting the episode once the surgery has been elected and prior to the hospital admission, which is consistent with many private sector models.

Response: We appreciate the interest expressed by the commenters in starting comprehensive care coordination prior to the hospital admission, and we recognize that the beneficiary's care which ultimately leads to the LEJR surgery, including the physician-patient relationship, often begins long before the surgical procedure. We also appreciate concerns about providers unbundling services and shifting costs to just prior to the episode, between the time the surgery has been elected and the hospital admission. However, beginning the episode too far in advance of the LEJR surgery would make it difficult to avoid bundling unrelated items, and starting the episode prior to the hospital admission is more likely to encompass costs that vary widely among beneficiaries, which would make the episode more difficult to price appropriately.

We appreciate commenters' suggestions of pre-surgical services and

programs that could support the continuum of care for CJR beneficiaries. However, identifying a specific set of related presurgical services to include in the episode, as recommended by some commenters, would be of little value in the model because many of the services that are typically necessary or the standard of care prior to surgery are often included in the IPPS payment under the three day payment window payment policies and are therefore already included in the CJR episode. We note that some of the related services suggested by commenters that are not typically included in the three-day payment window are intended to more broadly manage the clinical condition(s) that may have led to the LEJR, and as discussed previously in this section, the CJR model is designed to focus on the surgical procedure and the associated recovery. We also note that some of these suggested services would be applicable to a subset of CJR beneficiaries and, therefore, do not present a significant opportunity for improving efficiency and redesigning care management for the typical beneficiary receiving an LEJR.

We believe that using the date of admission as the start of the episode is appropriate as hospitals are unlikely to shift related services earlier than when is clinically indicated. With respect to expanding the waivers to presurgical services that are not currently covered or payable, we have finalized several waivers of Medicare program rules as discussed in section III.C.11. of this final rule specifically to assist participant hospitals in efficient and effective care coordination and care management for CJR beneficiaries, and we do not believe it would be consistent with the model design or otherwise necessary for the model test to implement waivers for the preoperative period. While we appreciate commenters' interest in providing additional presurgical services that may enhance care coordination and care management, the waivers of Medicare program rules are only available if the beneficiary is in the episode at the time a service under the waiver is furnished. We believe that allowing waivers in the preoperative period prior to the anchor hospitalization, based on an expectation that a beneficiary will be in a CJR Model episode, would not be appropriate as there is no guarantee that the beneficiary will actually initiate a CJR Model episode and qualify for services furnished under a waiver.

For purposes of the CJR model, we continue to believe that beginning the episode with the anchor hospitalization is most appropriate due to the clinical variability leading up to the joint replacement surgery and the challenge of distinguishing between related and unrelated services. We also believe that beginning the episode with the anchor hospitalization, and not prior to admission, would be easier to administer and provide more consistent episodes for testing the CJR Model. Therefore, we are finalizing our proposal to begin the episode with admission to an inpatient anchor hospitalization for MS–DRG 469 or MS–DRG 470 in accordance with the methodology described.

Comment: Commenters generally supported the proposed beneficiary inclusion criteria as reasonable and consistent with other programs. Some commenters suggested we exclude additional populations from CJR, namely beneficiaries with serious conditions or acute diseases, such as traumatic brain injury, spinal cord injuries, multiple-limb trauma, amputations, moderate to severe strokes, severe neuromuscular and musculoskeletal conditions, HIV infection, and cancer. A commenter recommended that we design a separate model to address the needs of patients with chronic conditions. A few commenters recommended excluding all patients on hospice.

Many commenters recommended that if we did not exclude high risk cases, we must develop more robust risk adjustment to account for socioeconomic, clinical, or other risk factors that are out of the hospital's control and impact patients' health and recovery. Some commenters were concerned that without accurate risk adjustment, hospitals will have an incentive to avoid higher-risk LEJR candidates. A commenter cited a study that found significant differences in Medicare spending per beneficiary during the 90-day episode based on various patient characteristics, such as type of LEJR surgery; emergency versus scheduled surgery; hip fractures versus degenerative conditions; patients age 85 or older; patients with multiple comorbidities, and patients who were dual eligible. The commenter asserted that robust risk adjustment based on the risk profile of each hospital's patients is essential for the CJR model because individual hospitals will not have enough enrollment to spread their risk. A few commenters recommended that at least the initial implementation of the Model should exclude vulnerable populations with complicated or intensive care needs until the CJR model demonstrates sufficient quality outcomes and has developed accurate risk adjustments and patient safeguards to ensure high-quality care for populations that the commenters believe could face serious care disadvantages in the CJR model.

Response: Many beneficiaries undergoing procedures that result in discharge from MS–DRG 469 and 470 have underlying conditions that may affect care throughout the episode or that may be influenced by the surgical procedure that initiates the episode. We believe it is important to include these beneficiaries in the model so that they can benefit from care coordination and management throughout the episode, and including the broadest feasible array of Medicare beneficiaries in the CJR model provides participant hospitals with greater incentive to redesign episode care. We also believe that patients in hospice would benefit from the improved comprehensive care coordination incentivized by the CJR model, and we refer readers to the related discussion in section III.B.2. of this final rule regarding our policy to include hospice claims in the episode.

We refer readers to section III.C.4.b. of this final rule for the final policy that will risk stratify the target prices based on the presence or absence of a hip fracture for CJR model beneficiaries. We believe that this risk stratification policy addresses many of the commenters' concerns that beneficiaries with serious conditions, acute diseases, and chronic conditions are likely to need more costly care throughout the CJR model episode that would have been inadequately paid under our proposal because these beneficiaries are those most likely to be present in the population receiving LEJR procedures emergently due to a hip fracture.

Comment: Several commenters recommended that CMS exclude beneficiaries who opted out of data sharing. These commenters asserted that it would be virtually impossible to manage risk and improve outcomes without claims data.

Response: As discussed in section III.E. of this final rule, we have decided not to finalize our proposal to allow beneficiaries the opportunity to decline having their data shared. We refer readers to section III.E. of this final rule for additional discussion of data sharing.

Comment: Some commenters suggested that CMS limit the CJR model to beneficiaries that live within a limited distance from participant hospitals so that the hospital would not be penalized for inadequately managing the PAC of medically complex patients from remote or distant locations.

Response: We expect that in some limited circumstances, participant

hospitals will have limited ability to coordinate care. However, following the care coordination that takes place in the hospital, we believe that much of the subsequent coordination for PAC can be accomplished through telecommunications that do not require the patient to remain within geographic proximity of the hospital. Moreover, the design of the model does not preclude hospitals from coordinating care with local providers outside of their immediate referral area. We also note that we have finalized several waivers of Medicare program rules, as discussed in section III.C.11. of this final rule, to facilitate efficient and effective care coordination for beneficiaries in remote or distant locations outside the immediate community. Therefore, we will not exclude beneficiaries who are referred to participant hospitals from other areas.

Comment: A commenter requested CMS to consider including beneficiaries enrolled in MA plans in the model as they are likely to be healthier and their inclusion will help hospitals maintain costs within their targets. The commenter recognizes that the CJR payment methodology makes it difficult to identify and attribute payment related to the LEJR episode. However, the commenter asserts that participant hospitals in states with a high percentage of beneficiaries enrolled in MA plans are more likely to care for CJR patients with a higher than average risk profile, which could make it more difficult for a hospital to maintain costs within the target rate.

Response: We appreciate the commenter's interest in increasing the population of beneficiaries included in the CJR model, and we recognize that participant hospitals with higher risk CJR beneficiaries may find it more challenging to maintain actual aggregate episode payments within their target price. However, as discussed previously in this section, Medicare makes capitated payments for beneficiaries enrolled in MA plans, and providers do not submit complete claims data to CMS. Therefore, we are finalizing our proposal not to include beneficiaries enrolled in MA plans because we are unable to capture or appropriately attribute to the episode the related Medicare payments.

Comment: A couple of commenters requested that CMS exclude episodes where the LEJR surgery was furnished either by an opt-out physician, because the principal procedure is not paid by Medicare, or by a non-participating physician who does not accept assignment. They requested that if such episodes are to be included, CMS should establish policies under which participant hospitals can provide reconciliation payments to and receive alignment payments from opt-out physicians as well as non-participating physicians.

Response: Consistent with the BPCI policy, we do not believe it would be appropriate to exclude beneficiaries from the CJR model if a physician who opted out of Medicare pursuant to § 405.420 or a non-participating physician performs the LEJR surgery during the anchor hospitalization. We would expect that beneficiaries undergoing LEJR procedures, regardless of the Medicare participation or opt-out status of the operating surgeon, would have similar needs for care coordination and management throughout the episode period that extends 90 days post-hospital discharge, and we see no reason that hospitals should not have the same quality and cost performance responsibility for these episodes. We note that less than 15 percent of episode spending, on average, would be expected to be paid for physicians' services, with more than 80 percent of the episode payment made for inpatient hospital and PAC services. Thus, for a beneficiary who otherwise meets the CJR model's inclusion criteria, a CJR model episode would begin at the time of the beneficiary's admission for the anchor hospitalization, regardless of whether an opt-out physician or non-participating physician performs the LEJR surgery during that stay.

We refer readers to section III.C.3. of this final rule for discussion of the effect on reconciliation payments on services furnished by non-participating and opt-out physicians and to section III.C.10.a. of this final rule for discussion of issues related to gainsharing payments and alignment payments.

Summary of Final Decisions: After consideration of the public comments we received, we are finalizing our proposal to begin the episode with admission for an inpatient anchor hospitalization for MS–DRG 469 or MS–DRG 470 in accordance with the methodology described. We also are finalizing our proposal as to the criteria for beneficiary inclusion in the model as follows:

- The beneficiary is enrolled in Medicare Part A and Part B throughout the duration of the episode.
- The beneficiary's eligibility for Medicare is not on the basis of ESRD.
- The beneficiary must not be enrolled in any managed care plan (for example, Medicare Advantage, Health Care Prepayment Plans, cost based health maintenance organizations).
- The beneficiary must not be covered under a United Mine Workers of America health plan, which provides healthcare benefits for retired mine workers.
- Medicare must be the primary payer.

The final policies for beginning an episode are set forth in § 510.210(a). The final policies for beneficiary inclusion are set forth in § 510.205.

b. Middle of the Episode

We proposed that once the episode begins for a beneficiary whose care is included, the episode continues until the end as described in the next section of this final rule, unless the episode is canceled because the beneficiary no longer meets the same inclusion criteria proposed for the beginning of the episode at any point during the episode. When an episode is canceled, we proposed that the services furnished to beneficiaries prior to and following the episode cancellation will continue to be paid by Medicare as usual but we will not calculate actual episode spending that would otherwise under CJR be reconciled against the target price for the beneficiary's care (see section III.C.6. of the proposed rule). As discussed in section III.C.11.a. of the proposed rule, if the beneficiary is in the episode at the time the service under the waiver is furnished, the waiver is available, even if the episode is later canceled.

In the proposed rule, we stated our belief that it would be appropriate to cancel the episode when a beneficiary's status changes during the episode such that they no longer meet the criteria for inclusion because the episode target price reflects full payment for the episode, yet we would not have full Medicare episode payment data for the beneficiary to reconcile against the target price.

In addition, we proposed that the following circumstances would also cancel the episode:

- The beneficiary is readmitted to an acute care hospital during the episode and discharged under MS–DRG 469 or 470 (in this case, the first episode would be canceled and a new LEJR episode would begin for the beneficiary).
- The beneficiary dies during the anchor hospitalization.
- The beneficiary initiates an LEJR episode under BPCI Models 1, 2, 3 or 4.

In the case of beneficiary death during the anchor hospitalization, we stated our belief that it would be appropriate to cancel the episode as there are limited efficiencies that could be expected during the anchor hospitalization itself. In the case of beneficiary readmission during the first

CJR episode for another LEJR (typically a planned staged second procedure), we stated our belief that it would not be appropriate to include two episodes in the model with some time periods overlapping, as that could result in attribution of the Medicare payment for 2 periods of PAC to a single procedure.

We sought comment on our proposals to cancel episodes once they have begun but prior to their end.

The following is a summary of the comments received and our responses.

Comment: Commenters were generally supportive of our proposals for canceling the episode, though many recommended additional circumstances for canceling the episode, such as adverse events which are beyond the hospital's control. Many commenters, including MedPAC, recommended that CMS cancel the episode if the beneficiary dies at any time during the episode, arguing that such cases could be extremely low or high cost and spending is, therefore, not typical. These commenters recommended that all episodes that end in patient death should be excluded from the calculations of the target price and reconciliation amounts, not just those episodes where patients die during the initial hospitalization as CMS proposed, as this type of episode of care could skew the data. Given that hospitals are held financially responsible for the entire 90-day episode, a few commenters suggested excluding all episodes with death for consistency and administrative simplicity. A commenter observed that a deceased beneficiary no longer meets all of the beneficiary inclusion criteria, and on that basis recommended that CMS cancel the episode when the patient dies. A commenter suggested also canceling episodes for any beneficiaries that die during the 30 day post-episode monitoring period. Some commenters suggested that other circumstances should cancel an episode, such as a beneficiary geographic move, change in beneficiary residence from a home to a facility, and loss of the beneficiary to follow up care.

Response: While beneficiary deaths during LEJR episodes are uncommon, we expect them to vary unpredictably across hospitals and, therefore, we agree that it would be appropriate to cancel episodes under these circumstances. We also agree that canceling all episodes during which a beneficiary dies is consistent with the otherwise applicable episode duration as the episode would not extend to 90 days hospital post-discharge. However, we would include episodes where the patient dies during the 30 days post-episode as this would not affect the variability of episode spending, and it would be appropriate to monitor for beneficiary death during the immediate post-episode period.

We expect some limited circumstances where participant hospitals will have limited ability to coordinate care. However, we believe that participant hospitals will be incentivized to seek creative solutions that do not rely on in-person services, and we are finalizing our proposal that all other beneficiary episodes would remain in the CJR model, regardless of where the beneficiary is located. Payment for beneficiaries in these circumstances will be reflected in the target prices based on historical utilization.

Comment: Commenters urged CMS to hold beneficiaries and providers financially harmless for care received as part of a CJR episode if the episode is later canceled. A few commenters supported the continued application of Medicare program waivers if an episode is canceled when a beneficiary's status changes, and a few commenters were unclear if waivers apply to beneficiaries who are retrospectively identified as ineligible for CJR program waivers due to changes in coverage status.

Response: As discussed previously in this section, we proposed that if the beneficiary is in the episode at the time the service under the program rule waiver is furnished, the waiver is available, even if the episode is later canceled. If the beneficiary is not in the episode at the time the service under the waiver is furnished, financial liability for these services would be determined in accordance with the policies outlined in the Medicare Claims Processing Manual (Pub. L. 100–04), Chapter 30. As we gain experience with CJR, we may revisit this issue in future rulemaking. We refer readers to section III.C.11. of this final rule for additional discussion and our finalized policy to apply waivers of programs rules if the beneficiary is in the episode at the time the service under the waiver is furnished, even if the episode is later canceled.

Comment: A commenter was concerned that initiation of a BPCI episode would cancel a CJR episode, when the CJR episode begins first. The commenter also requested clarification whether a BPCI episode for a different clinical condition, such as cardiac procedures, would cancel a CJR LEJR episode.

Response: We proposed and are finalizing our policy that a CJR episode would be canceled when a beneficiary initiates an LEJR episode under BPCI Models 1, 2, 3, or 4. A CJR beneficiary initiating a different clinical episode under BPCI Models 1, 2, 3, or 4 would remain in a CJR episode. We refer readers to section III.C.7.b. of this final rule for additional discussion of CJR beneficiary overlap with BPCI episodes.

Summary of Final Decisions: After consideration of the public comments we received, we are finalizing our proposal to cancel episodes once they have begun but prior to their end if the beneficiary no longer meets the same inclusion criteria proposed for the beginning of the episode at any point during the episode. We also are finalizing our proposal that the following circumstances would also cancel an episode:

- The beneficiary is readmitted to a participant hospital during the episode and discharged under MS–DRG 469 or 470.
- The beneficiary initiates an LEJR episode under BPCI Models 1, 2, 3 or 4.

We are modifying our proposal for canceling an episode when a beneficiary dies during an anchor hospitalization. Under our final policy, the following circumstance would also cancel an episode:

- The beneficiary dies at any time during the episode.

The final policies for cancellation of an episode are set forth in § 510.210(b). We note that § 510.210(b)(4) has been revised to state that an episode is canceled if the beneficiary dies during the episode.

c. End of the Episode

LEJR procedures are typically major inpatient surgical procedures with significant associated morbidity and a prolonged recovery period that often is marked by significant PAC needs, potential complications of surgery, and more intense management of chronic conditions that may be destabilized by the surgery. In light of the course of recovery from LEJRs for Medicare beneficiaries, we proposed that an episode in the CJR model end 90 days after discharge from the acute care hospital in which the anchor hospitalization (for MS–DRG 469 or 470) took place. Hereinafter, we refer to the proposed CJR model episode duration as the ''90-day post-discharge'' episode. To the extent that a Medicare payment for included services spans a period of care that extends beyond the episode duration, we proposed that these payments would be prorated so that only the portion attributable to care during the fixed duration of the episode is attributed to the episode spending.

We noted that for the vast majority of beneficiaries undergoing a hip or knee joint replacement, a 90-day post-

discharge episode duration encompasses the full transition from acute care and PAC to recovery and return to activities. We stated our belief that the 90-day post-discharge episode duration encourages acute care hospitals, physicians, and PAC providers to promote coordinated, quality care as the patient transitions from the inpatient to outpatient settings and the community.

In proposing the 90-day post-discharge duration for LEJR episodes in CJR, we took into consideration the literature regarding the clinical experiences of patients who have undergone THA or TKA procedures. In 2007–2008, the 30-day all-cause readmission rate for primary THA among Medicare beneficiaries was 8.5 percent, while the 90-day all-cause readmission rate was 11.9 percent, indicating that while the rate of readmission begins to taper after 30 days, readmissions continue to accrue throughout this 90 day window.[6] In single center studies, Schairer et al found unplanned 30-day hospital readmission rates were 3.5 percent and 3.4 percent and unplanned 90-day hospital admission rates were 4.5 percent and 6 percent for primary THA and TKA, respectively, demonstrating that the risk of readmission remains significantly elevated from 30 through 90 days post-hospital discharge.[7] [8] Further exploring the reasons for unplanned admission for TKAs within 90 days of a knee replacement procedure, Schairer et al found that 75 percent were caused by surgical causes such as arthrofibrosis and surgical site infection. Additional information on the common reasons for hospital readmission following TKA or THA can be obtained from The American College of Surgeons National Surgical Quality Improvement Program.[9] These data identified the top 10 reasons for readmission within 30 days of a hip or knee arthroplasty:

- Surgical site infections (18.8 percent).
- Prosthesis issues (7.5 percent).
- Venous thromboembolism (6.3 percent).
- Bleeding (6.3 percent).
- Orthopedic related (5.1 percent).
- Pulmonary (3.2 percent).
- Cardiac (2.4 percent).
- CNS or CVA (2.4 percent).
- Ileus or Obstruction (2.3 percent).
- Sepsis (2.1 percent).

In addition, the authors concluded that ''readmissions after surgery were associated with new post-discharge complications related to the procedure and not exacerbation of prior index hospitalization complications, suggesting that readmissions after surgery are a measure of post-discharge complications.'' Finally, with regard to the potential for readmission for joint replacement revision within a 90-day post-discharge episode, in a twelve-year study on Medicare patients conducted by Katz, et al., the risk of revision after THA remained elevated at approximately 2 percent per year for the first eighteen months and then 1 percent per year for the remainder of the follow-up period.[10] This study suggests that a longer episode, as opposed to a shorter episode, is more likely to simulate the increased risk of revision LEJR patients face.

In order to address the complication rates associated with elective primary total hip or knee arthroplasty, we developed an administrative claims-based measure (for a detailed description of the measure see section III.D. of the proposed rule). During the development of the Hospital-level Risk-Standardized Complication Rate (RSCR) following elective primary THA or TKA or both, complications of elective primary total hip or knee replacement were identified to occur within specific timeframes.[11] For example, analyses done during the development of the measure as well as Technical Expert Panel opinion found that—(1) Mechanical complications and periprosthetic joint infection/wound infection are still attributable to the procedure for the 90 days following admission for surgery; (2) death, surgical site bleeding, and pulmonary embolism are still likely attributable to the hospital performing the procedure for up to 30 days; and (3) medical complications of acute myocardial infarction (AMI), pneumonia, and sepsis/septicemia/shock are more likely to be attributable to the procedure for up to 7 days.

Other factors further supporting a 90-day post-discharge episode duration are the elevated risk of readmission throughout this time period, as well as the fact that treatment for pneumonia is considered by American Thoracic Society guidelines to be ''health care-associated'' if it occurs up to 90 days following an acute care hospitalization of at least 2 days.[12] According to the American Academy of Orthopedic Surgeons, patients undergoing total hip replacement should be able to resume most normal light activities of daily living within 3 to 6 weeks following surgery.[13] In a small randomized controlled trial of two approaches to hip arthroplasty, average time to ambulation without any assistive device was 22–28 days.[14] According to a 2011 systematic review of studies evaluating physical functioning following THA, patients have recovered to about 80 percent of the levels of controls by 8 months after surgery.[15]

We also refer readers to a study by the Assistant Secretary for Planning and Evaluation (ASPE) in the U.S. Department of Health and Human Services that assessed the mean payments for acute care, PAC, and physician services grouped in the MS–DRG 470.[16] In this study, CMS payment for services following an MS–DRG 470 hospitalization were concentrated within the first 30 days following discharge, with plateauing of payments between 60- or 90-days post-discharge.

[6] Cram P, Lu X, Kates SL, Singh JA, Li Y, Wolf BR. Total Knee Arthroplasty Volume, Utilization, and Outcomes Among Medicare Beneficiaries, 1 991–2010. JAMA. 2012;308(12):1227–1236. doi:10.1001/2012.jama.11153.

[7] Schairer WW, et al. Causes and frequency of unplanned hospital readmission after total hip arthroplasty. Clin Orthop Relat Res. 2014 Feb;472(2):464–70. doi: 1 0.1007/s11999–013–3121–5.

[8] Schairer WW, et al. What are the rates and causes of hospital readmission after total knee arthroplasty? Clin Orthop Relat Res. 2014 Jan;472(1):181–7. doi: 1 0.1007/s11999–013–3030–7.

[9] Merkow RP, Ju MH, Chung JW, et al. Underlying Reasons Associated With Hospital Readmission Following Surgery in the United States. JAMA. 2015;313(5):483–495. doi:10.1001/jama.2014.18614.

[10] Katz JN, et al. Twelve-Year Risk of Revision After Primary Total Hip Replacement in the U.S. Medicare Population. J Bone Joint Surg Am. 2012 Oct 1 7; 94(20): 1 825–1832. doi: 1 0.2106/JBJS.K.00569.

[11] Hospital Quality Initiatives. Measure Methodology. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* See Hip and Knee Arthroplasty Complications zip file under downloads. Accessed on April 10, 2015.

[12] Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. American Thoracic Society, Infectious Diseases Society of America. Am J Respir Crit Care Med. 2005;171(4):388.

[13] *http://orthoinfo.aaos.org/topic.cfm?topic=A00377.*

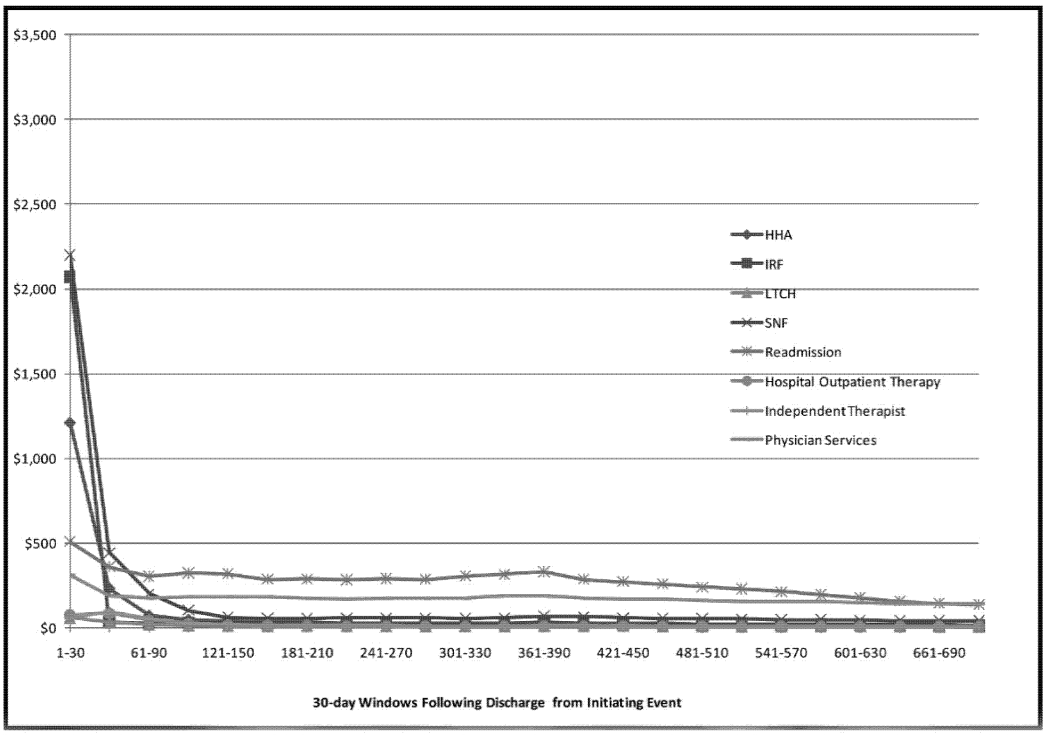
[14] Taunton MJ, et al. Direct Anterior Total Hip Arthroplasty Yields More Rapid Voluntary Cessation of All Walking Aids: A Prospective, Randomized Clinical Trial The Journal of Arthroplasty. Volume 29, Issue 9, Supplement, September 2014, Pages 169–172.

[15] Vissers MM, et al. Recovery of Physical Functioning After Total Hip Arthroplasty: Systematic Review and Meta-Analysis of the Literature. Physical Therapy May 2011 vol. 91 no. 5 615–629.

[16] Post-Acute Care Episodes Expanded Analytic File. Assistant Secretary for Planning and Evaluation. U.S. Department of Health and Human Services. April 2011.

Figure 1

Mean Acute, PAC, and Physician Payments Per PAC User Following Discharge From an Acute Initiating Event, by Type of Claim, MS-DRG 470, "Major Joint Replacement or Reattachment of Lower Extremity w/o MCC"



Note: All initiating events occurred in 2006. Twenty-four 30-day windows were constructed following discharge from the initiating event to follow service use for 2 years.

Source: RTI analysis of 2006, 2007, and 2008 Medicare claims (M3MM181).

Finally, payment and length of stay analyses found the average length of stay in PAC during a 90-day post-discharge episode for MS–DRG 470 to be 47.3 days, indicating that a longer period post-discharge of 90 days is reasonable as a proposal to end the episode of care.[17] We noted that these analyses did not include any time between hospital discharge and the start of PAC.

TABLE 6—COST AND LENGTH OF STAY STATISTICS FOR MS–DRG 470 FOR VARIOUS EPISODE DURATIONS

Statistics for DRG 470 (2006 data)	30-day episode	60-day episode	90-day episode
Mean Medicare spending per hospital discharge (acute+PAC+physician)	$18,838	$20,343	$21,125
Mean payment for anchor hospitalization	$10,463	$10,463	$10,463
Mean payment for PAC	$6,835	$8,339	$9,122
Mean payment for physicians (during anchor hospitalization)	$1,540	$1,540	$1,540
Mean payment for readmission (includes all PAC users, even if no readmission occurs during the episode)	$550	$929	$1,242
Mean length of stay (LOS) for PAC	25.5 days	39.6 days	47.3 days

Note: Data are per PAC user (88% of beneficiaries hospitalized under MS–DRG 470 are discharged to PAC). PAC users are defined as beneficiaries discharged to SNF, IRF, or LTCH within 5 days of discharge from the index acute hospitalization, or discharged to HHA or hospital outpatient therapy within 14 days of discharge from the index acute hospitalization. Mean LOS for PAC does not include any gap between hospital discharge date and start of PAC.

Other tests of bundled payment models for hip and knee replacement have used 90-day post-discharge episodes.[18] We also noted that despite BPCI Model 2 allowing participants a choice between 30-, 60-, or 90-day post-discharge episodes, over 86 percent of participants have chosen the 90-day post-discharge episode duration for the

[17] Analysis of Post-Acute Care Episode Definitions File. *http://innovation.cms.gov/initiatives/bundled-payments/learning-area.html.*

[18] Ridgely MS, et al. Bundled Payment Fails To Gain A Foothold In California: The Experience Of The IHA Bundled Payment Demonstration. Health Affairs, 33, no.8 (2014):1345–1352.

LEJR episode. Furthermore, a 90-day post-discharge episode duration aligns with the 90-day global period included in the Medicare Physician Fee Schedule (MPFS) payment for the surgical procedure.

We also considered proposing a 60-day post-discharge episode duration, but the full transition of care following LEJR would exceed this window for some beneficiaries, especially those who are discharged to an institutional PAC provider initially and then transition to home health or outpatient therapy services for continued rehabilitation. According to a report from ASPE on Medicare beneficiaries receiving PAC following major joint replacement in 2006, 13 percent first receive SNF services and then receive HHA services—with a total mean episode duration of 56.8 days.[19] An additional 9.2 percent receive HHA services first and then receive outpatient therapy services—with a total mean episode duration of 78.7 days. Finally, 6.7 percent receive IRF services first and then HHA services (total mean length of stay 55.3 days), and 4.8 percent receive SNF services first and then outpatient therapy services (total mean length of stay 71.5 days). The remainder only receives one type of PAC.

Therefore, in order to be inclusive of most possible durations of recovery, and services furnished to reach recovery, we proposed the 90-day post-discharge episode duration for CJR. We stated our belief that beneficiaries will benefit from aggressive management and care coordination throughout this episode duration, and hospitals will have opportunities under CJR to achieve efficiencies from care redesign during the 90-day post-discharge episode period.

We sought comment on our proposal to end the episode 90 days after the date of discharge from the anchor hospitalization, as well as on the alternative we considered of ending the CJR episode 60 days after the date of discharge.

The following is a summary of the comments received and our responses.

Comment: Most commenters supported the 90-day post-discharge episode duration. Many of these commenters provided rationales for supporting the 90-day duration (as compared to 60 days or other shorter durations), such as: It is a clinically appropriate length to manage an LEJR to recovery; it creates strong incentives for collaboration for multiple providers across the care continuum that improves care transitions and care coordination; it will promote better long-term results; it aligns with quality measures; and it is the most popular timeframe selected for BPCI Model 2. Some of these commenters asserted that a shorter duration is not sufficiently long to capture the vast majority of issues arising directly from LEJR procedures and could put beneficiary care at risk by encouraging providers to reduce utilization inappropriately or shift utilization outside of an episode.

A few commenters supported a 90-day episode duration, but recommended that we revise the 90-day post-discharge episode duration to begin from the date of surgery instead of discharge, thereby aligning the episode with the MPFS global surgical period and billing policies. A commenter who appeared to believe that CMS proposed to begin the CJR episode immediately after discharge from the anchor hospitalization and extend the episode 90 days post-hospital discharge, rather than upon admission for the anchor hospitalization as CMS actually proposed, asserted that beginning the episode after hospital discharge would make it difficult to understand and account for patient acuity changes within the episode in the post-discharge period as the hospital length-of-stay is related to the PAC acuity of the beneficiary following hospital discharge, especially if the beneficiary has comorbidities. In other words, the commenter believed that beneficiaries with comorbidities would be more likely to have longer anchor hospitalizations and associated higher intensity of PAC services, yet CMS would not understand these relationships if the anchor hospitalization was not included in the episode.

Several commenters supported a 60-day post-discharge episode duration because LEJR patients are nearly fully recovered within 60 days. Some commenters asserted that PAC services associated with LEJR rarely occur after 60 days post-discharge; some commenters cited data that the majority of services for patients with LEJR surgery occur within two months of discharge with only a 6.2 percent change in the total cost of an episode between a 60-day episode and a 90-day episode. Some of these commenters asserted that a 60-day episode would be sufficient to evaluate quality and cost, and a longer duration would increase the financial risk for hospitals without providing significant value to CMS. Some commenters asserted that a 90-day duration increases the risk that unrelated random events that occur well after surgery will disadvantage the hospitals by unfairly impacting participants' performance.

Some commenters recommended a hybrid approach, with every service within the first 30 days post-discharge assumed to be related unless specifically excluded, and services in days 31–90 included only if they meet specified criteria for relatedness.

Some commenters recommended that the episode end prior to 60 days post-discharge. A commenter recommended an episode length of 45 to 60 days, asserting that hospital admissions past the 45 to 60 day window would be for chronic medical admissions that are unrelated to the LEJR procedure. A few commenters recommended that we limit the episode to 30 days citing various rationales, such as: A SNF stay must commence within 30 days of a hospitalization; 30 days better aligns with other quality improvement initiatives such as readmissions; analyses by Medicare Payment Advisory Commission (MedPAC) and the Congressional Budget Office that found that the majority of a bundled payment's episode costs are incurred during the first 30 days; and hospitals may find it difficult to manage follow-up care after 30 days if patients have more than one residence. Several commenters asserted that multiple factors can exacerbate comorbidities in the period beyond 30 days post-operatively, and a model of longer duration that broadly defines related services could result in participant hospitals being more cautious about selecting patients for LEJR and complex patients being discouraged from seeking LEJR procedures in a participant hospital. A few of these commenters noted that Tennessee and Arkansas only include 30 days post-discharge for unrelated chronic conditions in their bundled payment episodes. A commenter shared its experience that, while nearly all patients are diligent about keeping 14-day and 30-day post-operative appointments, those with good outcomes are less likely to return for appointments at 90 days and beyond, resulting in potentially skewed outcomes as patients with complications are much more likely to keep a follow-up appointment at 90 days.

Some commenters recommended giving participant hospitals the flexibility to define the episode duration, either as a duration for all of a participant hospital's LEJR episodes, or to choose a duration based on a patient's clinical condition and comorbidities. A couple of commenters

[19] Examining Post-Acute Care Relationships in an Integrated Hospital. Assistant Secretary for Planning and Evaluation. U.S. Department of Health and Human Services. February 2009

recommended that if CMS offers participants the option to choose the duration, consistent with BPCI, CMS should lower the discount percentage for those willing to take the longer episodes. A commenter disagreed with CMS' cited rationale of the operational simplicity of a single duration for all LEJR episodes by noting that BPCI Model 2 operationalized a variety of different bundles and gave participants the choice of three durations for 48 different clinical episodes.

Other commenters suggested even longer episode durations. A commenter recommended increasing the episode duration to 150 days post-discharge to promote better long-term results and reduce the likelihood of delaying care beyond the end of the episode, specifically urging CMS to adopt a longer episode period for certain clinically-complex subpopulations with predictably longer recovery timeframes. For outcome and quality measurement purposes, some commenters recommended that participant hospitals be held accountable for a longer period, with suggestions of six months, a year, and even two to three years. A commenter recommended increasing the episode duration to two years to better manage the improvements for the entirety of the treatment. A commenter recommended increasing the episode duration to five years to account for the late effects of sub-optimal implant selection.

Response: We appreciate the support of many commenters for the proposed 90-day post-hospital discharge CJR model episode duration. We agree with the commenters that this relatively long episode duration should capture the great majority of health care services that are related to the episode, as well as the beneficiary's return to function and short- and medium-term health outcomes. We believe this episode duration provides participant hospitals with a substantial period of time in which to work to improve the quality and efficiency of LEJR episode performance for beneficiaries who undergo LEJR surgery at their hospital. We have substantial BPCI Model 2 experience with Awardees engaged in testing 90-day LEJR episodes, and note that the vast majority of Awardees have selected the 90-day episode duration, compared to the 30-day and 60-day alternative durations that are available in the model. Our goal is to incentivize efficient high quality care that returns people to the community, and we believe that a 90-day post-discharge duration reflects a full continuum of clinical services and transition of care following LEJR procedures for the average beneficiary, at which time the patient's functional recovery is relatively complete and the patient is able to resume most normal activities of daily living.

Due to the concentration of Medicare spending in the earlier part of the episode, we also believe that a 90-day episode duration only nominally increases the hospital's financial risk when compared to 30 or 60 days. While we understand that uncommon events during the 90-day episode may occur for an individual beneficiary, resulting in an unanticipated or unavoidable need for costly health care services, we believe that our episode definition that excludes unrelated items and services and our payment policies, namely the adjustment for high payment episodes and stop-loss policies discussed in sections III.C.3. and III.C.8. of this final rule, provide sufficient protections for participant hospitals from undue financial responsibility for the care of unrelated clinical conditions as well as for unusual circumstances. We also believe that shorter episode durations may incur a higher clinical risk for beneficiaries if participants delay services beyond the episode, and the risk to beneficiaries of this response by providers to episode payment that can be minimized by the longer 90-day episode duration that we proposed. We refer readers to sections III.F.3. and 5. of this final rule for discussion of our plans to monitor for access to care and delayed care.

In response to those commenters requesting a hybrid approach where CMS would include a broader set of related services in the 30 days following discharge from the anchor hospitalization and a more limited set of related services from days 31 to 90 because of the closer clinical link of a beneficiary's clinical conditions in the first 30 days to the events during the anchor hospitalization itself, we emphasize that the CJR model is an episode payment model where many Medicare beneficiaries who receive PAC services as part of their post-operative recovery from surgery will also have underlying health conditions that may be affected by the surgery itself and care throughout the recovery period and that require attentive, flexible management if good health outcomes are to be achieved. Because PAC services are designed to be comprehensive in nature, we believe that the same Part A and Part B services should be included throughout the episode duration because PAC providers should broadly address the beneficiary's health care needs in high quality, efficient episodes, even though the anchor hospitalization itself may be more remote from the beneficiary's health needs as the time from hospital-discharge increases. As discussed in section III.A.3. of this final rule, we have identified hospitals as the financially responsible organization for the episode, although episode quality and cost performance will clearly be related in part to the quality and efficiency of care furnished by other providers and suppliers treating the beneficiary throughout the episode. We expect that participant hospitals will develop the care pathways and partnerships with other providers and suppliers necessary for the hospital to be successful in this responsibility, and this model provides a variety of tools that should be helpful to participant hospitals, such as waivers of Medicare program rules, the opportunity to engage in certain financial arrangements, and the ability to offer certain beneficiary incentives (as discussed in sections III.C.11. and III.C.10. of this final rule, respectively).

We appreciate the interest of some commenters in significantly longer episodes than the 90 days post-hospital discharge period we proposed, in order to include the longer recovery period that some beneficiaries may require as well as to account for longer term health outcomes, because the timing or frequency of joint replacement revisions may be related to implant selection, surgical technique, or other aspects of the primary joint replacement procedure. However, as previously noted, we believe that a 90-day post-discharge duration reflects a full continuum of clinical services and transition of care following LEJR procedures for the average CJR beneficiary, and we do not believe it would be an appropriate test of the model to extend the CJR episode duration beyond 90 days post-hospital discharge to reflect the longer recovery needed by some beneficiaries. Moreover, as noted previously in this section, the CJR model focuses on the surgical procedure and the associated recovery, and at this time, we are not testing a model of longer term outcomes. Therefore, we are not going to incorporate a longer time period in the episode, and will not include periods beyond then, other than to monitor the 30-day post-episode period. The 30-day post-episode period is discussed in section III.C.8.d. of this final rule, where we describe the CJR model policy that holds participant hospitals financially responsible for significantly increased Medicare Parts A and B spending in the 30 days immediately following the end of the episode. We note that the

evaluation described in section IV. of this final rule will focus on a variety of key topics including potential unintended consequences such as cost shifting beyond the CJR model episode period and stinting on medically necessary and appropriate care. As such, CMS anticipates the examination of claims submitted beyond the 90-day episode will be incorporated in the evaluation strategy. Finally, we maintain that allowing for multiple durations would be administratively complex for a model of this scope as it would be akin to implementing multiple models concurrently, each with its own customized payment calculations, risk adjustments, and other elements. We do not believe a variable approach such as is used in BPCI, which is a voluntary model, is appropriate for this large test of LEJR episode payment for all IPPS hospitals in the selected MSAs, as it would greatly increase the administrative complexity of the CJR model. We also believe that a standard duration for all episodes is important for this test of LEJR episode payment in providing us with a larger sample of episodes of the same duration from which we can learn.

Regarding the request to align the CJR model episode duration with the MPFS by beginning the 90-day duration on the date of surgery, rather than on the date of discharge from the hospital, we do not agree with this suggestion. We believe that the 90-day global surgical period for LEJR procedures under the MPFS lends support for an episode duration under the CJR model that is similar, because beneficiaries have a significant post-operative recovery period throughout which close care coordination and management among treating providers is important to beneficiary return to function. The MPFS global payment policy sets an expectation that the operating surgeon plays a significant role in caring for beneficiaries in the typical case that extends up to 90 days following surgery. However, using this same 90-day accounting methodology under the CJR episode would lead to model episodes including variable post-discharge lengths because the duration of the anchor hospitalization, which can vary substantially, would count toward the 90 days. We are interested in testing under the CJR model an episode duration that is most likely to cover the time for the beneficiary's full recovery and return to the community so we believe that including a standard length of 90 days post-hospital discharge is the best way to ensure that each CJR beneficiary's episode includes the same length of post-hospital discharge recovery in the episode. We do not believe the minor 90-day definitional differences between this model and the MPFS global billing policies for LEJR procedures should create significant problems for physicians collaborating with participant hospitals in the episode care of CJR model beneficiaries.

In response to the commenter concerned that starting the bundle after hospital discharge would make it difficult to account for patient acuity changes post-discharge under the CJR model, we want to emphasize that the CJR model episode actually begins on the day of admission for the anchor hospitalization and extends 90 days post-hospital discharge, with the day of hospital discharge counting as the first day in the 90-day post-hospital discharge period. Thus, the episode includes the full anchor hospital length-of-stay that may affect changes in patient acuity in the post-discharge period. We note that according to this episode duration definition, episodes for individual beneficiaries will have a variable total length that depends on the length of the anchor hospitalization. For example, the average length-of-stay for MS–DRG 470 is 3 days, so the average CJR model episode length for an individual beneficiary would be 92 days. The average length-of-stay for MS–DRG 569 is 6 days, so the average CJR model episode length for an individual beneficiary would be 95 days. Despite their variable total length, all CJR model episodes will include the complete anchor hospitalization and 90 days post-hospital discharge and, therefore, will include all related items and services furnished to the beneficiary throughout the episode, including those provided to address beneficiary acuity changes during the hospitalization and post-discharge period.

Summary of Final Decisions: After consideration of the public comments we received, we are finalizing our proposal to end the episode 90 days after discharge from the anchor hospitalization. We are revising the definition of Episode of care to clarify that the day of discharge itself counts as the first day of the post-discharge period and adding the same clarification to § 510.210(a)

The final definitions policies for ending an episode are set forth in § 510.2 and

§ 510.210(a).

C. Methodology for Setting Episode Prices and Paying Model Participants Under the CJR Model

1. Background

As described in section II.B. of the proposed rule, we proposed to use the CJR episode payment model to incentivize participant hospitals to work with other health care providers and suppliers to improve quality of care for Medicare beneficiaries undergoing LEJR procedures and post-operative recovery, while enhancing the efficiency with which that care is provided. We proposed to apply this incentive by paying participant hospitals or holding them responsible for repaying Medicare based on their CJR episode quality and Medicare expenditure performance. The following sections describe our final decisions for the—

- Performance years covered by the model, the retrospective methodology that will be applied, and the application of two-sided risk beginning in the second year of the model;
- Adjustments that will be made to payments included in the episode;
- Episode price setting methodology;
- Use of quality performance in the payment methodology;
- Process for reconciliation;
- Adjustments for overlaps with other CMMI models and CMS programs;
- Limits and adjustments on hospitals' financial responsibility;
- Appeal procedures for reconciliation;
- Financial arrangements and beneficiary incentives; and
- Waivers of Medicare program rules.

2. Performance Years, Retrospective Episode Payment, and Two-Sided Risk Model

a. Performance Period

We proposed that the CJR model would have 5 performance years. The performance years would align with calendar years, beginning January 1, 2016. Table 7 includes details on which episodes would be included in each of the 5 performance years.

TABLE 7—PROPOSED PERFORMANCE YEARS FOR CJR MODEL

Performance year	Calendar year	Episodes included in performance year
1	2016	Episodes that start on or after January 1, 2016, and end on or before December 31, 2016.
2	2017	Episodes that end between January 1, 2017, and December 31, 2017, inclusive.
3	2018	Episodes that end between January 1, 2018, and December 31, 2018, inclusive.
4	2019	Episodes that end between January 1, 2019, and December 31, 2019, inclusive.
5	2020	Episodes that end between January 1, 2020, and December 31, 2020, inclusive.

Under our proposal, all episodes tested in this model would have begun on or after January 1, 2016 and ended on or before December 31, 2020. We noted that this definition would result in performance year 1 being shorter than the later performance years in terms of the length of time over which an anchor hospitalization could occur under the model. We also noted that some episodes that began in a given calendar year may be captured in the following performance year due to the episodes ending after December 31st (for example, episode beginning in December 2016 and ending in March 2017 would be part of performance year 2). We stated our belief that 5 years would be sufficient time to test the CJR model and gather sufficient data to evaluate whether it improves the efficiency and quality of care for an LEJR episode of care. Further, having fewer than 5 performance years may not provide sufficient time or data for evaluation. The 5-year performance period is consistent with the performance period used for other CMMI models (for example, the Pioneer Accountable Care Organization (ACO) Model).

The following is a summary of the comments received and our responses.

Comment: Several commenters supported our proposal for a 5-year performance period as well as our proposed start date of January 1, 2016. However, a substantial number of commenters expressed concerns over the proposed start date and requested that we delay implementation of the model. Most of these commenters expressed concerns about the ability of participants to successfully participate in the model, given the proposed timeframes. Commenters noted that participants would need additional time for activities such as developing a new infrastructure with respect to provider networks, which would include identifying and establishing contracts with collaborators as well as determining appropriate incentives and gainsharing structures; identifying and developing new care pathways and performance metrics; and developing as well as modifying accounting and IT systems. In particular, a number of commenters expressed concern with the proposed start date in light of the requirement that hospitals begin to assume risk in the second year of the model, which is discussed further later in this section. Moreover, given variation in hospital preparedness, these kinds of issues could be particularly acute for certain kinds of hospitals, for example, smaller hospitals or those with more limited resources. Also, as discussed in section III.E of this final rule, commenters noted that their ability to implement the previously stated changes would be impeded by not having received baseline and episode-level data from CMS until after the proposed start date. Commenters indicated that these data would be essential to identifying opportunities and strategies for quality and efficiency improvement, and that the model should be delayed until after they have had a chance to review and understand their own episode data.

We also received comments suggesting that implementation of the model is premature and that it should be delayed until certain actions or events have occurred, for example, until certain quality measures have been developed, data required under the Improving Medicare Post Acute Care Transformation Act of 2014 (Pub. L. 113–185, enacted October 6, 2014) (IMPACT Act) have been collected or analyzed, or CMS has considered the results of other bundled payment models such as BPCI. For example, several commenters requested a phased implementation of the CJR model, due to the limited evaluation results that have been publicly released to date for BPCI, and to allow for testing and monitoring of the CJR model prior to full implementation. Another commenter asserted that a phased-in approach to implementing CJR is appropriate, given that while episode-based payment models have shown potential to reduce cost, rigorous studies and evaluation data on episode-based payment models are limited. Some commenters expressed the view that CMS' timeline ignores multiple competing mandates that hospitals and other providers have, for example, ICD–10–CM implementation as well as EHR Meaningful Use and other quality-related programs.

In addition, we received a comment urging a delayed start date due to concerns on how requirements with respect to the civil monetary penalty (CMP) law (sections 1128A(a)(5), (b)(1) and (b)(2) of the Act), the Federal Anti-kickback statute (section 1128B(b)(1) and (2) of the Act), or the physician self-referral prohibition (section 1877 of the Act) would apply under the model. For example, a commenter noted that the proposed rule offered insufficient protection from certain statutory and regulatory risks associated with developing coordinated care arrangements among providers and that significant ambiguity and challenges existed with respect to compliance with these requirements.

Commenters also stated that in contrast to our proposed start date for the CJR model, CMS allowed voluntary BPCI participants, who were more likely to be well positioned to participate in an episode-based payment model, at least one year to consider their episode data, yet many of them likely found the program and timing demands challenging. Further, mandating the program, especially for unprepared participants, could result in even greater challenges, and increase the chance of failure and disruption of health care services for Medicare beneficiaries.

Some commenters offered examples of how, in their view, implementing the model by the proposed start date could result in unintended consequences such as reduced access for beneficiaries or lower care quality. For example, commenters suggested that the proposed timeframe could cause hospitals to make care redesign choices that reduced access for beneficiaries or certain kinds of beneficiaries such as those who posed greater risk or that care quality could be compromised because participants would have had insufficient time to implement new care practices.

Given these concerns, commenters generally requested that we delay the start date by a specific period of time, for example, by three months, six months, nine months or a year, with most commenters requesting a delay of nine months to a year. Some

commenters recommended delay periods of two years or more. In some cases, commenters tied their proposed delay period to an event, for example, some period of time subsequent to having received baseline and episode-level data from CMS. Some commenters requested that only the mandatory aspect of the model be delayed, allowing providers willing to participate the opportunity to do so or, in the event of a delayed start date, providers be permitted to voluntarily opt-in to the model prior to the date of implementation. As such, providers who had begun to prepare for the model could begin to generate cost savings while driving improvements in quality and patient experience for LEJR patients.

Response: We appreciate the comments we received in support of our proposed performance period and start date. We also appreciate and are persuaded by comments expressing concerns that our proposed start date does not provide sufficient time for participants to implement the kinds of changes needed to successfully participate in the model, particularly given that baseline data would not be available until after our proposed start date of January 1, 2016. Accordingly, this final rule will delay the start date of the model to April 1, 2016. Also, as indicated in section III.E.4 of this rule, we intend to make participating hospitals' baseline data available upon request in advance of the April 1, 2016 start date, which will allow participants the opportunity to assess their baseline data as they consider changes to their care practices in advance of the model's start date. Also, as discussed in section III.C.8. of this final rule, we are reducing the potential risk to participants in Year 2 by lowering the stop-loss limit from 10 percent to 5 percent (and from 20 percent to 10 percent in Year 3). We believe that these changes will both facilitate participants' abilities to be successful under this model and allow for a more gradual transition to full financial responsibility under the model.

Table 8 includes details on which episodes would be included in each of the 5 performance years under this delay.

TABLE 8—PERFORMANCE YEARS FOR CJR MODEL

Performance year	Calendar year	Episodes included in performance year
1	2016	Episodes that start on or after April 1, 2016, and end on or before December 31, 2016.
2	2017	Episodes that end between January 1, 2017, and December 31, 2017, inclusive.
3	2018	Episodes that end between January 1, 2018, and December 31, 2018, inclusive.
4	2019	Episodes that end between January 1, 2019, and December 31, 2019, inclusive.
5	2020	Episodes that end between January 1, 2020, and December 31, 2020, inclusive.

Under this revised schedule, all episodes tested in this model will have begun on or after April 1, 2016 and ended on or before December 31, 2020. Additional discussion on how this revised performance year schedule affects the use of quality measures for the model and the timeline for the reconciliation process is included in sections III.C.5. and III.C.6. of this final rule.

We do not agree that a longer delay is needed. Hospital participants will not be financially responsible for repayment to Medicare until the second performance year of the model. In addition, as discussed in section III.C.8. of this final rule, we have further limited financial risk to hospitals in performance years 2 and 3 by lowering stop-loss limits; specifically, from 10 percent to 5 percent in Year 2, and from 20 percent to 10 percent in Year 3. Finally, while we note that commenters are correct that voluntary BPCI participants received claims data prior to taking on risk under the BPCI model, and in some cases had more than a year to prepare for participation in BPCI, we believe that providing claims data to CJR participants in early 2016 and beginning the model April 1, 2016 is appropriate for several reasons. First, we note that under BPCI, voluntary participants in Phase I had the option of receiving claims data for multiple episodes, up to the 48 clinical episodes included in the BPCI initiative. The CJR model will only include one type of episode, and as such we believe it is reasonable for hospitals to begin to analyze data and identify care patterns and opportunities for care redesign for this episode in our stated implementation timeline. We also note that due to the gradual implementation of downside risk, we expect that hospitals would spend the first performance year of the model analyzing data, identifying care pathways, forming clinical and financial relationships with other providers and suppliers, and assessing opportunities for savings under the model, utilizing the quarterly claims data we provide to them. This is similar to the approach we took to allow hospitals to participate in Phase I of BPCI prior to entering Phase II (the risk-bearing phase). As noted in this section, participant hospitals would also be eligible to receive reconciliation payments for performance year 1 if actual spending is below the target price. We believe that our implementation timeline is reasonable, given the financial opportunity for hospitals to earn reconciliation payments for performance year 1 and the gradual transition to financial responsibility.

We are also not persuaded by commenters that implementation of the model is premature or that it should be delayed until results for BPCI or other episode-based payment models are available. While we anticipate that the BPCI model will offer valuable information that should assist CMS in developing bundling payment models, the CJR model will offer additional insights that are not available under the BPCI model; in particular, insights with respect to bundling payment models on a mandatory rather than voluntary basis. Thus, we will be able to observe how a bundling payment model might work with participants that would otherwise not participate in such a model. As such, we expect the results from this model should produce data that are more broadly representative than what might be achieved under a voluntary model. Also, this model tests a different target pricing approach than the one used in BPCI. BPCI uses a purely participant-specific pricing approach, rewarding participants for improving based on their historical performance. While this may incentivize historically less efficient participants to improve, there may not be as much incentive for already efficient participants. The regional target pricing approach for this model, though, would consider a participant hospital's performance relative to its regional peers. As part of this test, we will learn whether our alternative pricing approach in this model will better incentivize participants who are already delivering high quality and efficient care while

still incentivizing historically less efficient providers to improve. We would not be able to test such a regional pricing approach under a purely voluntary model because it is likely that only the already high quality and efficient providers would sign up.

We would note that we have released final evaluation results from the ACE demonstration, which determined that the demonstration led to reduced episode spending with no adverse impact on quality of care. Further, we note that the significant level of voluntary participation in BPCI, as well as high participation in LEJR episodes in particular in all BPCI models, signify the potential for financial opportunity for both hospitals and CMS to achieve savings and improve quality of care through an episode-based payment model targeting LEJR procedures. As further evaluation results for BPCI and other models are available, we will make such information available to the public, and if necessary, could incorporate lessons learned into the CJR model. In addition, in section III.F. of this final rule, we detail our plans to monitor care to ensure beneficiaries' access to quality and timely health care is maintained under the CJR model.

While we acknowledge the benefits of having more rigorous evidence to support the success of episode-based payment models, we believe that the aforementioned findings and encouraging preliminary evaluation data from our prior and current bundled payment models and demonstrations support our plan to more broadly test the model's effectiveness at this time. Moreover, the mission of the Innovation Center is to test models of care that reduce spending while maintaining or improving the quality of care furnished to Medicare, Medicaid and CHIP beneficiaries. Testing this model will provide additional information for CMS and providers on successful payment structures and care redesign strategies.

We also disagree that the model should be delayed simply because other similar efforts are currently ongoing. Rather, we would note that it is not uncommon for CMS to test multiple similar models concurrently rather than sequentially. For example, CMS currently has multiple primary care-focused models in testing, the Comprehensive Primary Care Initiative (CPCI) and the Multi-Payer Advanced Primary Care Practice (MAPCP) models. In addition, CMS has a permanent ACO program (the Medicare Shared Savings Program), as well as multiple other ACO models in the testing phase. We believe our decision to test the CJR model at this time is consistent with the approach taken for other models and programs to test payment models that may be similar in design but are targeted at different groups of providers. Such an approach provides CMS with additional information on the potential success of various model and program aspects and design features.

Likewise, we do not agree that the model should be delayed until certain other actions have occurred (for example, after additional quality measures have been developed or data required under the IMPACT Act have been analyzed) or because of the multiple competing mandates faced by hospitals and other providers. Since the Medicare program's inception, providers have and will continue to contend with constantly evolving statutory and administrative requirements that often require them to make concurrent changes in their practices and procedures. We do not believe the CJR model is dissimilar to those requirements.

As stated previously, some commenters urged a delayed start date due to concerns on how requirements with respect to the CMP law (sections 1128A(a)(5), (b)(1) and (b)(2) of the Act), the Federal Anti-kickback statute (section 1128B(b)(1) and (2) of the Act), or the physician self-referral prohibition (section 1877 of the Act) would apply under the model. In response, we would note that for programmatic reasons discussed elsewhere in this final rule and to give providers additional time to ensure compliance with applicable laws, we are delaying the start date of the model to April 1, 2016.

Also as discussed earlier in this section, some commenters pointed to the potential for unintended consequences that could result from our proposed start date, including impediments to beneficiary access and reduced quality of care. As discussed in section III.D of this final rule, we are including quality measures for purposes of evaluating hospitals' performance both individually and in aggregate across the model. Also, as discussed in section III.F of this final rule, we are making final policies and actions to monitor both care access and quality. We believe these features will help ensure that beneficiary access to high quality care is not compromised under the model.

Final Decision: We are modifying our proposed policy on the model performance years and establishing April 1, 2016 as the start date for the model. Accordingly, we are replacing ''January 1, 2016'' in § 510.200(a) with ''April 1, 2016.''

b. Retrospective Payment Methodology

As described in section III.B. of the proposed rule, we proposed that an episode in the CJR model begins with the admission for an anchor hospitalization and ends 90 days post-discharge from the anchor hospitalization, including all related services covered under Medicare Parts A and B during this timeframe, with limited exclusions and adjustments, as described in sections III.B., III.C.3., and III.C.7. of the proposed rule. The episodes would be attributed to the participant hospital where the anchor hospitalization occurred.

We proposed to apply the CJR episode payment methodology retrospectively. Under this proposal, all providers and suppliers caring for Medicare beneficiaries in CJR episodes would continue to bill and be paid as usual under the applicable Medicare payment system. After the completion of a CJR performance year, Medicare claims for services furnished to beneficiaries in that year that were included in the model would be grouped into episodes and aggregated, and participant hospitals' CJR episode quality and actual payment performance would be assessed and compared against episode quality thresholds and target prices, as described in sections III.C.5. and III.C.4. of the proposed rule, respectively. After the participant hospitals' actual episode performance in quality and spending are compared against the previous episode quality thresholds and target prices, we would determine if Medicare would make a payment to the hospital (reconciliation payment), or if the hospital owes money to Medicare (resulting in Medicare repayment). The possibility for hospitals to receive reconciliation payments or be subject to repayment (note: participant hospitals would not be subject to repayment for performance year 1) was further discussed in section III.C.2.c. of the proposed rule.

We considered an alternative option of paying for episodes prospectively by paying one lump sum amount to the hospital for the expected costs of the 90-day episode. However, we believed such an option would be challenging to implement at this time given the payment infrastructure changes for both hospitals and Medicare that would need to be developed to pay and manage prospective CJR episode payments. We noted that a retrospective episode payment approach is currently being utilized under BPCI Model 2. Also, we expressed our belief that a retrospective payment approach can accomplish the objective of testing episode payment in

a broad group of hospitals, including financial incentives to streamline care delivery around that episode, without requiring core billing and payment changes by providers and suppliers, which would create substantial administrative burden. However, we sought comment on potential ways to implement a prospective payment approach for CJR in future performance years of the model.

The following is a summary of the comments received and our responses.

Comment: Commenters submitted mixed responses on our proposed retrospective payment methodology. Many comments we received expressed support for our proposed retrospective model. Some of these commenters indicated that, since it would build upon existing payment system infrastructures and processes, a retrospective model would be most administratively feasible and straightforward as well as involve fewer infrastructure changes and logistical challenges than would be required under a prospective model. A commenter noted that a retrospective model would allow providers to gain experience with a bundling payment model without altering existing revenue cycle practices. Further, the availability of fee-for-service payments under a retrospective model would maintain a predictable cash flow for participants in the model.

Some commenters expressed support for the proposed retrospective methodology provided that certain conditions existed. For example, a commenter expressed support for this methodology provided that payment reconciliation could be available on a quarterly basis. Another commenter supported the retrospective methodology provided that beneficiaries had access to any provider they chose and were not limited to those with whom a hospital had a contractual arrangement.

Response: We appreciate the comments we received that were in support of our proposed retrospective payment methodology, and concur with commenters' views on some of the benefits of this model. As discussed further in section III.C.6. of this final rule, we are making final our proposed reconciliation on an annual basis. Also, as further discussed in section III.F.2. of this final rule, because hospitals in selected geographic areas will be required to participate in the model, individual beneficiaries will not be able to opt out of the CJR model. However, the payment model does not limit a beneficiary's ability to choose among Medicare providers and suppliers or the range of services that are available to them. Beneficiaries may continue to choose any Medicare enrolled provider or supplier, or any physician or practitioner who has opted out of Medicare, with the same costs, copayments and responsibilities as they have with other Medicare services. Also, although the proposed model would allow participant hospitals to enter into sharing arrangements with certain providers and suppliers and these preferred providers and suppliers may be recommended to beneficiaries as long as those recommendations are made within the constraints of current law, hospitals may not restrict beneficiaries to any list of preferred or recommended providers and suppliers that surpass any restrictions that already exist under current statutes and regulations.

Comment: In addition to the many commenters supporting our proposed retrospective methodology, we received many other comments that opposed our proposal and expressed support for some type of prospective payment model. Some commenters expressed the view that our proposed model was complex, complicated by variation in payment policies across Medicare FFS payment models, and needed further refinement. Others stated that as compared to a prospective payment model, a retrospective model is less effective at holding providers accountable or in stimulating the kinds of behavior changes that are needed to achieve the goals of the program. For example, because providers are expected to change their behavior in anticipation of a reward that might occur several months later, the model diminishes the incentive for providers to change their behavior. Moreover, bonuses and penalties are not sufficiently correlated with performance. Further, a retrospective model could limit the availability of resources for providers to invest in the changes needed to support and sustain behavior change and high-quality care.

Some of the criticisms we received focused on the potential effects of a retrospective model on beneficiaries' costs. For example, some commenters expressed concerns on whether beneficiaries would or even could see cost-sharing reductions when a provider achieves savings under a retrospective model. Another comment suggested that as compared to a prospective model, payments under a retrospective model are more difficult to be incorporated into tools designed to help consumers shop for facilities and providers and reduced pricing predictability for the consumer.

In light of these concerns, many commenters proposed that CMS adopt or eventually transition to some kind of prospective payment model or hybrid model. Commenters suggested that doing so would improve accountability for costs and quality, strengthen risk/reward relationships, better support efforts to transition away from FFS, encourage providers to adhere to evidence-based clinical guidelines, reduce unnecessary or duplicative care, and help participants invest early in supportive resources, such as health information technology, care coordination tools, and infrastructure development to support accountability for quality and costs. A commenter offered the view that information technology solutions are now available that support prospective payment models with minimal burden and disruption to hospitals—concerns that have discouraged the adoption of prospective models.

Some examples of prospective models that were suggested would be for CMS to—

- Establish an extended DRG that includes hospital, physician, and PAC services for some period of time (for example, 30, 60, 90 days);
- Make a prospective payment to hospitals that are then distributed to their partners based on volume, acuity, quality, and efficiency;
- Withhold some percentage of the total payment that would be intended for downstream partners. Hospitals would subsequently distribute these payments to partners based on their ability to meet quality and efficiency targets;
- Move toward a prospectively negotiated case rate to foster collaboration among all clinicians involved in patient care and provide predictable pricing. For example, give facilities a financial incentive to assume the greater risk and uncertainty inherent in a prospective bundle by reducing or eliminating the two percent discount from the payment benchmark or narrowing the definition of ''related care'' in the 90-day post-discharge; and
- Allow physicians to lead a team where the participating physician and their patient decide which other providers and suppliers would be involved in and what the treatment plan would be for the episode. The team would designate or create a jointly governed management organization that would be paid through new prospective episode codes. Other providers, including the hospital, could be paid by that same organization or through existing Medicare payment systems. Medicare would pay a single bundled

payment amount to cover the costs of all of the services in that episode. The hospital and other providers and suppliers on the team could be paid either through the management organization or through traditional Medicare payment systems, but only by one of these sources. Amounts paid through traditional payment systems would be deducted from the amount paid to the management organization.

In addition to comments supporting a prospective payment model, we received comments explicitly expressing concern about adopting such a model. For example, a commenter expressed the view that non-hospital providers and suppliers, including physicians and PAC providers, would likely be concerned with a policy that would allow hospitals complete authority to allocate payments among participating providers and suppliers or to be empowered with functions and authorities typically associated with Medicare Administrative Contractors (MACs). Moreover, a prospective payment methodology would exacerbate anti-competitive concerns with respect to the proposed model in general.

Response: We appreciate the comments we received in opposition to our proposed retrospective model. While we believe that our proposed retrospective payment model would be effective in encouraging providers to improve care quality while better controlling the costs of the care, we also share commenters' optimism on the potential benefits and effectiveness of prospective models with respect to improving accountability for costs and quality, strengthening risk/reward relationships, better supporting efforts to transition away from FFS, and encouraging providers to adhere to evidence-based clinical guidelines while reducing unnecessary or duplicative care. We also are pleased that information technology solutions are being developed to support prospective payment models.

We agree with commenters that there are complexities and potential complications associated with a retrospective model and anticipate that further refinements will likely be needed with whatever kind of bundling model that is implemented. Therefore, we do not believe that the complexities and potential complications with our proposed model are significantly different than what occurs with other Medicare payment models, particularly any of the more novel ones. Likewise, we do not believe that such complexities or complications would be mitigated simply by adopting a prospective model. Moreover, both CMS and some of the commenters have noted that adoption of a prospective model could result in potentially significant complexities and logistical issues as well.

We also do not agree with the view suggesting that adoption of a retrospective model could limit the availability of resources for providers to invest in the changes needed to improve care quality and costs. Under our retrospective model, participant hospitals and other providers and suppliers will continue to bill and be paid under FFS Medicare as they would in the absence of the model that should result in a revenue stream comparable to what they would be absent the model, all else equal.

While we agree with the comment stating that beneficiaries will not see a reduction in their cost-sharing for joint replacement services under this model, we do not see this as being unique to the CJR model or a reason to not test it. To the contrary, if successful, our model will improve the quality of care and outcomes for these beneficiaries as well as better control costs of care. For example, if successful, we believe the model could help to limit or mitigate avoidable costs incurred by these beneficiaries such as costs associated with avoidable hospital readmissions. Last, we also do not see the potential challenges of integrating a retrospective payment methodology into sites designed to compare health care options as a reason to not test our proposed model or as being an insurmountable problem.

Based on the comments that we received, we believe there is support for both prospective and retrospective payment models. We also continue to believe that a retrospective payment model can accomplish the objective of testing episode payments with a broad group of hospitals, by including financial incentives that will streamline care delivery while producing less administrative burden for providers than would be possible with a prospective model. Accordingly, we will be implementing a retrospective payment model at this time as we had proposed. We appreciate the various examples of prospective models that commenters suggested for CMS' consideration, and will consider these examples along with other options to potentially be tested in the future.

Final Decision: After considering the public comments we received, we are finalizing our proposal to implement a retrospective payment model.

c. Two-Sided Risk Model

We proposed to establish a two-sided risk model for hospitals participating in the CJR model. We proposed to provide episode reconciliation payments to hospitals that meet or exceed quality performance thresholds and achieve cost efficiencies relative to CJR target prices established for them, as was defined later in sections III.C.4. and III.C.5. of the proposed rule. Similarly, we proposed to hold hospitals responsible for repaying Medicare when actual episode payments exceed their CJR target prices in each of performance years 2 through 5, subject to certain proposed limitations discussed in section III.C.8. of the proposed rule. Target prices would be established for each participant hospital for each performance year.

We proposed that hospitals will be eligible to receive reconciliation payments from Medicare based on their quality and actual episode spending performance under the CJR model in each of CJR performance years 1 through 5. Additionally, we proposed to phase in the responsibility for hospital repayment of episode actual spending if episode actual spending exceeds their target price starting in performance year 2 and continuing through performance year 5. Under this proposal in performance year 1, participant hospitals would not be required to pay Medicare back if episode actual spending is greater than the target price.

We considered an episode payment structure in which, for all 5 performance years of the model, participant hospitals would qualify for reconciliation payments if episode actual spending was less than the episode target price, but would not be required to make repayments to Medicare if episode actual spending was greater than the episode target price. However, we noted our belief that not holding hospitals responsible for repaying excess episode spending would reduce the incentives for hospitals to improve quality and efficiency. We also considered starting the CJR payment model with hospital responsibility for repaying excess episode spending in performance year 1 to more strongly align participant hospital incentives with care quality and efficiency. However, we stated our view that hospitals may need to make infrastructure, care coordination and delivery, and financial preparations for the CJR episode model, and that those changes can take several months or longer to implement. With this consideration in mind, we proposed to begin hospitals' responsibility for repayment of excess episode spending

beginning in performance year 2 to afford hospitals time to prepare, while still beginning some incentives earlier (that is, reconciliation payments in year 1) to improve quality and efficiency of care for Medicare beneficiaries. We solicited comment on the proposed incentive structure for CJR.

In an effort to further ensure hospital readiness to assume responsibility for circumstances that could lead to a hospital repaying to Medicare actual episode payments that exceed the episode target price, we proposed to begin to phase in this responsibility for performance year 2, with full responsibility for excess episode spending (as proposed in the proposed rule) applied for performance year 3 through performance year 5. To carry out this ''phase in'' approach, we proposed during the first year of any hospital financial responsibility for repayment (performance year 2) to set an episode target price that partly mitigates the amount that hospitals would be required to repay (see section III.C.4.b. of the proposed rule), as well as more greatly limits (as compared to performance years 3 through 5) the maximum amount a hospital would be required to repay Medicare across all of its episodes (see section III.C.8. of the proposed rule).

Comment: Several commenters expressed support for our proposal to establish downside risk for participants as well as our proposal to gradually phase-in risk beginning in year 2. We received very few comments requesting the elimination of risk from the model. A commenter suggested that it was unfair to require hospitals to bear risk given that there were no limitations on beneficiary choices. Also, some commenters suggested that CMS consider excluding specific kinds of hospitals from the model, for example small hospitals or hospitals with low volume.

Most of the comments we received, however, requested that CMS ease the glide path to downside risk by either delaying the requirement for two to three years or by incorporating features to better limit risk, for example, by adjusting stop-loss caps. Some commenters requested that we modify the CJR model to be more like a shared savings model as is used in Shared Savings Program or the Pioneer ACO model. In their view, this option would be particularly attractive to smaller organizations with lower episode volumes that face a higher risk of random episode cost variation or those with limited financial resources.

Some commenters requested these changes because of concerns that hospitals have little or no experience bearing risk and thus need additional time to be ready to do so. Other commenters stated that our proposed timeframe for implementing the model and requiring hospitals to assume risk was simply too aggressive and offered too little time for hospitals to put in place the care procedures and infrastructure needed to be successful in the model and in a position to bear risk. In recommending that CMS delay downside risk, a commenter observed that payment features of other Medicare efforts such as BPCI and the Pioneer ACO model have been refined more than once since their implementation, which suggested that more can be learned about the appropriate framework for a risk model, particularly given that the CJR model is untested.

Response: We appreciate the comments we received in support of our proposal to phase-in downside risk to CJR participants beginning in Year 2 of the model. We are also encouraged that very few commenters opposed a requirement for participants to assume downside risk at some point in the model.

We disagree with the view that it is unfair to require hospitals to bear risk while beneficiaries retain the ability to choose among providers. As is the case with other new payment models such as the Shared Savings Program, the CJR model is intended to identify ways to improve care quality and better control costs in the Medicare FFS program. While Medicare beneficiaries may choose between Medicare FFS and Medicare Advantage, the majority of beneficiaries—roughly two-thirds in 2015—continue to choose the former. Accordingly, it is in the interest of the Medicare program and its beneficiaries for CMS to identify new models that both maintain beneficiary choice while improving care quality and costs. Also, while we appreciate suggestions to exclude certain kinds of hospitals, for example, small hospitals or hospitals with a low-volume of cases, we believe our methodology for selecting geographic units, as discussed in section III.A.4.of this final rule, as well as additional protections for certain kinds of these hospitals, as discussed in section III.C.8.c. of this final rule sufficiently address these concerns.

We also understand that commenters would like a more gradual transition to downside risk, and in response to the commenters' concerns, CMS has taken steps for hospitals to do so. As discussed in section III.C.8. of this final rule, we are reducing the potential risk to participants in Year 2 by lowering the stop-loss limit from 10 percent to 5 percent (and from 20 percent to 10 percent in Year 3). We believe these actions should assist participants both with respect to preparing for the assumption of risk as well as reducing the level of risk they must initially bear. We do not support the proposal to change the CJR model to a shared savings model as it is inconsistent with our intent of testing whether a bundled payments model will promote quality and financial accountability for episodes of care surrounding an LEJR or reattachment of a lower extremity procedure. Last, we recognize that our model, as would any model or program, will evolve and may require some adjustments over time. To the extent that this occurs with the CJR model, we would make adjustments that were deemed necessary, as we would do with any of these other models and programs; however, we do not believe the potential for model adjustments is a reason to delay the requirement for hospitals to bear risk in the absence of data suggesting that a problem actually exists.

Final Decision: After considering the public comments we received, we are finalizing our proposal to phase-in risk beginning in Year 2 of the model.

3. Adjustments to Payments Included in Episode

We proposed to calculate the actual episode payment amount by summing together Medicare payments for each non-cancelled CJR episode during the model's performance year for Parts A and B claims for services included in the episode definition, as discussed in section III.B. of this final rule. We proposed three adjustments to this general approach for—(1) Special payment provisions under existing Medicare payment systems; (2) payment for services that straddle the end of the episode; and (3) high payment episodes. We noted there would be further adjustments to account for overlaps with other Innovation Center models and CMS programs; we refer readers to section III.C.7. of the proposed rule.

We did not propose to adjust hospital-specific or regional components of target prices for any Medicare repayment or reconciliation payments made under the CJR model; CJR repayment and reconciliation payments would be not be included per the episode definition in section III.B. of this final rule. We stated in the proposed rule our belief that including reconciliation payments and Medicare repayments in target price calculations would perpetuate the initial set of target prices once CJR performance years are captured in the 3-historical-years of data used to set target

prices, as described in section III.C.4. of this final rule, beginning with performance year 3 when performance year 1 would be part of the 3-historical-years. Including any prior performance years' reconciliations or repayments in target price calculations would approximately have the effect of Medicare paying hospitals the target price, regardless of whether the hospital went below, above, or met the target price in the prior performance years before accounting for the reconciliation payments or repayments. We stated in the proposed rule our intent for target prices to be based on historical patterns of service actually provided, so we did not propose to include reconciliation payments or repayments for prior performance years in target price calculations.

a. Treatment of Special Payment Provisions Under Existing Medicare Payment Systems

Many of the existing Medicare payment systems have special payment provisions that have been created by regulation or statute to improve quality and efficiency in service delivery. IPPS hospitals are subject to incentives under the HRRP, the Hospital Value-Based Purchasing (HVBP) Program, the Hospital-Acquired Condition (HAC) Reduction Program, and the Hospital Inpatient Quality Reporting Program (HIQR) and Outpatient Quality Reporting Program (OQR). IPPS hospitals and CAHs are subject to the Medicare EHR Incentive Program. Additionally, the majority of IPPS hospitals receive additional payments for Medicare Disproportionate Share Hospital (DSH) and Uncompensated Care, and IPPS teaching hospitals can receive additional payments for Indirect Medical Education (IME). IPPS hospitals that meet a certain requirements related to low volume Medicare discharges and distance from another hospital receive a low volume add-on payment. As previously stated in section III.B.2.b. of this final rule, acute care hospitals may receive new technology add-on payments to support specific new technologies or services that substantially improve the diagnosis or treatment of Medicare beneficiaries and would be inadequately paid otherwise under the MS–DRG system. Also, some IPPS hospitals qualify to be sole community hospitals (SCHs) or MDHs, and they may receive enhanced payments based on cost-based hospital-specific rates for services; whether a SCH or MDH receives enhanced payments may vary year to year, in accordance with § 419.43(g) and § 412.108(g), respectively.

Medicare payments to providers of PAC services, including IRFs, SNFs, IPFs, HHAs, LTCHs, and hospice facilities, are conditioned, in part, on whether the provider satisfactorily reports certain specified data to CMS: The Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP), the Skilled Nursing Facility Quality Reporting Program (SNF QRP), the Inpatient Psychiatric Facility Quality Reporting Program (IPF QRP), the Home Health Quality Reporting Program (HH QRP), the Long-Term Care Hospital Quality Reporting Program (LTCH QRP), and the Hospice Quality Reporting Program. Additionally, IRFs located in rural areas receive rural add-on payments, IRFs serving higher proportions of low-income beneficiaries receive increased payments according to their low-income percentage (LIP), and IRFs with teaching programs receive increased payments to reflect their teaching status. SNFs receive higher payments for treating beneficiaries with human immunodeficiency virus (HIV). HHAs located in rural areas also receive rural add-on payments.

ASCs have their own Quality Reporting Program (ASC QRP). Physicians also have a set of special payment provisions based on quality and reporting: The Medicare EHR Incentive Program for Eligible Professionals, the Physician Quality Reporting System (PQRS), and the Physician Value-based Modifier Program.

In the proposed rule we stated our intent with the CJR model is not to replace the various existing incentive programs or add-on payments, but instead to test further episode payment incentives towards improvements in quality and efficiency beyond Medicare's existing policies. Therefore, we proposed that the hospital performance and potential reconciliation payment or Medicare repayment be independent of, and not affect, these other special payment provisions.

We proposed to exclude the special payment provisions as discussed previously when calculating actual episode payments, setting episode target prices, comparing actual episode payments with target prices, and determining whether a reconciliation payment should be made to the hospital or funds should be repaid by the hospital.

Not excluding these special payment provisions would create incentives that are not aligned with the intent of the CJR model. Not excluding the quality and reporting-related special payment provisions could create situations where a high-quality or reporting compliant hospital or both receiving incentive payments, or those hospitals that discharge patients to PAC providers that receive incentives for being reporting compliant, may appear to be ''high episode payment'' under CJR. Conversely, lower quality or hospitals not complying with reporting programs or both that incur payment reduction penalties, or hospitals that discharge to PAC providers that are not reporting compliant, may appear to be ''low episode payment'' under CJR. Such outcomes would run counter to CJR's goal of improving quality. Also, not excluding add-on payments for serving more indigent patients, having low Medicare hospital volume, being located in a rural area, supporting greater levels of provider training, choosing to use new technologies, and having a greater proportion of CJR beneficiaries with HIV from CJR actual episode payment calculations may inappropriately result in hospitals having worse episode payment performance. Additionally, not excluding enhanced payments for MDHs and SCHs may result in higher or lower target prices just because these hospitals received their enhanced payments in one historical year but not the other, regardless of actual utilization. In the proposed rule we stated our belief that excluding special payment provisions would ensure a participant hospital's actual episode payment performance is not artificially improved or worsened because of payment reduction penalties or incentives or enhanced or add-on payments, the effects of which we are not intending to test with CJR.

In addition to the various incentive, enhanced and add on payments, sequestration came into effect for Medicare payments for discharges on or after April 1, 2013, per the Budget Control Act of 2011 and delayed by the American Taxpayer Relief Act of 2012. Sequestration applies a 2 percent reduction to Medicare payment for most Medicare FFS services.

In order to operationalize the exclusion of the various special payment provisions in calculating episode expenditures, we proposed to apply the CMS Price (Payment) Standardization Detailed Methodology described on the QualityNet Web site at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350*. This pricing standardization approach is the same as used for the HVBP program's Medicare spending per beneficiary metric.

We sought comment on this proposed approach to treating special payment

provisions in the various Medicare payment systems.

Comment: Several commenters supported the exclusion of the various special payment provisions in calculating episode expenditures. They agreed that doing so would help isolate the effect of utilization and quality of delivered care differences and remove any distortions due to Medicare payment policies outside the control of providers.

A few commenters expressed concern about how hospitals would be paid the special payment adjustments that are removed in calculating episode expenditures. A commenter inquired whether CMS would account for vendor rebates for hip and knee implants and medical devices, because rebates are not uncommon and can impact the cost of an LEJR procedure to a hospital.

Response: We appreciate commenters' support to exclude the various special payment provisions in calculating episode expenditures.

As discussed in section III.C.2.b. of this final rule, we are finalizing our proposal such that all providers and suppliers caring for Medicare beneficiaries in CJR episodes will continue to bill and be paid as usual under the applicable Medicare payment system, and determination of any reconciliation payments or repayments to Medicare will be made retrospectively after the end of each performance year. Therefore, special payment adjustments will continue to be paid as usual under the applicable Medicare payment systems, but their effects will be excluded when reconciliation payment and repayment to Medicare determinations are made retrospectively. This final rule will not affect how hospitals are currently paid special payment adjustments.

Payments for hip and knee implants and medical devices will also continue as usual under the applicable Medicare payment systems. For inpatient admissions paid under IPPS, in particular, implants and medical devices not categorized as new technology add-on payment would be included in the MS–DRG payment and would not be reimbursed separately. To mirror the IPPS approach, we will not separately account for vendor rebates in the LEJR episode.

We note that as previously stated, we plan to utilize the CMS Price (Payment) Standardization approach in order to remove the effects of special payment provisions from calculations of historical and performance period episode spending. We will follow the methodology, with modifications as necessary to be consistent with our episode definition in section III.B. of this final rule and to ensure timely reporting of reconciliation results, for the performance year reconciliations, which begin 2 months after the conclusion of a performance year. We will account for the information available at the time due to claims runout, payment system updates, and the calculations necessary to fully implement the standardization methodology. We will utilize the methodology, consistent with our episode definition, for the target price calculations and subsequent reconciliation calculations 14 months after the conclusion of the performance year, in which we incorporate full claims runout and further account for overlap with other models. This approach will provide feedback and reconciliation payments, as available, to hospitals in a timely manner and as accurately as feasible, while ensuring the standardization approach is utilized for the subsequent calculation, which represents the final calculation for a given performance period.

Comment: Many commenters requested that CJR reconciliation payments made to participant hospitals be included when updating the set of 3-historical-years used for calculating CJR episode target prices. They stated that the participant hospitals would be providing care coordination services that may not be directly reimbursed under applicable Medicare FFS payment systems. These services would then, instead, be funded by reconciliation payments. While historical Medicare FFS claim payments would account for hospitals' costs for providing services reimbursed under Medicare FFS, they would not account for hospitals' costs for care coordination services not reimbursed under Medicare FFS. Commenters contended that if we do not include reconciliation payments when calculating target prices using the updated set of historical years, we may underestimate hospital costs and target prices.

Response: We agree that participant hospitals may undertake activities that promote care coordination and improved quality of care but are not directly reimbursed under applicable Medicare FFS payment systems. We appreciate commenters' suggestions to include reconciliation payments when updating the set of historical years used to calculate target prices. We also believe this logic could be extended to include repayments to Medicare to mirror the inclusion of reconciliation payments. However, in the proposed rule we did not propose an alternative to include reconciliation payments and repayments when updating the set of historical years used to calculate target prices, and because the first time this policy would take effect would be for performance year 3 (2018), we may revisit this policy in future rulemaking and allow for public comment on the aforementioned alternative. At this time we are not modifying our proposal to exclude CJR reconciliation payments and repayments to Medicare when updating the set of historical years used to set target prices.

Comment: A few commenters inquired whether claims from non-participating physicians or payments to physicians who have opted out of Medicare would be included for purposes of setting target prices and calculating actual episode spending for reconciliation and repayment amount calculations. Commenters contended that if claims from non-participating providers or payments to physicians who have opted out of Medicare are not included, target prices and actual episode spending may be underestimated.

Response: With the exception of those physicians and practitioners who have complied with our opt-out procedures (see 42 CFR 405.400 through 405.455), when a physician or supplier furnishes a service that is covered by Medicare, the physician or supplier is subject to the mandatory claim submission provisions of section 1848(g)(4) of the Social Security Act (the Act). Therefore, if a physician or supplier charges or attempts to charge a beneficiary for a service that is covered by Medicare, then the physician or supplier must submit a claim to Medicare. As a result, claims from both participating and non-participating physicians would be included in our target price and actual episode spending calculations.

Opt-out physicians are prohibited from billing and receiving payment (either directly or indirectly) from Medicare except for emergency and urgent care services provided the physician has not previously entered into a private contract with the beneficiary. Therefore, we agree that payments for services furnished by physicians who have opted out of Medicare would not be included in target price and actual episode expenditure calculations. However, we estimate only a small portion of physicians furnishing services to beneficiaries captured in the CJR model will have opted out of Medicare, and we estimate that physician services comprise less than 15 percent of the average CJR episode expenditure, and therefore we believe the impact of not capturing expenditures from physicians

who have opted out of Medicare will be small.

Additionally, there may be some participant hospitals with a disproportionately higher share of episodes for which services were furnished by physicians who have opted out of Medicare. Such participant hospitals would experience lower actual episode expenditures because payments for physicians who have opted out of Medicare would not be included. These hospitals' lower actual episode expenditures would be balanced by lower target prices because the payments for physicians who have opted out of Medicare would also be excluded in the historical episode expenditures, though this argument is primarily relevant in the early years of the CJR model before we move to 100 percent regional pricing as discussed in section III.C.4.b.(5) of this final rule. In the later years of this model, participant hospitals with disproportionately greater share of episodes for which services were furnished by Medicare opt-out physicians may unfairly benefit from regional target prices that are primarily based on the inclusion of expenditures for physician services. However, we believe this advantage to be small because physician expenditures comprise only a small portion of the average episode, and we expect very few physicians to opt out of Medicare.

Comment: A commenter inquired whether CMS would include IPPS capital payments in calculating target prices and actual episode expenditures, and if CMS' plan was to include them, they requested that such payments be excluded. The commenter stated that capital payments may vary by hospitals, and excluding capital payments would be consistent with the pricing standardization approach we proposed to reduce variations due to Medicare payment policies. The commenter also noted that excluding capital payments would be consistent with the approach taken in BPCI.

Response: In response to comments, we clarify that we will include IPPS capital payments in target price and actual episode expenditure calculations. IPPS capital payments are included in Medicare FFS payments, which we proposed to use to calculate target prices and actual episode expenditures. Consistent with our proposed treatment of special payment provisions, we do not intend to distort incentives based on IPPS capital payments that may vary across hospitals due to Medicare payment policies, as opposed to practice pattern and quality differences. By using the claims standardization approach previously described in this section, though, we will be able to remove the effect of variations due to Medicare payment policies (including wage index differences). We recognize that this approach of including IPPS capital payments would be different than the approach taken in BPCI. However, we note that other Medicare FFS payment systems, such as those for SNF and IRF, also are intended to cover providers' capital costs. Carving out the capital portion for IPPS payments would not be consistent with the inclusion of the capital portion for other Medicare FFS payment systems. Lastly, including IPPS capital payments affords participant hospitals an opportunity to achieve greater reconciliation payments if they are able to achieve efficiencies for the costs that the capital portion of IPPS payments would cover, which may or may not actually be capital costs.

Comment: Several commenters expressed concern about the regions that were selected for both the CJR model and the proposed HHVBP model.

Response: We refer readers to comments and responses to comments in section III.A.3 of this final rule for further discussion on the inclusion of regions selected for both the CJR model and the proposed HHVBP model, and we reference it here because the proposed HHVBP model would be another special payment provision that could affect Medicare payment amounts. We reemphasize that the intent of the CJR model is not to replace the various existing incentive programs or add on payments, and the claims standardization approach previously described in this section will remove the effect of any special payment provision, whether they currently exist or may be introduced in the future. Therefore, we do not believe any special payment provisions due to the proposed HHVBP model or other potential future special payment provisions to have an impact on the payments included in the CJR model target price and reconciliation calculations.

Comment: A commenter requested clarification on how the CJR model would interact with Medicare beneficiaries who have exhausted their benefits, and recommended that we modify Medicare beneficiaries' benefits so as to not allow their benefits to be exhausted while part of a CJR episode.

Response: We appreciate the commenter's suggestion. However, we did not propose any changes to Medicare beneficiaries' benefits, and we will not finalize any such changes in this final rule.

Final Decision: We are finalizing our proposal, without modification, to exclude special payment provisions from episode calculations. We clarify that we will include IPPS capital payments in target price and actual episode expenditure calculations. We also clarify that we will utilize the CMS Price Standardization approach previously referenced to remove the effect of any current and potential future special payment provisions. We may revisit in future rulemaking any modification to our policy to exclude reconciliation and recoupment payments when updating the historical data used to set target prices.

b. Treatment of Payment for Services That Extend Beyond the Episode

As we proposed a fixed 90-day post-discharge episode as discussed in section III.B. of the proposed rule, we stated our belief that there would be some instances where a service included in the episode begins during the episode but concludes after the end of the episode and for which Medicare makes a single payment under an existing payment system. An example would be a beneficiary in a CJR episode who is admitted to a SNF for 15 days, beginning on Day 86 post-discharge from the anchor CJR hospitalization. The first 5 days of the admission would fall within the episode, while the subsequent 10 days would fall outside of the episode.

We proposed that, to the extent that a Medicare payment for included episode services spans a period of care that extends beyond the episode, these payments would be prorated so that only the portion attributable to care during the episode is attributed to the episode payment when calculating actual Medicare payment for the episode. For non-IPPS inpatient hospital (for example, CAH) and inpatient PAC (for example, SNF, IRF, LTCH, IPF) services, we proposed to prorate payments based on the percentage of actual length of stay (in days) that falls within the episode window. Prorated payments would also be similarly allocated to the 30-day post-episode payment calculation in section III.C.8.d. of this final rule. In the prior example, one-third of the days in the 15-day length of stay would fall within the episode window, so under the proposed approach, one-third of the SNF payment would be included in the episode payment calculation, and the remaining two-thirds (because the entirety of the remaining payments fall within the 30 days after the episode ended) would be included in the post-episode payment calculation.

For HHA services that extend beyond the episode, we proposed that the

payment proration be based on the percentage of days, starting with the first billable service date (''start of care date'') and through and including the last billable service date, that fall within the CJR episode. Prorated payments would also be similarly allocated to the 30-day post-episode payment calculation in section III.C.8.d. of the proposed rule. For example, if the patient started receiving services from an HHA on day 86 after discharge from the anchor CJR hospitalization and the last billable home health service date was 55 days from the start of home health care date, the HHA claim payment amount would be divided by 55 and then multiplied by the days (5) that fell within the CJR episode. The resulting, prorated HHA claim payment amount would be considered part of the CJR episode. Services for the prorated HHA service would also span the entirety of the 30 days after the CJR episode spends, so the result of the following calculation would be included in the 30-day post-episode payment calculation: HHA claim payment amount divided by 55 and then multiplied by 30 days (the number of days in the 30-day post-episode period that fall within the prorated HHA service dates).

There may also be instances where home health services begin prior to the CJR episode start date, but end during the CJR episode. In such instances, we also proposed to prorate HHA payments based on the percentage of days that fell within the episode. Because these services end during the CJR episode, prorated payments for these services would not be included in the 30-day post-episode payment calculation discussed in section III.C.8.d. of the proposed rule. For example, if the patient's start of care date for a home health 60-day claim was February 1, the anchor hospitalization was March 1 through March 4 (with the CJR episode continuing for 90 days after March 4), and the patient resumed home care on March 5 with the 60-day home health claim ending on April 1 (that is, April 1 was the last billable service date), we would divide the 60-day home health claim payment amount by 60 and then multiply that amount by the days from the CJR admission through April 1 (32 days) to prorate the HHA payment. This proposed prorating method for HHA claims is consistent with how partial episode payments (PEP) are paid for on home health claims.

For IPPS services that extend beyond the episode (for example, readmissions included in the episode definition), we proposed to separately prorate the IPPS claim amount from episode target price and actual episode payment calculations as proposed in section III.C.8. of the proposed rule, called the normal MS–DRG payment amount for purposes of this final rule. The normal MS–DRG payment amount would be pro-rated based on the geometric mean length of stay, comparable to the calculation under the IPPS PAC transfer policy at § 412.4(f) and as published on an annual basis in Table 5 of the IPPS/LTCH PPS Final Rules. Consistent with the IPPS PAC transfer policy, the first day for a subset of MS–DRGs (indicated in Table 5 of the IPPS/LTCH PPS Final Rules) would be doubly weighted to count as 2 days to account for likely higher hospital costs incurred at the beginning of an admission. If the actual length of stay that occurred during the episode is equal to or greater than the MS–DRG geometric mean, the normal MS–DRG payment would be fully allocated to the episode. If the actual length of stay that occurred during the episode is less than the geometric mean, the normal MS–DRG payment amount would be allocated to the episode based on the number of inpatient days that fall within the episode. If the full amount is not allocated to the episode, any remainder amount would be allocated to the 30 day post-episode payment calculation discussed in section III.C.8.d. of the proposed rule. The proposed approach for prorating the normal MS–DRG payment amount is consistent with the IPPS transfer per diem methodology.

The following is an example of prorating for IPPS services that extend beyond the episode. If beneficiary has a readmission for MS–DRG 493—lower extremity and humerus procedures except hip, foot, and femur, with complications—into an IPPS hospital on the 89th day after discharge from a CJR anchor hospitalization, and is subsequently discharged after a length of stay of 5 days, Medicare payment for this readmission would be prorated for inclusion in the episode. Based on Table 5 of the IPPS/LTCH PPS Final Rule for FY 2015, the geometric mean for MS–DRG 493 is 4 days, and this MS–DRG is indicated for double-weighting the first day for proration. This readmission has only 2 days that falls within the episode, which is less than the MS–DRG 493 geometric mean of 4 days. Therefore, the normal MS–DRG payment amount associated with this readmission would be divided by 4 (the geometric mean) and multiplied by 3 (the first day is counted as 2 days, and the second day contributes the third day), and the resulting amount is attributed to the episode. The remainder one-fourth would be captured in the post-episode spending calculation discussed in section III.C.8. of the proposed rule. If the readmission occurred on the 85th day after discharge from the CJR anchor hospitalization, and the length of stay was 7 days, the normal MS–DRG payment amount for the admission would be included in the episode without proration because length of stay for the readmission falling within the episode (6 days) is greater than or equal to the geometric mean (4 days) for the MS–DRG.

We considered an alternative option of including the full Medicare payment for all services that start during the episode, even if those services did not conclude until after the episode ended, in calculating episode target prices and actual payments. Previous research on bundled payments for episodes of PAC services noted that including the full payment for any claim initiated during the fixed episode period of time will capture continued service use. However, prorating only captures a portion of actual service use (and payments) within the bundle.[20] As discussed in section III.B. of this final rule, the CJR model proposed an episode length that extends 90 days post-discharge, and Table 5 in section III.B.3.c. of the proposed rule demonstrates that the average length of stay in PAC during a 90-day episode with a MS–DRG 470 anchor hospitalization is 47.3 days. Therefore, the length of the episode under CJR (90 days) should be sufficient to capture the vast majority of service use within the episode, even if payments for some services that extend beyond the episode duration are prorated and only partly attributed to the episode.

The following is a summary of comments received and our responses.

Comment: Several commenters supported the pro-rating of payments for services that extend beyond the episode. They agreed that pro-rating would help ensure target prices and actual episode payments reflect services that were furnished during the episode. A commenter requested clarification on how payments for IRFs would be pro-rated. Another commenter stated that the first day for pro-rated surgical MS–DRGs paid under IPPS should be weighted by more than the two-times weight proposed; the commenter believed that a multiplier of up to 4.5 would more accurately describe hospitals' costs for the first day of surgical inpatient admissions reimbursed under Medicare IPPS.

[20] *http://aspe.hhs.gov/health/reports/09/pacepifinal/report.pdf.*

Response: We appreciate commenters' support for pro-rating payments for services that extend beyond the episode. As described in section III.C.3.b of this final, IRF payments will be pro-rated based on the percentage of actual length of stay (in days) that falls within the episode window. Prorated IRF payments would also be similarly allocated to the 30 day post episode payment calculation in section III.C.8.d. of this final rule.

We agree that costs for inpatient stays may not be equal for each day of an inpatient admission, and the distribution of costs may differ between surgical and non-surgical inpatient stays. We acknowledge there may be different methodologies to calculate how much more costs are incurred on the first day of a stay. However, we will maintain consistency with the IPPS per diem transfer policy that uses a two-times weight for the first day for a subset of MS–DRGs as described in § 412.4(f) and published on an annual basis in Table 5 of the IPPS/LTCH PPS Final Rules. We also note that many surgical readmissions are excluded from the episode definition described in section III.B. of this final rule, which should mitigate the impact of this prorating approach on surgical readmissions that extend beyond the episode.

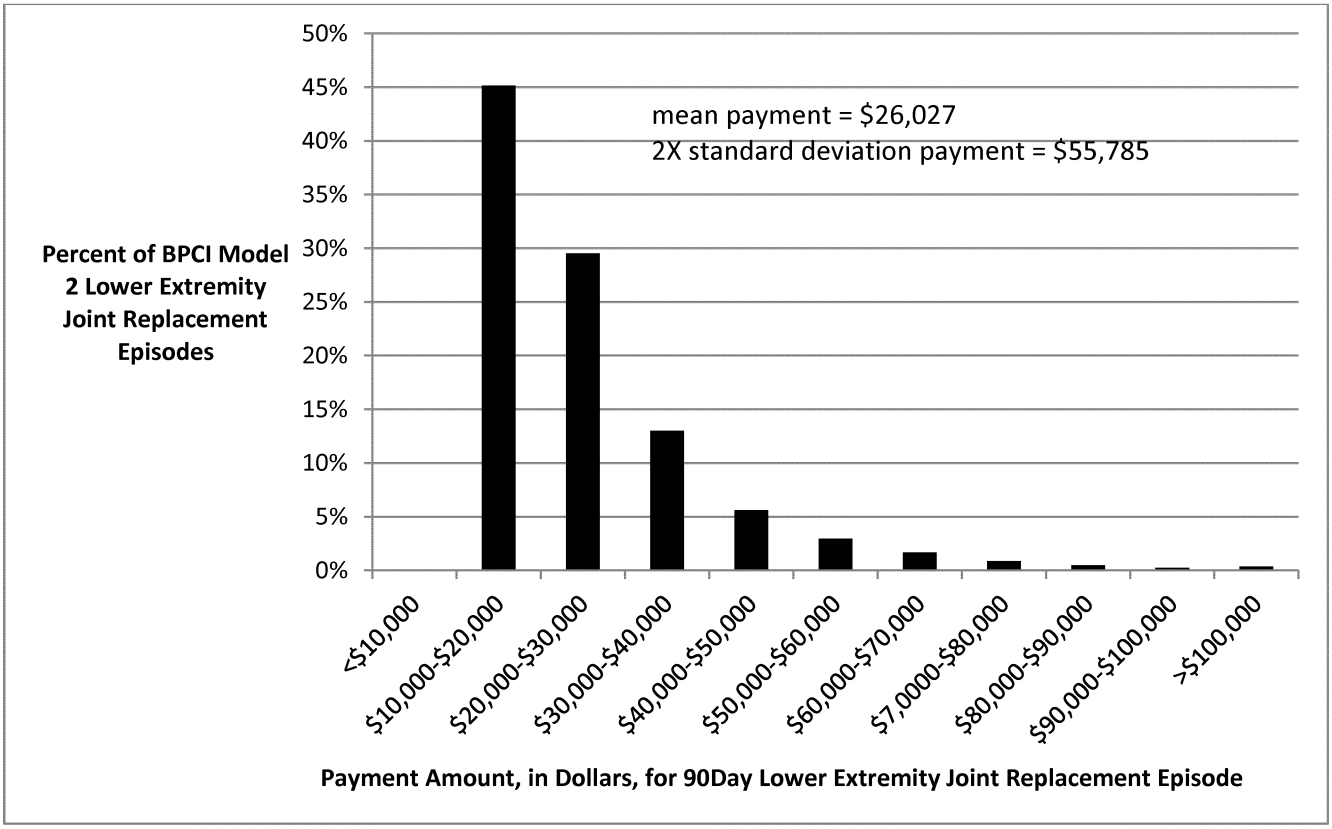
Final Decision: After consideration of the public comments we received, we are finalizing the proposal to prorate payments for services that extend beyond the episode when calculating actual episode payments, setting episode target prices, and calculating reconciliation and repayment amounts.

c. Pricing Adjustment for High Payment Episodes

Given the broad proposed LEJR episode definition and 90-day post-discharge episode duration proposed for CJR, we want to ensure that hospitals have some protection from the variable repayment risk for especially high payment episodes, where the clinical scenarios for these cases each year may differ significantly and unpredictably. We did not believe the opportunity for a hospital's systematic care redesign of LEJR episodes has significant potential to impact the clinical course of these extremely disparate high payment cases.

The BPCI Model 2 uses a generally similar episode definition as proposed for CJR and the vast majority of BPCI episodes being tested for LEJR are 90 days in duration following discharge from the anchor hospitalization. Similarly in the proposed rule, we stated our belief that the distribution of 90-day LEJR episode payment amounts utilizing the BPCI Model 2 episode definition as displayed in Figure 2 provides information that is relevant to policy development regarding CJR episodes.

FIGURE 2: ESTIMATED NATIONAL DISTRIBUTION OF LEJR 90 day EPISODE PAYMENT AMOUNTS[1 2]



Source: Medicare FFS Part A and B claims from October 1, 2013 to September 30, 2014.

1. Assumes no changes in volume or utilization pattern.

2. Payment reflects wage index removal.

As displayed, the mean episode payment amount is approximately $26,000. Five percent of all episodes are paid at two standard deviations above the mean payment or greater, an amount that is slightly more than 2 times the mean episode payment amount. While these high payment cases are relatively uncommon, we stated in the proposed rule our belief that incorporation of the full Medicare payment amount for such high payment episodes in setting the target price and correspondingly in Medicare's aggregate actual episode payment that is compared to the target price for the episode may lead in some cases to excessive hospital responsibility for these episode expenditures. This may be especially true when hospital responsibility for repayment of excess episode spending is introduced in performance year 2. The hospital may have limited ability to moderate spending for these high payment cases. Our proposal to exclude IPPS new technology add-on payments and separate payment for clotting factors for the anchor hospitalization from the episode definition limits excessive financial responsibility under this model of extremely high inpatient payment cases that could result from costly hospital care furnished during the anchor hospitalization. However, in the proposed rule we stated our belief that an additional pricing adjustment in setting episode target prices and calculating actual episode payments is necessary to mitigate the hospital responsibility for the actual episode payments for high episode payment cases resulting from very high Medicare spending within the episode during the period after discharge from the anchor hospitalization, including for PAC, related hospital readmissions, and other items and services related to the LEJR episode.

Thus, in order to limit the hospital's responsibility for the previously stated high episode payment cases, we proposed to utilize a pricing adjustment for high payment episodes that would incorporate a high payment ceiling at two standard deviations above the mean episode payment amount in calculating the target price and in comparing actual episode payments during the performance year to the target prices.

Specifically, when setting target prices, we would first identify for each anchor MS–DRG in each region (discussed further in section III.C.4. of this final rule) the episode payment amount that is two standard deviations above the mean payment in the historical dataset used (discussed further in section III.C.4. of the proposed rule). Any such identified episode would have its payment capped at the MS–DRG anchor and region-specific value that is two standard deviations above the mean, which would be the ceiling for purposes for calculating target prices. We note that the calculation of the historical episode high payment ceiling for each region and MS–DRG anchor would be performed after other steps, including removal of effects of special payment provisions and others described in section III.C.4.c. of this final rule.

When comparing actual episode payments during the performance year to the target prices, episode payments for episodes in the performance year would also be capped at two standard deviations above the mean. The high episode payment ceiling for episodes in a given performance year would be calculated based on MS–DRG anchor-specific episodes in each region. We discuss further how the high episode payment ceiling would be applied when comparing episode payments during the performance year to target prices in section III.C.6. of this final rule.

While this approach generally lowers the target price slightly, it provides a basis for reducing the hospital's responsibility for actual episode spending for high episode payment cases during the model performance years. When performing the reconciliation for a given performance year of the model, we would array the actual episode payment amounts for all episodes being tested within a single region, and identify the regional actual episode payment ceiling at two standard deviations above the regional mean actual episode payment amount. If the actual payment for a hospital's episode exceeds this regional ceiling, we would set the actual episode payment amount to equal the regional ceiling amount, rather than the actual amount paid by Medicare, when comparing a hospital's episode spending to the target price. Thus, a hospital would not be responsible for any actual episode payment that is greater than the regional ceiling amount for that performance year. We proposed to adopt this policy for all years of the model, regardless of the reconciliation payment opportunity or repayment responsibility in a given performance year, to achieve stability and consistency in the pricing methodology. We stated in the proposed rule our belief that this proposal provides reasonable protection for hospitals from undue financial responsibility for Medicare episode spending related to the variable and unpredictable course of care of some Medicare beneficiaries in CJR episodes, while still fully incentivizing increased efficiencies for approximately the 95 percent of episodes for which we estimate actual episode payments to fall below this ceiling.[21] We sought comment on our proposal to apply a pricing adjustment in setting target prices and reconciling actual episode payments for high payment episodes.

The following is a summary of the comments received and our responses.

Comment: Many commenters supported the proposal for a high episode payment ceiling at two standard deviations above the mean episode payment amount in calculating the target price and in comparing actual episode payments during the performance year to the target prices. They agreed that such a ceiling would help limit financial exposure to participant hospitals from outlier episodes. Some commenters requested the option of choosing specific risk tracks as provided under BPCI (for example, high episode payment ceiling at 75th, 95th, or 99th percentile).

Response: We appreciate commenters' support for a high episode payment ceiling. We acknowledge that BPCI offers different risk tracks with different outlier protection features from which participants can choose, and that we did not propose to provide CJR participant hospitals with choice of risk tracks or outlier protection policy. However, with the blending of regional and hospital-specific historical episode expenditure data that we are finalizing in section III.C.4.b.(5) of this final rule to calculate target prices, applying different risk tracks or outlier protection policies to different hospitals would distort target price calculations; this is not an issue in BPCI because target prices are calculated using only hospital-specific historical episode expenditure data. Additionally, we continue to believe that setting a high episode payment ceiling at two standard deviations above the mean episode payment amount, along with the phasing in of responsibility for hospital repayment in performance year 1 as discussed in section III.C.2 of this final rule, will be sufficient to limit financial exposure due to outlier episodes. We will finalize our proposal to use a common outlier policy for all participant hospitals.

Comment: Many commenters requested that CMS risk adjust episode spending based on patients' hip fracture status, among other clinical and demographic dimensions.

Response: We refer readers to comments and responses to comments

[21] Medicare FFS Parts A and B claims, CJR episodes as proposed, between October 1, 2013 and September 30, 2014.

in section III.C.4.b.(1) of this final rule for further discussion on risk stratification for hip fracture status, and we reference it here because changes to risk stratification would impact how a high payment episode ceiling would function. As discussed in the responses to comments in section III.C.4.b.(1) of this final rule, we will modify our policy in this final rule so as to set different target prices both for episodes anchored by MS–DRG 469 vs. MS–DRG 470 and for episodes with hip fractures vs. without hip fractures. Given this change, we will also modify the proposed approach to apply the high payment episode ceiling. Specifically, instead of calculating and applying high payment episode ceilings for each region and anchor MS–DRG combination, we will now calculate and apply high payment episode ceilings for each region, anchor MS–DRG, and hip fracture status combination.

Final Decision: After consideration of the public comments we received, we are finalizing the proposal to apply high episode payment ceilings when calculating actual episode payments, setting episode target prices, and calculating reconciliation and repayment amounts. However, we do note that the approach to calculate and apply the high episode payment ceilings will be adapted to account for the risk stratification based on hip fracture status discussed in section III.C.4.b. of this final rule.

4. Episode Price Setting Methodology

a. Overview

Whether a participant hospital receives reconciliation payments or is made responsible to repay Medicare for the CJR model will depend on the hospital's quality and actual payment performance relative to episode quality and target prices. Quality performance and its tie to payments is further discussed in section III.C.5. of this final rule, and the remainder of this section will discuss the proposed approach to establishing target prices.

We proposed to establish CJR target prices for each participant hospital. For episodes beginning in performance years 1, 3, 4, and 5, a participant hospital would have eight target prices, one for each of the following:

- MS–DRG 469 anchored episodes that were initiated between January 1 and September 30 of the performance year, if the participant hospital successfully submits data on the voluntary patient-reported outcome measure proposed in section III.C.5. of the proposed rule.
- MS–DRG 470 anchored episodes that were initiated between January 1 and September 30 of the performance year, if the participant hospital successfully submits data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 469 anchored episodes that were initiated between October 1 and December 31 of the performance year, if the participant hospital successfully submits data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 470 anchored episodes that were initiated between October 1 and December 31 of the performance year, if the participant hospital successfully submits data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 469 anchored episodes that were initiated between January 1 and September 30 of the performance year, if the participant hospital does not successfully submit data on the voluntary patient-reported outcome measure.
- MS–DRG 470 anchored episodes that were initiated between January 1 and September 30 of the performance year, if the participant hospital does not successfully submit data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 469 anchored episodes that were initiated between October 1 and December 31 of the performance year, if the participant hospital does not successfully submit data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 470 anchored episodes that were initiated between October 1 and December 31 of the performance year, if the participant hospital does not successfully submit data on the proposed voluntary patient-reported outcome measure.

For episodes beginning in performance year 2, a participant hospital would have 16 target prices. These would include the same combinations as for the other 4 performance years, but one set for determining potential reconciliation payments, and the other for determining potential Medicare repayment amounts, as part of the phasing in of two-sided risk discussed later in this section. Further discussion on our proposals for different target prices for MS–DRG 469 versus MS–DRG 470 anchored episodes, for episodes initiated between January 1 and September 30 versus October 1 and December 31, and for participant hospitals that do and do not successfully submit data on the proposed patient-reported outcome measure can be found in sections III.C.4.b. and III.C.5. of the proposed rule.

We intend to calculate and communicate episode target prices to participant hospitals prior to the performance period in which they apply (that is, prior to January 1, 2017, for target prices covering episodes initiated between January 1 and September 30, 2017; prior to October 1, 2017 for target prices covering episodes initiated between October 1 and December 31, 2017). We stated in the proposed rule our belief that prospectively communicating prices to hospitals will help them make any infrastructure, care coordination and delivery, and financial refinements they may deem appropriate to prepare for the new episode target prices.

The proposed approach to setting target prices incorporated the following features:

- Set different target prices for episodes anchored by MS–DRG 469 versus MS–DRG 470 to account for patient and clinical variations that impact hospitals' cost of providing care.
- Use 3 years of historical Medicare payment data grouped into episodes of care according to the episode definition in section III.B. of the proposed rule, hereinafter termed historical CJR episodes. The specific set of 3-historical-years used would be updated every other performance year.
- Apply Medicare payment system (for example, IPPS, OPPS, IRF PPS, SNF, MPFS, etc.) updates to the historical episode data to ensure we incentivize hospitals based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond hospitals' control. Because different Medicare payment system updates become effective at two different times of the year, we would calculate separate target prices for episodes initiated between January 1 and September 30 versus October 1 and December 31.
- Blend together hospital-specific and regional historical CJR episode payments, transitioning from primarily provider-specific to completely regional pricing over the course of the 5 performance years, to incentivize both historically efficient and less efficient hospitals to furnish high quality, efficient care in all years of the model. Regions would be defined as each of the nine U.S. Census divisions.
- Normalize for provider-specific wage adjustment variations in Medicare payment systems when combining provider-specific and regional historical CJR episodes. Wage adjustments would

be reapplied when determining hospital-specific target prices.

• Pool together CJR episodes anchored by MS DRGs 469 and 470 to use a greater historical CJR episode volume and set more stable prices.

• Apply a discount factor to serve as Medicare's portion of reduced expenditures from the CJR episode, with any remaining portion of reduced Medicare spending below the target price potentially available as reconciliation payments to the participant hospital where the anchor hospitalization occurred.

Further discussion on each of the individual features can be found in section III.C.4.b. of this final rule. In section III.C.4.c. of this final rule, we also provide further details on the proposed sequential steps to calculate target prices and how each of the pricing features would fit together.

The following is a summary of the comments received and our responses.

Comment: Commenters responded on several of the proposed pricing features, including how quality performance would affect payment, and we refer readers to comments and responses to comments in sections III.C.4.b and III.C.5 for further discussion on changes to how quality would be tied to payment as described in the proposed rule. We reference these comments here because any changes to the proposed episode price setting methodology and link between quality performance and payment would impact the number of target prices for each participant hospital.

Response: As further discussed in section III.C.4.b.(1) of this final rule, we are modifying the proposed rule to risk stratify (and set different prices) based on not just different anchor MS–DRGs but also patients' hip fracture status. As discussed in section III.C.4.b.(9) of this final rule, we are modifying our policy in this final rule so as to use lower discount factors for purposes of determining the hospital's responsibility for excess episode spending not only in performance year 2, but also in performance year 3. Additionally, as discussed in section III.C.5 of this final rule, we are modifying the proposed rule so as to provide different levels of quality incentive payments that would modulate participant hospitals' effective target price discount factor based on their quality performance. Because of these changes, each participant hospital in performance years 1, 4, and 5 will have 8 potential target prices for each combination of anchor MS–DRG (469 vs. 470), hip fracture status (with hip fracture vs. no hip fracture), and episode initiation date (between April 1 and September 30 vs. between October 1 and December 31 for performance year 1, and between January 1 and September 30 vs. between October 1 and December 31 for performance years 2 through 5). Each participant hospital in performance years 2 and 3 will have 16 target prices for the same combinations in performance years 1, 4, and 5, but with one group of 8 potential target prices for purposes of calculating reconciliation payments and another group of 8 potential target prices for purposes of determining hospital's responsibility for excess episode spending.

b. Pricing Features

(1) Different Target Prices for Episodes Anchored by MS–DRG 469 Versus MS–DRG 470

For each participant hospital we proposed to establish different target prices for CJR episodes initiated by MS–DRG 469 versus MS–DRG 470. MS–DRGs under the IPPS account for some of the clinical and resource variations that exist and that impact hospitals' cost of providing care. Specifically, MS–DRG 469 is defined to identify, and provide hospitals a higher Medicare payment to reflect the higher hospital costs for, hip and knee procedures with major complications or comorbidities. Therefore, we proposed to risk stratify and calculate separate target prices for each participant hospital for CJR episodes with MS–DRG 469 versus MS–DRG 470 anchor hospitalizations.

We considered risk adjusting the episode target prices by making adjustments or setting different prices based on patient-specific clinical indicators (for example, comorbidities). However, we did not believe there is a sufficiently reliable approach that exists suitable for CJR episodes beyond MS–DRG-specific pricing, and there is no current standard on the best approach. At the time of developing the proposed rule Tennessee, Ohio, and Arkansas are launching multi-payer (including Medicaid and commercial payers, excluding Medicare) bundles and include hip and knee replacement as an episode.[22] [23] [24] These states' hip and knee episode definitions and payment models are consistent with, though not the same as, the proposed CJR episode described in the proposed rule. However, each of these three states uses different risk adjustment factors. This variation across states supported our stated belief in the proposed rule that there is currently no standard risk adjustment approach widely accepted throughout the nation that could be used under CJR, a model that would apply to hospitals across multiple states. Therefore, we did not propose to make risk adjustments based on patient-specific clinical indicators.

We also considered making risk adjustments based on the participant hospital's average Hierarchical Condition Category (HCC) score for patients with anchor CJR hospitalizations. The CMS–HCC risk adjustment model quantifies a beneficiary's risk by examining the beneficiary's demographics and historical claims data and predicting the beneficiary's total expenditures for Medicare Parts A and B in an upcoming year. However, the CMS–HCC risk adjustment model's intended use is to pay Medicare Advantage (MA) plans appropriately for their expected relative costs. For example, MA plans that disproportionately enroll the healthy are paid less than they would have been if they had enrolled beneficiaries with the average risk profile, while MA plans that care for the sickest patients are paid proportionately more than if they had enrolled beneficiaries with the average risk profile. The CMS–HCC risk adjustment model is prospective. It uses demographic information (that is, age, sex, Medicare/Medicaid dual eligibility, disability status) and a profile of major medical conditions in the base year to predict Medicare expenditures in the next year.[25] As previously noted, the CMS–HCC risk adjustment model is used to predict total Medicare expenditures in an upcoming year, and may not be appropriate for use in predicting expenditures over a shorter period of time, such as the CJR episode, and may not be appropriate in instances where its use is focused on LEJRs. Therefore, since we have not evaluated the validity of HCC scores for predicting Medicare expenditures for shorter episodes of care or for specifically LEJR beneficiaries, we did not propose to risk

[22] Tennessee Health Care Innovation Initiative. *http://www.tn.gov/HCFA/strategic.shtml.* Accessed on April 16, 2015.

[23] Ohio Governor''s Office of Health Transformation. Transforming Payment for a Healthier Ohio, June 8, 2014. *http://www.healthtransformation.ohio.gov/LinkClick.aspx?fileticket=TDZUpL4a-SI%3d&tabid=138*, Accessed on April 16, 2014.

[24] Total Joint Replacement Algorithm Summary, Arkansas Health Care Payment Improvement Initiative, November 2012. *http://www.paymentinitiative.org/referenceMaterials/Documents/TJR%20codes.pdf.* Accessed on April 17, 2015.

[25] Pope, C. et al., Evaluation of the CMS–HCC Risk Adjustment Model Final Report. Report to the Centers for Medicare & Medicaid Services under Contract Number HHSM–500–2005–00029I. RTI International. Research Triangle Park, NC. March, 2011.

adjust the target prices using HCC scores for the CJR model.

We also considered risk stratifying or setting different prices for different procedures, such as different prices for hip versus knee replacements, but we did not believe there would be substantial variation in episode payments for these clinical scenarios to warrant different prices or adjustments. Moreover, Medicare IPPS payments, which account for approximately 50 percent [26] of CJR episode expenditures, do not differentiate between hip and knee procedures, mitigating procedure-specific variation for the anchor hospitalization. Furthermore, there are no widely accepted clinical guidelines to suggest that PAC intensity would vary significantly between knee and hip replacements. We sought comment on our proposal to price episodes based on the MS–DRG for the anchor hospitalization, without further risk adjustment.

The following is a summary of the comments received and our responses.

Comment: Many commenters stated that proper risk adjustment is necessary for the success of this model, and that anchor MS–DRG-specific pricing can help but is not sufficient on its own. Proper risk adjustment would account for differences in episode spend due to patient variations that are out of providers' control. They stated that MS–DRGs may capture variations within the inpatient setting, but do not reflect patient variations post-discharge. Inappropriate risk adjustment could lead to access issues for higher risk patients and increased volume of LEJR procedures for younger/healthier patients by participant hospitals looking to lower their average episode expenditures.

Most commenters who wrote on the issue suggested risk adjustment or complete exclusion for episodes with hip fractures, partial hip replacements, and emergent (versus non-emergent or elective) procedures. Some commenters provided analysis on hip fractures, in particular, and demonstrated episodes with hip fractures are significantly more expensive than those without hip fractures. Other clinical and demographic dimensions offered for risk adjustment or exclusion include the following: Procedure (total hip [THA] vs. total knee [TKA] vs. partial hip [PHA] vs. ankle vs. limb reattachment); socioeconomic status; patient functional status; age; and comorbidities. Requests from commenters for risk adjustment based on the previously stated dimensions were usually paired with requests to also exclude patients from the CJR model, and we encourage readers to read comments in section III.B.2.a. of this final rule for additional details on the clinical and demographic dimensions requested for risk adjustment or exclusion.

Some commenters who wrote on the issue of risk adjustment disputed CMS' statement in the proposed rule that there is no standard risk adjustment approach widely accepted throughout the nation. They pointed to examples of existing risk adjustment approaches that could be used for CJR episodes, such as Optum's Procedure Episode Grouper (PEG), Truven's Medical Episode Grouper (MEG), Health Care Incentives Improvement Institute's (HCI3) risk adjustment model, CMS's HCCs model, and CMS's risk-adjusted quality/efficiency metric for elective LEJR episodes: Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).

Response: In response to comments, we undertook further analysis. Our analysis showed that episodes with hip fractures, identified by historical anchor hospitalization claims with an ICD–9–CM hip fracture code as the principal diagnosis, have approximately 70 percent greater historical average episode expenditures than episodes without hip fractures, even for episodes within the same anchor MS–DRG, confirming analyses shared by some commenters that also showed episodes with hip fractures to have significantly greater average expenditures.[27] PHA episodes and emergent episodes had similarly higher historical average expenditures than TKA and THA episodes and non-emergent episodes, respectively. There are clearly patient-specific conditions that lead to significant episode expenditure variations, even within the same MS–DRG.

On the basis of the comments and our further analysis, we agree with commenters that proper risk adjustment is necessary to appropriately incentivize participant hospitals to deliver high quality and efficient care. We acknowledge that a comprehensive risk adjustment methodology beyond just setting different prices by anchor MS–DRGs could more accurately risk adjust episodes for patient-specific clinical and demographic factors that would drive variations in CJR episode expenditures.

We disagree with commenters, though, that there is an already existing, widely accepted risk adjustment methodology for CJR episodes. The HCC model, as discussed earlier in this section, is not designed to predict costs within CJR episodes and may not accurately predict CJR episode expenditures. Commercial claims groupers such as Optum's PEG, Truven's MEG, and HCI3's risk adjustment model utilize different episode definitions from how we will define CJR episodes. Additionally, these commercial groupers have yet to be validated for a Medicare population; we believe there may be a different set of risk factors that predict episode expenditures for Medicare beneficiaries than those used to predict episode expenditures for younger and generally healthier individuals with commercial insurance. We also acknowledge that CMS has designed a risk-adjusted quality/efficiency metric for elective LEJR episodes: Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA). This metric, though, has been developed for a different episode definition; most notably, this risk-adjusted metric excludes emergent episodes while the CJR episode definition does not exclude emergent episodes, as discussed in section III.B. of this final rule.

We do believe that there are opportunities to learn from existing comprehensive risk adjustment models, and we may explore how a comprehensive risk adjustment model such as these may be adapted for the CJR model in the future.

In the meantime, though, we also believe we can improve upon the proposed approach of only setting different target prices by anchor MS–DRG. Specifically, we can account for the impact of hip fracture status (with hip fracture vs. without hip fracture), procedure choice (PHA vs. TKA or THA), and emergence status (emergent vs. non-emergent) on episode expenditures. According to our analysis, though, there was significant correlation between incidence of hip fractures, partial hip procedures, and emergent procedures—94 percent of partial hip replacement episodes and 93 percent of emergent episodes are for patients with hip fractures. Because of the correlation between these three factors, we believe we can account for all three by risk stratifying based on hip fracture status alone. We believe hip fracture status is a more appropriate dimension on which

[26] Medicare FFS Parts A and B claims, CJR episodes, as proposed in this rule, between October 2013 and September 2014.

[27] Medicare FFS Parts A and B claims, CJR episodes, as proposed in the proposed rule, between October 2013 and September 2014.

to risk stratify because it reflects patients' clinical status, as opposed to partial hip replacements and emergent procedures which are influenced by providers' care delivery decisions.

In light of the comments and our additional analysis, we will modify our proposed policy to risk stratify, or set different target prices, both for episodes anchored by MS–DRG 469 vs. MS–DRG 470 and for episodes with hip fractures vs. without hip fractures. By adding hip fracture status to our risk stratification approach, we believe we can capture a significant amount of patient-driven episode expenditure variation. Additionally, because of the high correlation between incidence of hip fractures, partial hip procedures, and emergent procedures, we do not believe we need to add any procedure-specific and emergent status factors for risk stratification. We still believe, as stated in the proposed rule that PAC intensity would not vary significantly between TKA and THA for beneficiaries without hip fractures.

We will identify episodes with hip fractures using ICD–9–CM or ICD–10–CM diagnosis codes, where the hip fracture diagnosis is the principal diagnosis on the anchor hospitalization claim for an LEJR procedure. Our goal is to identify those CJR episodes where the primary surgical treatment for the hip fracture is an LEJR procedure furnished during the anchor hospitalization. The historical episodes with hip fracture diagnosis codes on the anchor hospitalization claim will be used to set the hip fracture episode target prices under the CJR model, and episodes during the CJR model with hip fracture diagnosis codes on the anchor hospitalization claim will be reconciled at the hip fracture episode target prices.

In order to develop the initial list of ICD–9–CM hip fracture diagnosis codes used to identify those historical episodes with hip fracture for calculating hip fracture episode target prices, to implement changes to the list to account for the transition to the ICD–10–CM diagnosis code set that will be used to identify episodes during the model performance years that will receive fracture episode target prices, and to make other changes as necessary based on annual ICD–10–CM coding changes or to address issues raised by the public throughout the model performance years, we are implementing the following subregulatory process, which mirrors the subregulatory process we will use for the episode definition exclusions list described in section III.B.2 of this final rule. We will use this process on an annual, or more frequent, basis to update the ICD–CM hip fracture diagnosis code list and to address issues raised by the public.

As part of this process, we will first develop the potential ICD–CM hip fracture diagnosis codes based on our assessment according to the following standards:

- The ICD–CM diagnosis code is sufficiently specific that it represents a bone fracture for which a physician could determine that a hip replacement procedure, either a PHA or a THA, could be the primary surgical treatment.
- The ICD–CM diagnosis code is the primary reason (that is, principal diagnosis code) for the anchor hospitalization.

We will then post a list of potential hip fracture diagnosis codes (whether ICD–9–CM diagnosis codes, as necessary to develop initial target prices, or ICD–10–CM diagnosis codes to be utilized during the model performance years) to the CMS Web site at *http://innovation.cms.gov/initiatives/cjr/* to allow for public input on our planned application of these standards, and then we will adopt the ICD–CM hip fracture diagnosis code list with posting to the CMS Web site of the final ICD–CM hip fracture diagnosis code list after our consideration of the public input.

With public release of this final rule, we are initiating this subregulatory process to develop a final ICD–9–CM hip fracture diagnosis code list that will be used to identify historical anchor hospitalizations for beneficiaries with hip fracture for purposes of determining episode spending in the historical period and developing initial target prices for the model. The potential ICD–9–CM hip fracture diagnosis code list is posted on the CJR Web site at *http://innovation.cms.gov/initiatives/cjr/*. Given our objective to quickly develop target prices and provide them to participant hospitals in the timeframe described in section III.C.4. of this final rule, we will allow for public input on this list for 14 days after the public release of this final rule. Public comments will be submitted via an email address posted on the CJR Web site along with the list of potential ICD–9–CM hip fracture diagnosis codes previously referenced. We will consider the public's input and then, after consideration, we will post the final ICD–9–CM hip fracture diagnosis code list to the CMS Web site. This list will be used to calculate the first set of target prices communicated to participant hospitals. Within 30 days of public release of the final rule, we will again initiate this subregulatory process to identify ICD–10–CM hip fracture diagnosis codes by posting the potential ICD–10–CM hip fracture diagnosis code list on the CMS Web site and seeking public input, so we can provide in a timely manner the final list of ICD–10–CM hip fracture diagnosis codes prior the beginning of the first model performance year.

Final Decision: After consideration of the public comments we received, we are modifying the proposed rule to risk stratify (and set different target prices) based on not just different anchor MS–DRGs but also patients' hip fracture status. We will identify episodes with hip fractures using ICD–9–CM or ICD–10–CM diagnosis codes in the principal position on the claim for the anchor hospitalization. We are instituting a subregulatory process in order to allow for public comment and to finalize the ICD–9–CM and ICD–10–CM diagnosis codes to be used in identifying hip fracture cases in the CJR model, which we are initiating as of the public release of this final rule. We refer readers to the list of ICD–9–CM diagnosis codes posted on the CJR model Web site at *http://innovation.cms.gov/initiatives/cjr/*.

This policy is codified at § 510.300(a).

(2) Three Years of Historical Data

We proposed to use 3 years of historical CJR episodes for calculating CJR target prices. The set of 3-historical-years used would be updated every other year. Specifically—

- Performance years 1 and 2 would use historical CJR episodes that started between January 1, 2012 and December 31, 2014;
- Performance years 3 and 4 would use historical episodes that started between January 1, 2014 and December 31, 2016; and
- Performance year 5 would use episodes that started between January 1, 2016 and December 31, 2018.

We considered using fewer than 3 years of historical CJR episode data, but we are concerned with having sufficient historical episode volume to reliably calculate target prices. We also considered not updating the historical episode data for the duration of the model. However, we stated in the proposed rule our belief that hospitals' target prices should be regularly updated on a predictable basis to use the most recent available claims data, consistent with the regular updates to Medicare's payment systems, to account for actual changes in utilization. We are not proposing to update the data annually, given the uncertainty in pricing this could introduce for participant hospitals. We also note that the effects of updating hospital-specific data on the target price could be limited

as the regional contribution to the target price grows, moving to two-thirds in performance year 3 when the first historical episode data update would occur.

The following is a summary of the comments received and our responses.

Comment: Commenters generally supported using historical expenditures to set target prices. Several commenters expressed concern that updating the 3 years of historical CJR episode data every other year would effectively make participant hospitals compete against themselves without consideration of whether they are already efficient. Some of these commenters cited that BPCI does not update its historical data for the entirety of the BPCI model, and some other commenters noted that Medicare Shared Savings Program resets its historical benchmark every three years with each new participation agreement. There were also a few commenters that supported updating the 3 years of historical CJR episode data every 2 years because it was better than doing so every year.

Some commenters also stated that if we do update the historical data, we should include previous reconciliation payments and repayments to Medicare for the participant hospitals. We refer readers to comments and responses to comments in section III.C.3 of this final rule for further discussion on this comment.

Some commenters proposed alternative approaches to getting to target prices other than using and updating historical data. Some commenters suggested using a negotiations/bidding process approach to get to target prices; Medicare would negotiate with or request bids from providers for providing services covered under the CJR episode definition. Some other commenters suggested applying some sort of inflation factor, such as a CMS market basket update, for future years of the model instead of updating the 3 years of historical CJR episode data. These alternatives to using and updating the historical CJR episode data would help prevent a participant hospital from competing against its historical self, even if it is already efficient, in order to qualify for reconciliation payments.

Response: We appreciate commenters' support for using historical expenditures to set target prices. We acknowledge that BPCI does not update participants' historical data and Medicare Shared Savings Program does not reset participating entities' benchmark for 3 years (until the beginning of a new agreement period). However, these programs employ alternative mechanisms to account for recent national trends reflecting changes in industry wide practice patterns. BPCI, for example, retrospectively applies a national trend factor to trend forward historical episode expenditure data and capture changes in nationwide practice patterns between the time period used in the historical data and the performance period. BPCI participants are not penalized or rewarded for mirroring nationwide practice pattern trends. In BPCI, however, participants' target prices are determined retrospectively after the close of each performance period. We intend to calculate and communicate target prices prior to the start of each performance year, as discussed in section III.C.4.a of this final rule, so we cannot utilize the retrospective national trend factor approach as used in BPCI.

Instead, we proposed to capture changes in nationwide practice patterns by updating every other year the historical CJR episode data used to set target prices. We recognize that this approach of updating the historical episode data every other year effectively assumes a zero percent change in utilization between the latest year of historical episode data and the performance year. We believe this can be a valid estimate for a few years (for example, 2014 as the latest year of historical episode data for 2017 target prices; update historical episode data for 2018 target prices), but it is less likely to hold true for longer periods of time (for example, 2014 as the latest year of historical episode data for 2020 target prices; no update to historical episode data). Therefore, we believe updating the historical episode data is necessary. While updating the historical episode data more frequently (that is, every year, instead of every other year) would lessen our reliance on an assumption of zero percent utilization change, doing so may exacerbate commenters' concerns that already efficient hospitals would have to compete against themselves, as discussed further later in this section.

We appreciate commenters' concerns that it may be unsustainable for already efficient participant hospitals to continuously improve, and that participant hospitals may undertake activities that promote care coordination and improved quality of care but are not directly reimbursed under applicable Medicare FFS payment systems. If we were using 100 percent hospital-specific pricing, updating the historical data used to set target prices without including reconciliation payments would create a lower and harder to achieve target price for participant hospitals that previously increased efficiency. As discussed in section III.C.3 of this final rule, we may revisit in future rulemaking our decision to exclude reconciliation payments and repayment amounts when updating the set of historical years used to set target prices. Additionally, as we transition to regional pricing over the course of the model, participant hospitals will no longer compete against their historical selves but rather strive to outperform their regional peers. Under regional pricing, an already efficient hospital may be able to achieve actual episode expenditures below the regional target price without having to become even more efficient. By performance year 3, when the first update to historical episode data would occur, the majority of the target price would be based on the regional component, not the hospital-specific component, as described in section III.C.4.b.(5) of this final rule.

We appreciate commenters' suggestions on using alternative approaches to setting target prices. We may consider such approaches for future model tests.

Final Decision: After consideration of the public comments we received, we are finalizing the proposal, without modification, to use three years of historical expenditures, updated every other year, to set target prices.

(3) Trending of Historical Data to the Most Recent Year of the Three

We acknowledge that some payment variation may exist in the 3 years of historical CJR episodes due to updates to Medicare payment systems (for example, IPPS, OPPS, IRF PPS, SNF PPS, etc.) and national changes in utilization patterns. Episodes in the third of the 3-historical-years may have higher average payments than those from the earlier 2 years because of Medicare payment rate increases over the course of the 3-historical-years. We do not intend to have CJR incentives be affected by Medicare payment system rate changes that are beyond hospitals' control. In addition to the changes in Medicare payment systems, average episode payments may change year over year due to national trends reflecting changes in industry-wide practice patterns. For example, readmissions for all patients, including those in CJR episodes, may decrease nationally due to improved industry-wide surgical protocols that reduce the chance of infections. We do not intend to provide reconciliation payments to (or require repayments from) hospitals for achieving lower (or higher) Medicare expenditures solely because they followed national changes in practice

patterns. Instead, we aim to incentivize hospitals based on their hospital-specific inpatient and PAC delivery practices for LEJR episodes.

To mitigate the effects of Medicare payment system updates and changes in national utilization practice patterns within the 3 years of historical CJR episodes, we proposed to apply a national trend factor to each of the years of historical episode payments. Specifically, we proposed to inflate the 2 oldest years of historical episode payments to the most recent year of the 3-historical-years described in section III.C.4.b.(2) of the proposed rule. We proposed to trend forward each of the 2 oldest years using the changes in the national average CJR episode payments. We also proposed to apply separate national trend factors for episodes anchored by MS–DRG 469 versus MS–DRG 470 to capture any MS–DRG-specific payment system updates or national utilization pattern changes. For example, when using CY 2012–2014 historical episode data to establish target prices for performance years 1 and 2, under our proposal we would calculate a national average MS–DRG 470 anchored episode payment for each of the 3-historical-years. The ratio of the national average MS–DRG 470 anchored episode payment for CY 2014 to that of CY 2012 would be used to trend 2012 MS–DRG 470 anchored episode payments to CY 2014. Similarly, the ratio of the national average MS–DRG 470 anchored episode payment for CY 2014 to that of CY 2013 would be used to trend 2013 episode payments to CY 2014. The previously stated process would be repeated for MS–DRG 469 anchored episodes. Trending CY 2012 and CY 2013 data to CY 2014 would capture updates in Medicare payment systems as well as national utilization pattern changes that may have occurred.

We considered adjusting for regional trends in utilization, as opposed to national trends. However, we stated in the proposed rule our belief that any Medicare payment system updates and significant changes in utilization practice patterns would not be region-specific but rather be reflected nationally.

We sought comment on our proposal to nationally trend historical data to the most recent year of the 3 being used to set the target prices.

The following is a summary of the comments received and our responses.

Comment: Some commenters supported the use of national trends for trending historical data to the most recent of the 3 being used to set the target prices. Some commenters suggested blending regional, instead of national, trends to be consistent with how target prices will be blended, as discussed in section III.C.4.b.(5) of this final rule. Some commenters inquired how trending historical data would capture changes in Medicare FFS fee schedules.

Response: We appreciate commenters' support for the use of national trends for trending historical data. This trending of historical data to the most recent of the 3 being used to set target prices would capture both Medicare FFS fee schedule and practice pattern changes. Medicare FFS fee schedule changes would be captured in the trend factor calculations; for example, if Medicare FFS fee schedules change so as to increase overall payments by 4 percent between the oldest and most recent year of historical episode data, the national trend factor applied to the oldest year of historical episode data would be 1.04 (assuming no change in utilization patterns). Medicare FFS fee schedule changes apply across the nation, and we believe that major changes to practice patterns would be nationwide and not constrained to any one region.

Comment: Many commenters requested for risk adjustment based on patients' hip fracture status, among other clinical and demographic dimensions.

Response: We refer readers to comments and responses to comments in section III.C.4.b.(1) of this final rule for further discussion on risk stratification, and we reference it here because changes to risk stratification would impact how we would trend historical data to the most recent year of the three being used. As discussed in the responses to comments in section III.C.4.b.(1) of this final rule, we will modify our proposal so as to set different target prices both for episodes anchored by MS–DRG 469 vs. MS–DRG 470 and for episodes with hip fractures vs. without hip fractures. Given this change, we must also modify the proposed approach to apply national trend factor. Specifically, instead of calculating different national trend factors just for anchor MS–DRGs 469 vs. 470, we will calculate different national trend factors for each combination of anchor MS–DRG (469 vs. 470) and hip fracture status (with hip fracture vs. without hip fracture) using the methodology we proposed.

Final Decision: After consideration of the public comments we received, we are finalizing the proposal to trend historical data to the most recent of the 3 being used to set target prices, though instead of calculating different national trend factors just for anchor MS–DRGs 469 vs. 470, we will calculate different national trend factors for each combination of anchor MS–DRG (469 vs. 470) and hip fracture status (with hip fracture vs. without hip fracture).

(4) Update Historical Episode Payments for Ongoing Payment System Updates

We proposed to prospectively update historical CJR episode payments to account for ongoing Medicare payment system (for example, IPPS, OPPS, IRF PPS, SNF, MPFS, etc.) updates to the historical episode data and ensure we incentivize hospitals based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond hospitals' control. Medicare payment systems do not update their rates at the same time during the year. For example, IPPS, the IRF PPS, and the SNF payment system apply annual updates to their rates effective October 1, while the hospital OPPS) and MPFS apply annual updates effective January 1. To ensure we appropriately account for the different Medicare payment system updates that go into effect on January 1 and October 1, we proposed to update historical episode payments for Medicare payment system updates and calculate target prices separately for episodes initiated between January 1 and September 30 versus October 1 and December 31 of each performance year. The target price in effect as of the day the episode is initiated would be the target price for the whole episode. Note that in performance year 5, the second set of target prices would be for episodes that start and end between and including October 1 and December 31 because the fifth performance period of the CJR model would end on December 31, 2020. Additionally, a target price for a given performance year may apply to episodes included in another performance year. For example, an episode initiated in November 2016, and ending in February 2017 would have a target price based on the second set of 2016 target prices (for episodes initiated between October 1 and December 31, 2016), and it would be captured in the CY 2017 performance year (performance year 2) because it ended between January 1 and December 31, 2017. We refer readers to section III.C.3.c. of the proposed rule for further discussion on the definition of performance years.

We proposed to update historical CJR episode payments by applying separate Medicare payment system update factors each January 1 and October 1 to each of the following six components of each hospital's historical CJR payments:

- Inpatient acute.
- Physician.

- IRF.
- SNF.
- HHA.
- Other services.

A different set of update factors would be calculated for January 1 through September 30 versus October 1 through December 31 episodes each performance year. The six update factors for each of the previously stated components would be hospital-specific and would be weighted by the percent of the Medicare payment for which each of the six components accounts in the hospital's historical episodes. The weighted update factors would be applied to historical hospital-specific average payments to incorporate ongoing Medicare payment system updates. A weighted update factor would be calculated by multiplying the component-specific update factor by the percent of the hospital's historical episode payments the component represents, and summing together the results. For example, let us assume 50 percent of a hospital's historical episode payments were for inpatient acute care services, 15 percent for physician services, 35 percent for SNF services, and 0.0 percent for the remaining services. Let us also assume for this example that the update factors for inpatient acute care services, physician services, and SNF services are 1.02, 1.03, and 1.01, respectively. The weighted update factor in this example would be the following: (0.5 * 1.02) + (0.15*1.03) + (0.35*1.01) = 1.018. The hospital in this example would have its historical average episode payments multiplied by 1.018 to incorporate ongoing payment system updates. The specific order of steps, and how this step fits in with others, is discussed further in section III.C.4.c. of this final rule.

Each of a hospital's six update factors would be based on how inputs have changed in the various Medicare payment systems for the specific hospital. Additional details on these update factors will be discussed later in this section.

Region-specific update factors for each of the previously stated components and weighted update factors would also be calculated in the same manner as the hospital-specific update factors. Instead of using historical episodes attributed to a specific hospital, region-specific update factors would be based on all historical episodes initiated at any CJR eligible hospital within the region. For purposes of this rule, CJR eligible hospitals are defined as hospitals that are paid under IPPS and not a participant in BPCI Model 1 or in the risk-bearing period of Models 2 or 4 for LEJR episodes, regardless of whether or not the MSAs in which the hospitals are located were selected for inclusion in the CJR model. CJR episodes initiated at a CJR eligible hospital will for purposes of this rule be referred to as CJR episodes attributed to that CJR eligible hospital.

We considered an alternative option of trending the historical episode payments forward to the upcoming performance year using ratios of national average episode payment amounts, similar to how we proposed to trend the 2 oldest historical years forward to the latest historical year for historical CJR episode payments in section III.C.4.b.(3) of the proposed rule. Using ratios of national average episode payment amounts would have the advantage of also capturing changes in national utilization patterns in addition to payment system updates between the historical years and the performance year. However, such an approach would need to be done retrospectively, after average episode payments can be calculated for the performance year, because it would rely on the payments actually incurred in the performance period, data that would be not be available before the performance period. While the proposed approach of using component-specific weighted update factors may be more complicated than the previously stated alternative to use ratios of national average episode payment amounts, we stated in the proposed rule our belief that the additional complication is outweighed by the value to hospitals of knowing target prices before the start of an episode for which the target price would apply. We sought comment on this proposed approach of updating historical episode payments for ongoing Medicare payment system changes.

We did not propose to separately and prospectively apply an adjustment to account for changes in national utilization patterns between the historical and performance years. If a prospective adjustment factor for national utilization pattern changes were applied, it may only be meaningful in performance years 2 and 4, when the historical data used to calculate target prices would not be updated, but another year of historical data would be available. In any of the other 3 performance years, the latest available historical year of data would already be incorporated into the target prices. Given that we proposed to refresh the historical data used to calculate target prices every 2 years, we did not believe an additional adjustment factor to account for national practice pattern changes is necessary to appropriately incentivize participant hospitals to improve quality of care and reduce episode payments.

The following is a summary of the comments received and our responses.

Comment: Several commenters noted that the Medicare payment system update factors were complicated to calculate. Some commenters supported the use of calculating Medicare payment system update factors at the hospital-specific and regional levels to reflect practice pattern variations, while some others proposed using national update factors to incentivize reduction in medically unnecessary and/or inappropriate practice pattern variations.

A couple of commenters also inquired whether the Medicare payment system update factors accounted for changes Medicare FFS payment system changes. A commenter requested we freeze MS–DRG weights for MS–DRGs 469 and 470 if the weights decrease in any given year as part of the annual Medicare FFS IPPS payment system updates.

Response: We acknowledge that the Medicare payment system update factor calculations are complex, but we believe the complexity is necessary to account for Medicare FFS payment system changes. We will use these payment system update factors to ensure that we incentivize hospitals based on utilization and practice patterns, not Medicare payment system rate changes. While changes to Medicare FFS rates for individual services would be applicable nationwide, the relative composition of each service in historical episodes will likely vary by hospital and region. Calculating payment system update factors at the hospital-specific and regional levels will more accurately capture the effects of payment system changes.

We also note that we are finalizing a modification to the equations used to calculate update factors for those payment systems that apply annual updates to their rates effective October 1 of each year. In lieu of calculating the update factors for inpatient acute, SNF, and IRF services using the values applicable at the end of latest historical year used to calculate target prices, we will use a blend of the values applicable during the latest historical year. Such a change will account for the payment systems that update payment rates on a fiscal year cycle, ensure we are calculating update factors based on the payment rates that apply to a given period to the extent feasible, and result in more accurate target price calculations. We reflect this change in the sections III.C.4.b.(4)(a),

III.C.4.b.(4)(c), and III.C.4.b.(4)(d) of this final rule

We believe freezing MS–DRG weights would run counter to our objective to accurately account for the effects of Medicare FFS payment system changes. If we freeze MS–DRG weights and the weights decrease, we may inappropriately overestimate target prices.

Comment: Some commenters requested to have a single set of target prices for the entire calendar year, as opposed to two different sets of target prices that would account for intra-year Medicare FFS payment systems updates: one set for January 1 through September 30, and a second set for October 1 through December 31. These commenters stated that a single target price for the entire year may be easier to communicate to participant hospitals, and that the effect of mid-calendar year changes in Medicare FFS (for example, October 1 IPPS changes) could be estimated and reconciled against a single set of target prices for the entire calendar year.

Response: We appreciate commenters' desire for simplicity. However, we would not know the extent of October 1 Medicare FFS payment system updates prior to January of the same year. Additionally, the October update includes payment system updates for IPPS, which accounts for the plurality of historical CJR episode expenditures. Without knowing the magnitude of Medicare FFS payment system updates, we do not believe we could reliably calculate target prices. Any estimate would likely require corrections after the end of the performance year, rendering the initial target price unreliable and unrepresentative of the target price used for reconciliation.

Comment: Several commenters recommended that we modify the definition of 'CJR eligible hospitals,' the term used to identify hospitals included in calculations for the regional component of target prices (discussed further in section III.C.4.b.(5) of this final rule), to not exclude hospitals that are participants in BPCI Model 1 or in the risk bearing period of Models 2 or 4 for LEJR episodes. They recommended that some regions may have a greater proportion of these BPCI participants, and excluding them from the calculations for the regional component of target prices would not accurately reflect the region's historical expenditures. Additionally, with fewer hospitals included, the region component of target prices would be more significantly impacted by the performance of just CJR participant hospitals.

Response: We agree with commenters' arguments to include hospitals that are participants in BPCI Model 1 or in the risk bearing period of Models 2 or 4 for LEJR episodes when calculating the regional component of CJR target prices. Including these BPCI hospitals would more accurately reflect the region's historical expenditures, independent of the level of BPCI participation in the region. Therefore, we are not finalizing our proposal to exclude these hospitals from the regional calculation. We will modify the definition of ''CJR eligible hospitals'' to include these BPCI hospitals so that their data is included in the regional component of target prices. We will treat these BPCI participants as though they were any other non-BPCI-participating hospital—we would not apply the BPCI discount factor to claims payments nor include BPCI reconciliation or repayments for these BPCI hospitals. We do not intend to reduce target prices for participant hospitals just because they are located in a region with greater BPCI participation; instead, we want to ensure that we are calculating a representative regional component for target prices. In order to reduce potential confusion, we will also rename ''CJR eligible hospitals'' to be ''CJR regional hospitals''.

We also clarify that BPCI LEJR episodes will be included in the historical data used to calculate the hospital-specific component of target prices. There may be some CJR participant hospitals who were previously participants in BPCI Model 2; there may be some BPCI Model 2 episodes in the historical data initiated by PGPs for which the LEJR procedure took place at the CJR participant hospital; or there may be some BPCI Model 3 episodes in the historical data for which the LEJR procedure took place at the CJR participant hospital. Including the BPCI LEJR episodes from the historical data used to calculate the hospital-specific component of target prices would parallel the previously discussed approach to include BPCI LEJR episodes in the regional component of target prices. Again, as previously discussed for the regional component of target prices, we would not apply the BPCI discount factor to claim payments nor include BPCI reconciliation or repayments for the hospital-specific component of target prices.

Final Decision: After consideration of the public comments we received, we are modifying our proposal to update historical episode payments for ongoing payment system updates so as to include in the definition of ''CJR eligible hospitals'' that are participants in BPCI Model 1 or in the risk bearing period of Models 2 or 4 for LEJR episodes, and rename ''CJR eligible hospitals'' to be ''CJR regional hospitals.'' We are also finalizing a modification to how we calculate update factors to more accurately capture payment system rate changes throughout the calendar year for inpatient acute, IRF, and SNF services. The modification is reflected in III.C.4.b.(4)(a), III.C.4.b.(4)(c), and III.C.4.b.(4)(d) of this final rule.

(a) Inpatient Acute Services Update Factor

The proposed inpatient acute services update factor would apply to payments for services included in the episode paid under the IPPS. This would include payments for the CJR anchor hospitalization and related readmissions at hospitals paid under IPPS, but not payments for related readmissions at CAHs during the episode window. Payments for related readmissions at CAHs would be captured under the update factor for other services in section III.C.4.b.(4)(f) of the proposed rule.

The update factor applied to the inpatient acute services component of each participant hospital and region's historical average episode payments would be based on how inputs for the Medicare IPPS have changed between the latest year used in the historical 3 years of episodes and the upcoming performance period under CJR. We proposed to use changes in the following IPPS inputs to calculate the inpatient acute services update factor: IPPS base rate and average of MS–DRG weights, as defined in the IPPS/LTCH Final Rules for the relevant years. The average MS–DRG weight would be specific to each participant hospital and region to account for hospital and region-specific inpatient acute service utilization patterns. Hospital-specific and region-specific average MS–DRG weights would be calculated by averaging the MS–DRG weight for all the IPPS MS–DRGs included in the historical episodes attributed to each participant hospital and attributed to CJR eligible hospitals in the region, respectively; including MS–DRGs for anchor admissions as well as those for subsequent readmissions that fall within the episode definition. Expressed as a ratio, the inpatient acute services adjustment factor would equal the following:

- The numerator is based on values applicable for the upcoming performance period (PP) for which a target price is being calculated.

• The denominator is based on a blend of values applicable in the latest of the 3 historical years used in the target price (TP) calculations, weighted to account for the values applicable prior to October 1, and values applicable starting October 1 when IPPS updates for the new fiscal year are in effect. Note that this weighting incorporates a modification to our proposed methodology for calculating update factors, as previously discussed in section III.C.4.(b)(4) of this final rule.

Therefore, the inpatient acute services update factor formula is shown as—

$$\frac{\text{Base Rate}_{PP} * \text{average MSDRG weight}_{PP}}{\text{Base Rate}_{TP} * \text{average MSDRG weight}_{TP}}$$

(b) Physician Services Update Factor

The proposed physician services update factor would apply to payments for services included in the episode paid under the MPFS for physician services. We proposed to use changes in the following MPFS inputs to calculate the physician services update factor of each participant hospital and region's historical average episode payments: RVUs; work, practice expense, and malpractice (MP) liability geographic practice cost indices (GPCIs); and national conversion factor, as defined in the MPFS Final Rule for the relevant years. Hospital-specific and region-specific RVU-weighted GPCIs would be calculated to account for hospital and region-specific physician service utilization patterns. Hospital-specific and region-specific RVU-weighted GPCIs would be calculated by taking the proportion of RVUs for work, practice expense, and MP liability for physician services included in the historical episodes and attributed to each participant hospital and attributed to CJR eligible hospitals in the region, respectively, and multiplying each proportion by the relevant GPCI.

Expressed as a ratio, the physician services update factor would equal the following:

• The numerator is based on GPCI values applicable for the upcoming performance period (PP) for which a target price is being calculated.

• The denominator is based on GPCI values applicable at the end of the latest of the 3 historical years used in the target price (TP) calculations.

Therefore, the proposed physician services update factor formula is shown as—

$$\frac{\text{RVU} - \text{weighted GPCI}_{PP} * \text{Conversion factor}_{PP}}{\text{RVU} - \text{weighted GPCI}_{TP} * \text{Conversion factor}_{TP}}$$

(c) IRF Services Update Factor

The proposed IRF services update factor applies to payments for services included in the episode paid under the Medicare inpatient rehabilitation facility prospective payment system (IRF PPS). We proposed to use changes in the IRF Standard Payment Conversion Factor, an input for the IRF PPS and defined in the IRF PPS Final Rule for the relevant years, to update Medicare payments for IRF services provided in the episode. The IRF Standard Payment Conversion Factor is the same for all IRFs and IRF services, so there is no need to account for any hospital-specific or region-specific IRF utilization patterns; each participant hospital and region would use the same IRF services update factor.

Expressed as a ratio, the IRF PPS update factor would equal the following:

• The numerator is based on values applicable for the upcoming performance period (PP) for which a target price is being calculated.

• The denominator is based on a blend of values applicable in the latest of the 3 historical years used in the target price (TP) calculations, weighted to account for the values applicable prior to October 1, and values applicable starting October 1 when IRF PPS updates for the new fiscal year are in effect. Note that this weighting incorporates a modification to our proposed methodology for calculating update factors, as previously discussed in section III.C.4.(b)(4) of this final rule.

Therefore, the IRF services update factor formula is shown as—

$$\frac{\text{IRF Standard Payment Conversion factor}_{PP}}{\text{IRF Standard Payment Conversion factor}_{TP}}$$

(d) SNF Services Update Factor

The proposed SNF services update factor would apply to payments for services included in the episode and paid under the SNF PPS, including payments for SNF swing bed services. The update factor applied to the SNF services component of each participant hospital and region's historical average episode payments would be based on how average Resource Utilization Group (RUG–IV) Case-Mix Adjusted Federal Rates for the Medicare SNF PPS (defined in the SNF PPS Final Rule) have changed between the latest year used in the historical 3 years of episodes and the upcoming performance period under CJR. The average RUG–IV Case-Mix Adjusted Federal Rates would be specific to each participant hospital and region to account for hospital and region-specific SNF service utilization patterns. Hospital-specific and region-specific average RUG–IV Case-Mix Adjusted Federal Rates would be calculated by averaging the RUG–IV Case-Mix Adjusted Federal Rates for all SNF services included in the historical episodes attributed to each participant hospital and attributed to CJR eligible hospitals in the region, respectively. We note that the RUG–IV Case-Mix Adjusted Federal Rate may vary for the same RUG, depending on whether the SNF was categorized as urban or rural.

Expressed as a ratio, the SNF services update factor would equal the following:

• The numerator is based on values applicable for the upcoming

performance period (PP) for which a target price is being calculated.

- The denominator is based on a blend of values applicable in the latest of the 3 historical years used in the target price (TP) calculations, weighted to account for values applicable prior to October 1, and values applicable starting October 1 when SNF PPS updates for the new fiscal year are in effect. Note that this weighting incorporates a modification to our proposed methodology for calculating update factors, as previously discussed in section III.C.4.(b)(4) of this final rule.

Therefore, the SNF services update factor formula is shown as—

$$\frac{\text{Average RUG IV Case Mix Adjusted Federal Rate}_{PP}}{\text{Average RUG IV Case Mix Adjusted Federal Rate}_{TP}}$$

(e) HHA Services Update Factor

The proposed HHA services update factor would apply to payments for services included in the episode and paid under the HH PPS, but exclude payments for Low Utilization Payment Adjustment (LUPA) claims (claims with four or fewer home health visits) because they are paid differently and would instead be captured in the update factor for other services in section III.C.4.b.(f) of the proposed rule. The update factor applied to the home health services component of each participant hospital and region's historical average episode payments would be based on how inputs for the Medicare HH PPS have changed between the latest year used in the historical 3 years of episodes and the upcoming performance period under CJR. We proposed to use changes in the HH PPS base rate and average of home health resource group (HHRG) case-mix weight, inputs for the HHA PPS and defined in the HHA PPS Final Rule for the relevant years, to calculate the home health services update factor. The average HHRG case-mix weights would be specific to each participant hospital and region to account for hospital and region-specific home health service utilization patterns. Hospital-specific and region-specific HHA services update factors would be calculated by averaging the HHRG case-mix weights for all home health payments (excluding LUPA claims) included in the historical episodes attributed to each participant hospital and attributed to CJR eligible hospitals in the region, respectively.

Expressed as a ratio, the HHA adjustment factor would equal the following:

- The numerator is based on values applicable for the upcoming performance period (PP) for which a target price is being calculated.
- The denominator is based on values applicable at the end of the latest of the 3 historical years used in the target price (TP) calculations.

Therefore, the proposed HHA services update factor formula is shown as—

$$\frac{\text{60 Day Episode Rate}_{PP} * \text{average HHRG weight}_{PP}}{\text{60 Day Episode Rate}_{TP} * \text{average HHRG weight}_{TP}}$$

(f) Other Services Update Factor

The other services update factor would apply to payments for services included in the episode and not paid under the IPPS, MPFS, IRF PPS, or HHA PPS (except for LUPA claims). This component would include episode payments for home health LUPA claims and CJR related readmissions at CAHs. For purposes of calculating the other services update factor, we proposed to use the Medicare Economic Index (MEI), a measure developed by CMS for measuring the inflation for goods and services used in the provision of physician services.[28] We would calculate the other services update factor as the percent change in the MEI between the latest year used in the TP calculation and its projected value for the upcoming performance period. Because MEI is not hospital or region-specific, each participant hospital and region would use the same other services update factor.

[28] Medicare Market Basket Data. *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketData.html.*

(5) Blend Hospital-Specific and Regional Historical Data

We proposed to calculate CJR episode target prices using a blend of hospital-specific and regional historical average CJR episode payments, including CJR episode payments for all CJR eligible hospitals in the same U.S. Census division as discussed further in section III.C.4.b.(6) of the proposed rule. Specifically, we proposed to blend two-thirds of the hospital-specific episode payments and one-third of the regional episode payment to set a participant hospital's target price for the first 2-performance years of the CJR model (CY 2016 and CY 2017). For performance year 3 of the model (CY 2018), we proposed to adjust the proportion of the hospital-specific and regional episode payments used to calculate the episode target price from two-thirds hospital-specific and one-third regional to one-third hospital-specific and two-thirds regional. Finally, we proposed to use only regional historical CJR episode payments for performance years 4 and 5 of the model (CY 2019 and CY 2020) to set a participant hospital's target price, rather than a blend between the hospital-specific and regional episode payments. The specific order of steps, and how this step fits in with others, is discussed further in section III.C.4.c. of the proposed rule. We welcome comment on the appropriate blend between hospital-specific and regional episode payments and the change in that blend over time.

We considered establishing episode target prices using only historical CJR hospital-specific episode payments for all 5 performance years of the model (that is, episode payments for episodes attributed to the participant hospital, as previously described in section III.C.2. of the proposed rule). Using hospital-specific historical episodes may be appropriate in other models such as BPCI Model 2 where participation is voluntary and setting a region-wide target price could lead to a pattern of selective participation in which inefficient providers decline to participate, undermining the model's ability to improve the efficiency and quality of care delivered by those providers, while already-efficient providers receive windfall gains even if they do not further improve efficiency. Because CJR model participants will be required to participate in the model,

solely using hospital-specific historical episode data is not necessary to avoid this potential concern. Furthermore, using only hospital-specific historical CJR episode payments may provide little incentive for hospitals that already cost-efficiently deliver high quality care to maintain or further improve such care. These hospitals could receive a relatively low target price because of their historical performance but have fewer opportunities for achieving additional efficiency under CJR. They would not receive reconciliation payments for maintaining high quality and efficiency, while other hospitals that were less efficient would receive reconciliation payments for improving, even if the less historically efficient hospitals did not reach the same level of high quality and efficiency as the more historically efficient hospitals. Using only hospital-specific historical CJR episode payments may also not be sufficient to curb inefficient care or overprovision of services for hospitals with historically high CJR episode payments. In such instances, using hospital-specific historical episode payments for the CJR model could result in Medicare continuing to pay an excessive amount for episodes of care provided by inefficient hospitals, and inefficient hospitals would stand to benefit from making only small improvements. Thus, we did not propose to set target prices based solely on hospital-specific data for any performance years of the model.

We considered establishing the episode target price using only historical CJR regional episode payments for all 5 performance years of the model. Though regional target pricing would reward the most efficient hospitals for continuing to provide high quality and cost efficient care, we are concerned about providing achievable incentives under the model for hospitals with high historical CJR average episode payments. We stated in the proposed rule our belief that a lower regional price for such hospitals would leave them with little financial incentive in performance year 1, especially without any responsibility to repay payments in excess of the target price as described in section III.C.3. of the proposed rule. Thus, we did not propose to set target prices solely on regional data for the entire duration of the model.

Therefore, we proposed initially to blend historical hospital-specific and regional-historical episode payments and then transition to using regional-only historical episode payments in establishing target prices to afford early and continuing incentives for both historically efficient and less efficient hospitals to furnish high quality, efficient care in all years of the model. Our proposal more heavily weights a hospital's historical episode data in the first 2 years of the model (two-thirds hospital-specific, one-third regional), providing a reasonable incentive for both currently efficient and less efficient hospitals to deliver high quality and efficient care in the early stages of model implementation. Beginning in performance year 3, once hospitals have engaged in care redesign and adapted to the model parameters, we proposed to shift to a more heavily weighted regional contribution (one-third hospital-specific, two-thirds regional in performance year 3) and ultimately to a regional target price for performance years 4 and 5. We stated in the proposed rule our belief that by performance year 4, setting target prices based solely on regional historical data would be feasible because hospitals would have had 3 years under this model to more efficiently deliver high quality care, thereby reducing some of the variation across hospitals. We stated in the proposed rule our belief that transitioning to regional only pricing in the latter years of the model would provide important information about the reduction in unnecessary variation in LEJR episode utilization patterns within a region that can be achieved.

We stated in the proposed rule our belief that transitioning to regional-only pricing in the latter years of the model may provide valuable information regarding potential pricing strategies for successful episode payment models that we may consider for expansion in the future. As discussed previously, substantial regional and hospital-specific variation in Medicare LEJR episode spending currently exists for beneficiaries with similar demographic and health status, so we are proposing that the early CJR model years will more heavily weight historical hospital-specific experience in pricing episode for a participant hospital. Once the hospital has substantial experience with care redesign, we expect that unnecessary hospital-specific variation in episode spending will be minimized so that regional-only pricing would be appropriate as we have proposed. We noted that, like episode payment under the CJR model, Medicare's current payment systems make payments for bundles of items and services, although of various breadths and sizes depending on the specific payment system. For example, the IPPS pays a single payment, based on national prices with geography-specific labor cost adjustments, for all hospital services furnished during an inpatient hospitalization, such as nursing services, medications, medical equipment, operating room suites, etc. Under the IPPS, the national pricing approach incentivizes efficiencies and has, therefore, led to a substantial reduction in unnecessary hospital-specific variation in resource utilization for an inpatient hospitalization. On the other hand, the episode payment approach being tested under BPCI Model 2 relies solely on provider-specific pricing over the lifetime of the model, assuming the number of episode cases is sufficient to establish a reliable episode price, an approach that has potential limitations were expansion to be considered. Thus, we stated in the proposed rule our belief that our proposal for CJR will provide new, important information regarding pricing for even larger and broader bundles of services once unnecessary provider-specific variation has been minimized that would supplement our experience with patterns and pricing under existing payment systems and other episode payment models. We expect that testing of CJR will contribute further information about efficient Medicare pricing strategies that result in appropriate payment for providers' resources required to furnish high quality, efficient care to beneficiaries who receive LEJR procedures. This is essential information for any consideration of episode payment model expansion, including nationally, in the future, where operationally feasible and appropriate pricing strategies, including provider-specific, regional, and national pricing approaches would need to be considered.

We proposed an exception to the blended hospital-specific and regional pricing approach for hospitals with low historical CJR episode volume. We proposed to define hospitals with low CJR episode volume as those with fewer than 20 CJR episodes in total across the 3-historical-years used to calculate target prices. We stated in the proposed rule our belief that calculating the hospital-specific component of the blended target price for these historically low CJR episode volume hospitals may be subject to a high degree of statistical variation. Therefore, for each performance year, we proposed to use 100 percent regional target pricing for participant hospitals who have fewer than twenty historical CJR episodes in the 3-historical-years used to calculate target prices, as described in section III.C.4.b.(2) of the proposed rule. We note that the 3-historical-years used

to calculate target prices would change over the course of the model, as described in section III.C.4.b.(2) of the proposed rule, and when that happens, the twenty episode threshold would be applied to the new set of historical years. If all IPPS hospitals nationally participated (for estimation purposes, only) in CJR, we estimate about 5 percent of hospitals would be affected by this proposed low historical CJR episode volume provision.[29] A minimum threshold of twenty episodes is almost equal to the minimum number of admissions required in the Medicare HRRP. HRRP payment adjustment factors are, in part, determined by procedure/condition-specific readmission rates for a hospital. HRRP requires at least 25 procedure/condition-specific admissions to calculate the procedure/condition-specific readmission rate and to be included in the hospital's overall HRRP payment adjustment factor. Though the proposed minimum threshold of twenty episodes is slightly less than the 25 admissions required for HRRP, we stated in the proposed rule our belief that because we would not be calculating infrequent events such as readmissions, we can achieve a stable price with slightly fewer episodes.

We also proposed an exception to the blended hospital-specific and regional pricing approach for participant hospitals that received new CCNs during the 24 months prior to the beginning of, or during, the performance year for which target prices are being calculated. These participant hospitals with new CCNs may have formed due to a merger between or split from previously existing hospitals, or may be new hospitals altogether. As a general principle, we aim to incorporate into the target prices all the historical episodes that would represent our best estimate of CJR historical payments for these participant hospitals with new CCNs. For participant hospitals with new CCNs that formed from a merger between or split from previously existing hospitals, we proposed to calculate hospital-specific historical payments using the episodes attributed to the previously existing hospitals. These hospital-specific historical payments would then be blended with the regional historical payments according to the approach previously described in this section. For participant hospitals with new CCNs that are new hospitals altogether, we proposed to use the approach previously described in this section for hospitals with fewer than 20 CJR episodes across the 3-historical-years used to calculate target prices. In other cases, due to an organizational change a hospital may experience a change to an already existing CCN during the 24 months prior to the beginning of, or during, the performance year for which target prices are being calculated. For example, one hospital with a CCN may merge with a second hospital assigned a different CCN, and both hospitals would then be identified under the single CCN of the second hospital. While there may be more than 20 CJR episodes under the second hospital's CCN in total across the 3-historical-years used to calculate target prices, in this scenario our use of only those cases under the second hospital's CCN in calculating hospital-specific historical payments would fail to meet our general principle of incorporating into target prices all the historical episodes that would represent our best estimate of CJR historical payments for these now merged hospitals. In this scenario, we proposed to calculate hospital-specific payments for the remaining single CCN (originally assigned to the second hospital only) using the historical episodes attributed to both previously existing hospitals. These hospital-specific historical payments would then be blended with the regional historical payments according to the approach previously described in this section in order to determine the episode price for the merged hospitals bearing a single CCN.

We sought comment on this proposed approach for blending hospital-specific and regional historical payments.

The following is a summary of the comments received and our responses.

Comment: Many commenters supported the proposal to blend hospital-specific and regional historical episode data to calculate target prices. They explained that this balanced the incentivizes for already efficient hospitals to continue great performance, and allowed hospitals with historically high episode expenditures sufficient time to create care pathways and implement practice pattern changes before getting to 100 percent regional pricing in years 4 and 5 of the CJR model. Some other commenters recommended for hospital-specific pricing only because any definition of region would not properly account for variations due to factors such as patient characteristics, socioeconomic factors, and access to care.

Some commenters recommended that instead of blending regional and hospital-specific historical average CJR episode payments, we use the higher of the two to reward hospitals that are already efficient.

Some commenters recommended that we delay the transition to regional pricing in order to afford more time for hospitals with high historic episode expenditures, some commenters supported our proposal to get to 100 percent regional pricing by year 4, and some others recommended that we accelerate the transition to regional pricing to appropriately reward already efficient participant hospitals.

Response: We appreciate commenters' support for blending hospital-specific and regional historical episode data to calculate target prices. We appreciate that the pace of transitioning to regional pricing may benefit some participant hospitals more than others. However, we believe that the proposed approach to get to 100 percent regional pricing by year 4 strikes an appropriate balance between providing participant hospitals time to adapt while providing important information about the reduction in unnecessary variation in LEJR episode utilization patterns within a region that can be achieved.

We believe that only using hospital-specific pricing would not reward already efficient participant hospitals for maintaining high performance; participant hospitals that are already delivering efficient and high quality care would find it challenging to improve upon their own historical performance in order to qualify for reconciliation payments. Similarly, we believe that using the higher of regional and hospital-specific prices would not sufficiently incentivize inefficient participant hospitals to become more efficient; participant hospitals that have historically high episode expenditures would have less of an incentive to become significantly more efficient over the course of the model if they can qualify for reconciliation payments by improving only slightly relative to their own historical performance, while still being less efficient than their regional peers.

We acknowledge the importance of properly accounting for variations in patient-specific clinical characteristics, socioeconomic conditions, and access to care to appropriately incentivize participant hospitals to deliver high quality and efficient care. We refer readers to response to comments in section III.C.4.b.(1) of this final rule for further discussion on risk stratification to account for such variations. We also acknowledge that incorporating a regional component of historical episode data into a participant hospital's target prices may increase the presence of the variations as

[29] Medicare FFS Parts A and B claims, CJR episodes, as proposed in this rule, between October 2013 and September 2014.

commenters stated, thereby making appropriate risk adjustment and/or risk stratification that much more important. As discussed in the response to comments in section III.C.4.b.(1) of this final rule, we will risk stratify based on anchor MS–DRG and hip fracture status, and we may explore more comprehensive risk adjustment approaches.

Comment: Several commenters recommended modifying the definition of low volume as it is used to determine which participant hospitals receive 100 percent regional target prices because they do not have a sufficient number of CJR episodes in the 3-historical-years of data used to calculate target prices. Commenters suggested increasing the low volume threshold for hospital-specific and regional target pricing from 20 to, for example, 100 episodes, because 20 episodes was not sufficient to remove random variation.

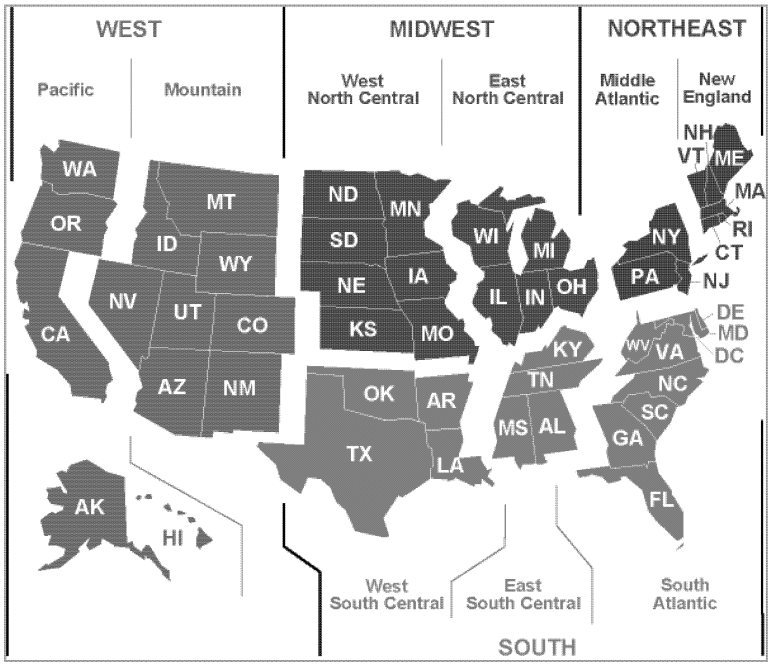
Response: We agree with commenters that a greater number of participant hospital-specific episodes would better remove the effects of random variation. However, if we increase the low volume threshold for blending hospital-specific and regional target prices, more participant hospitals would receive 100 percent regional prices in the first three performance years of the model, and their target prices would not incorporate any data from hospital-specific historical experience. Let us take as an example a participant hospital that has 50 episodes in the 3-historical-years of data used to calculate target prices for performance year 1, and let us assume that the hospital-specific portion of its target price is higher than the regional component. This participant hospital would need to become more efficient so as to achieve actual episode expenditures below its target prices. By blending the hospital-specific and regional components of the target price, this hospital has a higher target price than it would have had it received a 100 percent regional price. With the higher target price, the participant hospital has a greater opportunity to improve its efficiency and qualify for reconciliation payments. The blending of regional and hospital-specific target prices affords historically less efficient hospitals an opportunity to be rewarded for improvement in the earlier performance years, while they prepare for transitioning to 100 percent regional pricing by performance year 4. We want to afford this transition opportunity to as many participant hospitals as possible, while minimizing the effect of random variations for hospitals with few historical episodes. In the proposed rule, we compared our proposed low volume threshold of 20 episodes to the threshold used for Medicare's HRRP program. We continue to believe that 20 episodes in the 3-historical-years of data used to calculate target prices is the appropriate ''low volume'' threshold for blending target prices that mitigates effects of random variation while still incorporating hospital-specific historical experience and affording participant hospitals an opportunity to transition to 100 percent regional pricing.

Final Decision: After consideration of the public comments we received, we are finalizing the proposal to blend hospital-specific and regional historical expenditures in setting target prices, though we note that the term ''CJR eligible hospitals' is being renamed to ''CJR regional hospitals'' as discussed in response to comments in section III.C.4.b.(4) of this final rule.

(6) Define Regions as U.S. Census Divisions

In all 5 performance years we proposed to define ''region'' as one of the nine U.S. Census divisions [30] in Figure 3.

FIGURE 3: U.S. CENSUS DIVISIONS[31]



[30] There are four census regions—Northeast, Midwest, South, and West. Each of the four census regions is divided into two or more ''census divisions''.''. Source: *https://www.census.gov/geo/reference/gtc/gtc_census_divreg.html.*. Accessed on April 15, 2015.

We considered using states, HRRs, and the entire U.S. as alternative options to U.S. Census divisions in defining the region used in blending provider-specific and regional historical episode data for calculating target prices. However, HRR definitions are specifically based on referrals for cardiovascular surgical procedures and neurosurgery, and may not reflect referral patterns for orthopedic procedures. Using the entire U.S. would not account for substantial current regional variation in utilization, which is significant for episodes that often involve PAC use, such as LEJR procedures.[32] Finally, we considered using states as regions but were concerned that doing so would not allow for sufficient LEJR episode volume to set stable regional components of target prices, especially for participant hospitals in small states. We believe U.S. Census divisions provide the most appropriate balance between very large areas with highly disparate utilization patterns and very small areas that would be subject to price distortions due to low volume or hospital-specific utilization patterns.

We sought comment on our proposal to define a region as the U.S. Census division for purposes of the regional component of blended target prices under CJR.

The following is a summary of the comments received and our responses.

Comment: Some commenters supported the use of U.S. Census divisions as regions. Some commenters, though, stated U.S. Census divisions are too large with significant practice and PAC access variations, resulting in different average historical expenditures across hospitals in the same U.S. Census division. Some commenters suggested an alternative of using MSAs as regions; MSAs would align with the provider selection process, and the smaller unit for regions would better capture regional practice pattern differences. Other commenters, including MedPAC, stated that we should define the entire nation as the region (that is, national pricing) because we should be striving towards eliminating regional variations in practice patterns.

Response: We appreciate commenters' support for the use of U.S. Census divisions as regions. Especially given that commenters proposed both larger regions (that is, national pricing) and smaller regions (that is, MSAs), we still believe U.S. Census divisions provide the most appropriate balance between very large areas with highly disparate utilization patterns and very small areas that would be subject to price distortions due to low volume or hospital specific utilization patterns.

Comment: Several commenters noted that some of the selected MSAs for participation in CJR span two different U.S. Census divisions. These commenters stated that the true cost for hospitals in the same MSA would likely not be different, and significant differences in pricing would create unfair market advantages due to a hospital's address within an MSA. They suggested blending the regional target price component of the two U.S. Census divisions that are being spanned for each of these MSAs, reflecting the distribution of the population within the MSA/census regions.

Response: We agree with commenters that the true cost for hospitals in the same MSA may not be different, and significant differences in pricing may create unfair market advantages due to a hospital's address within an MSA. We will modify our proposal and apply the same regional target price component to target pricing for all participant hospitals within an MSA, even if the MSA spans two U.S. Census divisions. There are three selected MSAs for participation in CJR that span two U.S. Census divisions: St. Louis, Cincinnati, and Cape Girardeau.

We considered the approach suggested by commenters—blending the two regional target price components based on the population distribution. However, using 2010 U.S. Census data, we determined that at least 75 percent of the population in the previously mentioned MSAs resides in just one of the U.S. Census divisions that the MSA spans. For simplicity, we will completely group MSAs that span U.S. Census divisions together with the U.S. Census divisions in which the Census estimates the majority of people reside, as shown in Table 9:

TABLE 9—REGION GROUPING FOR SELECTED MSAS THAT SPAN U.S. CENSUS DIVISIONS

MSA	Original U.S. Census divisions spanned by MSA (state included in MSA)	U.S. Census division used for CJR region
St. Louis, MO-IL	West North Central (MO), East North Central (IL)	West North Central.
Cincinnati, OH-KY-IN	East North Central (OH, IN), East South Central (KY)	East North Central.
Cape Girardeau, MO-IL	West North Central (MO), East North Central (IL)	West North Central.

Final Decision: After consideration of the public comments we received, we are modifying our proposal to define regions as U.S. Census divisions so as to ascribe the same regional component of target prices for participant hospitals in MSAs that span U.S. Census divisions. Specifically, as described in Table 9, selected MSAs that span U.S. Census divisions will be attributed to one U.S. Census division for purposes of calculating the regional component of CJR target prices.

(7) Normalize for Provider-Specific Wage Adjustment Variations

We note that some variation in historical CJR episode payments across hospitals in a region may be due to wage adjustment differences in Medicare's payments. In setting Medicare payment rates, Medicare typically adjusts facilities' costs attributable to wages and wage-related costs (as estimated by the Secretary from time to time) by a factor (established by the Secretary) reflecting the relative wage level in the geographic area of the facility or practitioner (or the beneficiary residence, in the case of home health and hospice services) compared to a national average wage level. Such adjustments are essential for setting accurate payments, as wage levels vary significantly across geographic areas of the country. However, having the wage level for one hospital influence the regional-component of hospital-specific and regional blended target prices for another hospital with a different wage level would introduce unintended pricing distortions not based on utilization pattern differences.

[31] *http://www.eia.gov/consumption/commercial/census_maps.cfm.*

[32] Hussey PS, Huckfeldt P, Hirshman S, Mehrotra A. Hospital and regional variation in Medicare payment for inpatient episodes of care [published online April 13, 2015]. JAMA Intern Med. doi:10.1001/jamainternmed.2015.0674.

In order to preserve how wage levels affect provider payment amounts, while minimizing the distortions introduced when calculating the regional-component of blended target prices, we proposed to normalize for wage index differences in historical episode payments when calculating and blending the regional and hospital-specific components of blended target prices. Calculating blended target prices from historical CJR episodes would help ensure we incentivize hospitals based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond hospitals' control.

We proposed to normalize for provider-specific wage index variations using the IPPS wage index applicable to the anchor hospitalization (that is, the IPPS wage index used in the calculation of the IPPS payment for the anchor hospitalization). The anchor hospitalization accounts for approximately 50 percent of the total episode expenditures, and the IPPS wage index is applied to IPPS payments in a similar manner as wage indices for other Medicare payment systems are applied to their respective payments.[33] Therefore, we proposed that the IPPS wage index applicable to the anchor hospitalization for each historical episode be used to normalize for wage index variations in historical episode payments across hospitals when calculating blended target prices. We proposed to specifically perform this normalization using the wage normalization factor (0.7 * IPPS wage index + 0.3) to adjust the labor-related portion of payments affected by wage indices. The 0.7 approximates the labor share in IPPS, IRF PPS, SNF, and HHA Medicare payments. We would normalize for provider-specific wage index variations by dividing a hospital's historical episode payments by the wage normalization factor.

We proposed to reintroduce the hospital-specific wage variations by multiplying episode payments by the wage normalization factor when calculating the target prices for each participant hospital, as described in section III.C.4.c. of the proposed rule. When reintroducing the hospital-specific wage variations, the IPPS wage index would be the one that applies to the hospital during the period for which target prices are being calculated (for example, FY 2016 wage indices for the target price calculations for episodes that begin between January 1 and September 30, 2016). The specific order of steps, and how this step fits in with others, is discussed further in section III.C.4.c. of the proposed rule. We sought comment on our proposal to normalize for wage index differences using participant hospitals' wage indices in order to calculate blended target prices.

The following is a summary of the comments received and our responses.

Comment: Commenters emphasized the need to account for wage index differences. Not accounting for these differences accurately may unfairly disadvantage some hospitals. Some commenters expressed concern about using 0.7 as the labor share for the labor related portions of Medicare FFS payments; the weight index weight varies by Medicare FFS payment system, and in IPPS in particular, the weight can be either 0.688 or 0.620, depending on the IPPS hospital's wage index. Some other commenters noted that using only the IPPS wage index for the anchor hospital would not accurately normalize expenditures for PAC providers who have their own wage indices. Some of these commenters recommended we blend hospital and PAC providers' wage indices. Some commenters requested clarification on how we would account for wage index differences between baseline and performance periods.

Response: We acknowledge the need to accurately account for wage index differences so that we incentivize based on practice patterns and not Medicare FFS fee schedule differences. We recognize that the proposed approach of using the anchor hospital's wage index and 0.7 as the labor share for the labor related portions of Medicare FFS payments would only approximately normalize and reapply wage indices.

In response to commenters, we will modify our proposal and normalize for wage indices at the claim level for both historical episode expenditures and actual episode expenditures in each performance year by using the wage index normalization algorithm included in the CMS Price (Payment) Standardization Detailed Methodology discussed in section III.C.3 of this final rule, the same methodology we finalized to exclude the various special payment provisions in calculating episode expenditures. By normalizing claims for wage indices in the historical episode expenditure data at the claim level, we will accurately account for wage indices and labor shares for various providers and suppliers under the different Medicare FFS payment systems. This will be a more accurate way than what we proposed to achieve the same goal of accounting for wage index differences so that we incentivize based on practice patterns and not Medicare FFS wage adjustment differences. We will also normalize claims for wage indices in performance year data, as we discuss further in response to comments in section III.C.6.a. of this final rule.

We believe it is still important to reintroduce wage index variations near the end of the target price calculation methodology. Participant hospitals may use their reconciliation payments to invest in care coordination or care delivery infrastructure, and we expect that the costs for such investments would vary by geography due to differences in local wages. For example, we expect that hiring a care coordinator would cost a participant hospital more in the New York metro region than in a rural part of New Mexico. If we do not reintroduce wage index variations into target price calculations, we would calculate reconciliation and repayment amounts that would not capture labor cost variation throughout the country, and participant hospitals in higher labor cost regions may see relatively less financial incentive to invest in improved care quality and efficiency. We intend to incentivize all hospitals to reduce episode spending under the CJR model, regardless of local labor cost variations.

We will use the proposed approach to reintroduce wage index variations—apply the participant hospital's wage index to episode spending, using 0.7 as the labor share. While commenters are correct that the IPPS labor share can be 0.688 or 0.620, depending on the participant hospital's wage index, the labor share for PAC providers also varies across Medicare FFS payment systems: ~0.695 for SNF PPS and IRF PPS, and ~0.785 for HH PPS. Given this range for the labor share across Medicare FFS payment systems, we believe that using 0.7 is an appropriate estimate of the labor share for reintroducing wage index variations. Additionally, as commenters pointed out, PAC providers have their own wage indices. Because wage index variations are reintroduced near the end of the target price calculation methodology and after other features, such as blending, pooling, and update factors are applied, we do not believe there is a simple approach to reintroduce wage index variations at the claim level. We acknowledge that using the participant hospital's wage index and 0.7 as the labor share would only be an approximation of the wage index variations, but this approximation would not change whether a participant hospital qualifies for reconciliation

[33] Medicare FFS Parts A and B claims, CJR episodes, as proposed in this rule, between October 2013 and September 2014.

payments or is obligated to repay Medicare because we would apply wage index normalization at the claim level for both target price calculations (as previously discussed) as well as calculations of actual episode spending (as discussed in response to comments in section III.C.6.a. of this final rule), and the wage index variation would be reintroduced in the same manner to both target price calculations (as previously discussed) and actual episode spending calculations (as discussed in response to comments in section III.C.6.a. of this final rule). We believe that this approach to reintroducing wage index variations is sufficient to modulate the reconciliation and repayment amounts to reflect local labor cost variations.

Final Decision: After consideration of the public comments we received, we are modifying our proposal so as to normalize for wage indices at the claim level by using the wage index normalization algorithm included in the CMS Price (Payment) Standardization Detailed Methodology discussed in section III.C.3., the same claim-level standardization methodology we finalized in section III.C.3.a. to exclude the various special payment provisions in calculating episode expenditures. We are finalizing the proposal to reintroduce wage index differences into calculations of historical and actual episode spending based on the participant hospital's wage index and 0.7 as the labor cost share.

(8) Combination of CJR Episodes Anchored by MS–DRGs 469 and 470

We proposed to pool together CJR episodes anchored by MS–DRGs 469 and 470 for target price calculations to use a greater historical CJR episode volume and set more stable target prices. We note that we would still calculate separate target prices for episodes anchored by MS–DRGs 469 versus 470, described later in this section.

To pool together MS–DRG 469 and 470 anchored episodes, we proposed to use an anchor factor and hospital weights. The anchor factor would equal the ratio of national average historical MS–DRG 469 anchored episode payments to national average historical MS–DRG 470 anchored episode payments. The national average would be based on episodes attributed to any CJR eligible hospital. The resulting anchor factor would be the same for all participant hospitals. For each participant hospital, a hospital weight would be calculated using the following formula, where episode counts are participant hospital-specific and based on the episodes in the 3-historical-years used in target price calculations:

$$\frac{\textit{Count of MS DRG 469 and MS DRG 470 anchored episodes}}{\textit{MS DRG 469 anchored episode count} * \textit{anchor factor} + \textit{MS DRG 470 anchored episode count}}$$

A hospital-specific pooled historical average episode payment would be calculated by multiplying the hospital's hospital weight by its combined historical average episode payment (sum of MS–DRG 469 and 470 anchored historical episode payments divided by the number of MS–DRG 469 and 470 historical episodes).

The calculation of the hospital weights and the hospital-specific pooled historical average episode payments would be comparable to how case mix indices are used to generate case mix-adjusted Medicare payments. The hospital weight essentially would count each MS–DRG 469 triggered episode as more than one episode (assuming MS–DRG 469 anchored episodes have higher average payments than MS–DRG 470 anchored episodes) so that the pooled historical average episode payment, and subsequently the target price, is not skewed by the hospital's relative breakdown of MS–DRG 469 versus 470 anchored historical episodes.

The hospital-specific pooled historical average payments would be modified by blending and discount factors, as described in section III.C.4.c. of the proposed rule. Afterwards, the hospital-specific pooled calculations would be ''unpooled'' by setting the MS–DRG 470 anchored episode target price to the resulting calculations, and by multiplying the resulting calculations by the anchor factor to produce the MS–DRG 469 anchored target prices.

We would calculate region-specific weights and region-specific pooled historical average payments following the same steps proposed for hospital-specific weights and hospital-specific pooled average payments. Instead of grouping episodes by the attributed hospital as is proposed for hospital-specific calculations, region-specific calculations would group together episodes that were attributed to any CJR eligible hospital located within the region. The hospital-specific and region-specific pooled historical average payments would be blended together as discussed in section III.C.4.b.(3) of the proposed rule. The specific order of steps, and how this step fits in with others, is discussed further in section III.C.4.c. of the proposed rule.

We considered an alternative option of independently setting target prices for MS–DRG 470 and 469 anchored episodes without pooling them. However, hospital volume for MS–DRG 469 was substantially less than for MS–DRG 470. In 2013 across all IPPS hospitals, there were more than 10 times as many MS–DRG 470 anchored episodes as compared to MS–DRG 469 anchored episodes.[34] In the same analysis, the median number of episodes for a hospital with at least 1 episode for the MS–DRG anchored episode was more than 80 for MS–DRG 470 anchored episodes, though fewer than 10 for MS–DRG 469 anchored episodes. Calculating target prices for MS–DRG 469 anchored episodes separately for each participant hospital may result in too few historical episodes to calculate reliable target prices. We also considered pooling together MS–DRG 469 and 470 anchored episodes without any anchor factor or hospital weights. However, internal analyses suggest that average episode payments for these two MS–DRG anchored episodes significantly differed; CJR episodes initiated by MS–DRG 469 had payments almost twice as large as those initiated by MS–DRG 470.[35] This difference is reasonable given that Medicare IPPS payments differ for MS–DRG 469 and 470 admissions, and inpatient payments comprise approximately 50 percent of CJR episode payments. Thus, pooling together MS–DRG 469 and 470 anchored episodes without any anchor factor or hospital weights would introduce distortions due only to case-mix differences.

The following is a summary of the comments received and our responses.

[34] Source: CCW Part A and Part B claims for CJR episodes beginning in CY 2013.

[35] Medicare FFS Parts A and B claims, CJR episodes, as proposed in this rule, between October 2013 and September 2014.

Comment: Many commenters requested for risk adjustment based on patients' hip fracture status, among other clinical and demographic dimensions.

Response: We refer readers to comments and responses to comments in section III.C.4.b.(1) of this final rule for further discussion on risk stratification, and we reference it here because changes to risk stratification would impact how we would combine CJR episodes anchored by MS–DRGs 469 and 470. As discussed in the responses to comments in section III.C.4.b.(1) of this final rule, we will modify our proposal so as to risk stratify and set different target prices both for episodes anchored by MS–DRG 469 vs. MS–DRG 470 and for episodes with hip fractures vs. without hip fractures. To fully incorporate this change, we will also modify the proposed approach to calculate anchor factors and hospital and regional weights so as to apply them to four groups of target prices, instead of two groups; otherwise, the approach will be the same as proposed. Specifically, we will have three anchor factors, instead of one:

$$anchor\ factor\ for\ MS-DRG\ 469\ with\ hip\ fracture = \frac{Natl.avg.\ MS-DRG\ 469\ with\ hip\ fracture\ episode\ spend}{Natl.avg.MS-DRG\ 470\ without\ hip\ fracture\ episode\ spend}$$

$$anchor\ factor\ for\ MS-DRG\ 469\ without\ fracture = \frac{Natl.avg.\ MS-DRG\ 469\ without\ hip\ fracture\ episode\ spend}{Natl.avg.MS-DRG\ 470\ without\ hip\ fracture\ episode\ spend}$$

$$anchor\ factor\ for\ MS-DRG\ 470\ with\ hip\ fracture = \frac{Natl.avg.\ MS-DRG\ 470\ with\ hip\ fracture\ episode\ spend}{Natl.avg.MS-DRG\ 470\ without\ hip\ fracture\ episode\ spend}$$

Additionally, hospital and regional weights will be calculated using the following formula:

$$\frac{Count\ of\ MS\ DRG\ 469\ and\ MS\ DRG\ 470\ anchored\ episodes}{\begin{array}{c}MS\ DRG\ 469\ anchored\ with\ hip\ fracture\ episode\ count*anchor\ factor\ for\ MS-DRG\ 469\ with\ hip\ fracture\ +\\ MS-DRG\ 469\ anchored\ without\ hip\ fracture\ episode\ count*anchor\ factor\ for\ MS-DRG\ 469\ without\ fracture+\\ MS-DRG\ 470\ anchored\ with\ hip\ fracture\ episode\ count*anchor\ factor\ for\ MS-DRG\ 470\ with\ hip\ fracture+\\ MS\ DRG\ 470\ anchored\ without\ hip\ fracture\ anchored\ episode\ count\end{array}}$$

Final Decision: After consideration of the public comments we received, we are finalizing our proposal, with modification to calculate anchor factors and hospital and regional weights while incorporating the previously discussed changes to risk adjust not only on anchor MS–DRG but also hip fracture status. Additionally, note that the term ''CJR eligible hospitals'' is being renamed to ''CJR regional hospitals'' as discussed in response to comments in section III.C.4.b.(4) of this final rule.

(9) Discount Factor

When setting an episode target price for a participant hospital, we proposed to apply a discount to a hospital's hospital-specific and regional blended historical payments for a performance period to establish the episode target price that would apply to the participant hospital's CJR episodes during that performance period and for which the hospital would be fully, or partly, accountable for episode spending in relationship to the target price, as discussed in section III.C.3. of the proposed rule. We expect participant hospitals to have significant opportunity to improve the quality and efficiency of care furnished during episodes in comparison with historical practice, because this model would facilitate the alignment of financial incentives among providers caring for beneficiaries throughout the episode. This discount would serve as Medicare's portion of reduced expenditures from the CJR episode, with any episode expenditure below the target price potentially available as reconciliation payments to the participant hospital where the anchor hospitalization occurred. We proposed to apply a 2 percent discount for performance years 1 through 5 when setting the target price. We stated our belief in the proposed rule that applying a 2 percent discount in setting the episode target price allows Medicare to partake in some of the savings from the CJR model, while leaving considerable opportunity for participant hospitals to achieve further episode savings below the target price that they would be paid as reconciliation payments, assuming they meet the quality requirements as discussed in section III.C.5 of the proposed rule.

The proposed 2 percent discount is similar to the range of the discounts used for episodes in the ACE demonstration.[36] In the Medicare ACE,

[36] IMPAQ International. Evaluation of the Medicare Acute Care Episode (ACE) Demonstration: Final Evaluation Report. Columbia, MD: IMPAQ International; May 2013. *http://downloads.cms.gov/*

Continued

a demonstration program that included orthopedic procedures such as those included in CJR, participant hospitals negotiated with Medicare discounts of 2.5 to 4.4 percent of all Part A orthopedic services and 0.0 to 4.4 percent of all Part B orthopedic services during the inpatient stay (excluding PAC). Hospitals received the discounted payment and reported that they were still able to achieve savings.[37] We stated our belief in the proposed rule that there is similar, if not potentially more, opportunity for savings in the CJR payment model because it includes acute inpatient, as well as PAC, an area of episode spending that accounts for approximately 25 percent of CJR episode payments and exhibits more than 2 times the episode payment variation [38] than that of acute inpatient hospitalization.[39] We stated in the proposed rule our belief that with the proposed 2 percent discount, participant hospitals have an opportunity to create savings for themselves as well as Medicare, while also maintaining or improving quality of care for beneficiaries.

The proposed 2 percent discount also matches the discount used in the BPCI Model 2 90-day episodes, and is less than the discount used in BPCI Model 2 30-day and 60-day episodes (3 percent). Hundreds of current BPCI participants have elected to take on responsibility for repayment in BPCI Model 2 with a 2 to 3 percent discount. Because many BPCI participants volunteered to participate in a bundled payment model with a discount, we stated in the proposed rule our belief that a discount percent that is within, and especially a discount of 2 percent that is at the lower end of, the BPCI discount range would allow CJR participant hospitals to create savings for both themselves and Medicare.

As stated previously in section III.C.3. of the proposed rule, we proposed to phase in the financial responsibility of hospitals for repayment of actual episode spending that exceeds the target price starting in performance year 2. In order to help hospitals transition to taking on this responsibility, we proposed to apply a reduced discount of one percent in performance year 2 for purposes of determining the hospital's responsibility for excess episode spending, but maintain the 2 percent discount for purposes of determining the hospital's opportunity to receive reconciliation payment for actual episode spending below the target price. For example, under this proposal in performance year 2, a hospital that achieves CJR actual episode payments below a target price based on a 2 percent discount would retain savings below the target price, assuming the quality thresholds for reconciliation payment eligibility are met (discussed in section III.C.5. of the proposed rule) and the proposed performance year stop-gain limit (discussed in section III.C.8. of the proposed rule) does not apply. Medicare would hold responsible for repayment hospitals whose CJR actual episode payments exceed a target price based on a one percent discount, assuming the proposed performance year 2 stop-loss limit (discussed in section III.C.8. of the proposed rule) does not apply. Hospitals that achieve CJR actual episode payments between a 2 percent-discounted target price and 1 percent-discounted target price would neither receive reconciliation payments nor be held responsible for repaying Medicare. The decision on which percent-discounted target price applies will be made by evaluating actual episode payments in aggregate after the completion of performance year 2, and the same percent-discounted target price would apply to all episodes that are initiated in performance year 2. We proposed to apply this reduced one percent discount for purposes of hospital repayment responsibility only in performance year 2 and apply the 2 percent discount for excess episode spending repayment responsibility for performance years 3 through 5. Under this proposal, the discount for determination of reconciliation payment for episode actual spending below the target price would not deviate from 2 percent through performance years 1 through 5.

In section III.C.5. of the proposed rule, we proposed voluntary submission of data for a patient-reported outcome measure. We proposed to incent participant hospitals to submit data on this measure by reducing the discount percentage by 0.3 percentage points for successfully submitting data, as defined in section III.D. of the proposed rule. By successfully submitting data on this metric for episodes ending in performance years 1, 2, 3, 4, and or 5, we would adjust the discount percentage in the corresponding year(s) as follows:

- For episodes beginning in performance year 2, set the discount percentage in a range from 2 percent to 1.7 percent for purposes of determining the hospital's opportunity to receive reconciliation payment for actual episode spending below the target price, and set the discount percentage in a range from 1 percent to 0.7 percent for purposes of determining the amount the hospital would be responsible for repaying Medicare for actual episode spending above the target price.
- For episodes beginning in performance years 3 through 5, set the discount percentage in a range from 2 percent to 1.7 percent for purposes of reconciliation payment and Medicare repayment calculations.

The determination of whether the hospital successfully submitted data on the patient-reported outcome measure cannot be made until after the performance year ends and data is reported. Therefore, participant hospitals would be provided target prices for both scenarios whether the successfully submit data or not and such determination will happen at the time of payment reconciliation (discussed further in section III.C.6. of the proposed rule).

We sought comment on our proposed discount percentage of 2 percent for CJR episodes, our proposal to reduce the discount to 1 percent on a limited basis in performance year 2, and our proposal to reduce the discount by 0.3 percentage points for successfully reporting patient-reported outcomes data in the corresponding year.

The following is a summary of the comments received and our responses.

Comment: Many commenters expressed concern about participant hospitals taking on financial risk in the CJR model. We refer readers to comments in section III.C.2, of this final rule for more discussion of such comments, and we reference them here because these comments may impact how the proposed discount factor is used to phase in risk for participant hospitals.

Response: As discussed in the responses to comments in section III.C.2. of this final rule, we appreciate commenters' concerns about participant hospitals' ability to manage risk. In the proposed rule, we proposed to use several design elements to phase in risk to better help transition participant hospitals. One of these design elements to phase risk in was the use of a reduced discount factor by 1 percentage point for

files/cmmi/ACE-EvaluationReport-Final-5-2-14.pdf. Accessed April 16, 2015.

[37] IMPAQ International. Evaluation of the Medicare Acute Care Episode (ACE) Demonstration: Final Evaluation Report. Columbia, MD: IMPAQ International; May 2013. *http://downloads.cms.gov/files/cmmi/ACE-EvaluationReport-Final-5-2-14.pdf.* Accessed April 16, 2015.

[38] Variation for purposes of this calculation refers to standard deviation of inpatient and institutional post-acute episode payments as a percentage of average inpatient and post-acute episode payments, respectively.

[39] Medicare FFS Parts A and B claims, CJR episodes, as proposed in this rule, between October 2013 and September 2014.

purposes of calculating repayment amounts in performance year 2, as discussed earlier in this section. In response to commenters' concerns, we will extend the use of a reduced discount factor for purposes of calculating repayment amounts to apply not only in performance year 2, but also in performance year 3.

Comment: Many commenters offered a variety of suggestions to CMS's proposal and alternatives considered to link quality and payment in the CJR model, including varying the discount percentage incorporated in the target price at reconciliation based on the participant hospital's quality performance. We refer readers to comments in section III.C.5 of this final rule for greater discussion of comments on linking quality and payment in the CJR mode.

Response: As discussed in the responses to comments later in this final rule in section III.C.5. of this final rule, we are modifying the proposed rule so as to use a composite score methodology to link quality and payment in the CJR model. With this composite score methodology, each hospital will receive a discount factor of 3 percent, though the discount factor would be 2 percent for purposes of calculating repayments to Medicare in performance years 2 and 3, reflecting the proposed discount factor reduction by 1 percentage point and the extension to performance year 3 of this reduction, to phase in downside risk, as discussed in the previous response.

Each participant hospital may qualify for a quality incentive payment. The quality incentive payment would not be a separate payment stream, but rather it would alter a hospital's effective discount factor used to calculate its target prices. Depending on a participant hospital's quality performance, in performance years 1, 4, and 5, the quality incentive payments could result in effective discount factors ranging from 3 percent to 1.5 percent. In performance years 2 and 3, the quality incentive payments could result in effective discount factors for purposes of calculating reconciliation payments ranging from 3 percent to 1.5 percent, and for purposes of calculating repayment amounts from 2 percent to 0.5 percent. We note that the lower effective discount factors for calculating repayment amounts in performance years 2 and 3 reflect the reduction by 1 percentage point in discount factor to phase in downside risk.

If hospitals' quality performance during the CJR model mirrors historical quality performance, we expect the majority of the participant hospitals to qualify for an effective discount factor of 2 percent each performance year for purposes of reconciliation payment calculations, the same discount factor proposed for all participant hospitals in the proposed rule. By using a range of discount factors, we will offer more participant hospitals an opportunity to qualify for reconciliation payments, and we will be able to better reward the highest quality participant hospitals.

We refer readers to responses to comments in section III.C.5 of this final rule for more details on quality incentive payments, effective discount factors, the link between quality and payment, and how participant hospitals may perform based on historical quality performance.

Comment: Some commenters recommended that we not apply a discount factor to any hospital because it would effectively function as a rate cut for MS–DRGs 469 and 470. Some of these commenters suggested we could achieve savings using a shared savings methodology (for example, participant hospitals would receive 50 percent of actual episode performance below undiscounted target prices, and would repay 50 percent of actual episode performance above undiscounted target prices).

Response: We disagree with commenters that a discount factor is the equivalent of a rate cut. We are providing participant hospitals the opportunity to qualify for reconciliation payments for delivering high quality and efficient care for LEJR episodes, and reconciliation payments may likely exceed the value of the discount factor.

The discount factor will serve as Medicare's portion of reduced expenditures from the CJR episode. We acknowledge that there are other potential mechanisms, including shared savings methodologies, to provide savings to Medicare while also incentivizing participant hospitals. However, we also believe that a discount model, as proposed, can also incentivize participant hospitals to deliver high quality and efficient care while also providing savings to Medicare. We appreciate commenters' suggestions and we may consider alternative methodologies, such as shared savings, in the future.

Comment: Several commenters requested that we not apply a discount factor to hospitals that are already efficient because they would not be able to achieve further efficiencies. It would be challenging for these efficient hospitals to qualify for reconciliation payments if benchmarked against a target price that incorporates a discount factor.

Response: Commenters' concerns could be valid if we were basing target prices only on hospital-specific episode expenditure data. However, because we are blending hospital-specific and regional components in the target price calculation, and transitioning to completely regional target prices by performance year 4, target prices for more efficient hospitals likely would be higher than what they would be under a hospital-specific only pricing approach. We believe that with the blending and transition to regional pricing, historically efficient and high quality participant hospitals have a significant opportunity to qualify for reconciliation payments. Additionally, as discussed in the response to comments in section III.C.5. of this final rule, we are modifying our proposal to provide lower effective discount factors used to calculate target prices for participant hospitals with better quality performance. Therefore, high quality participant hospitals will have a lower hurdle to overcome to qualify for reconciliation payments. We will continue to incorporate a discount percentage into the target price for every participant hospital, and we will use a reduced discount factor for participant hospitals with high quality performance, as stated previously in this section's responses to comments and in section III.C.5. of this final rule.

Comment: Commenters requested upfront investments to fund care delivery (for example, care coordination), infrastructure, and quality reporting changes that participant hospitals may need to make, similar to how some ACOs use upfront investments in other models and programs (for example, an initiative similar to the ACO Investment Model for Medicare Shared Savings Program participants). Commenters suggested we fund these upfront investments in a number of ways, including the following: a supplemental lump sum payment at the start of the model; increase, instead of discount, historical episode expenditures by 2 percent; or transition in an increasing discount factor, getting to 2 percent by the end of the model.

Response: We thank the commenter for the suggestion and for recognizing the importance of potential care delivery, infrastructure, and quality reporting changes participant hospitals may need to make for an episode-based payment model such as CJR. However, we do not believe that an additional upfront payment mechanism such as a per-beneficiary-per-month payment or an additional payment per episode will be necessary for hospitals to

successfully participate in this model. In BPCI, a similar episode-based payment model, participants have been able to improve episode expenditure performance without such additional upfront payment mechanisms.

Additionally, we believe there may be low investment opportunities for participant hospitals to achieve high quality and efficiency and qualify for reconciliation payments in this model. For example, participant hospitals may refer to high quality and efficient PAC providers when appropriate, and updates to discharge and referral patterns may be informed using already publicly available quality data and historical episode expenditure data provided by CMS and discussed in section III.E. of this final rule. PAC expenditures account for a significant proportion of historical CJR episode expenditures (approximately 30 percent [40]), and changes to discharge and referral patterns could have significant impact on participant hospitals' actual episode expenditure performance. We note that this rationale may not hold true for other models (for example, patient-centered medical homes, ACOs) where providers are responsible for beneficiaries' cost of care over a longer period of time.

We also reiterate that as discussed in section III.C.5.b. of this final rule, the quality measures selected for this model are already in use for mandatory CMS quality reporting programs, such as the IQR program. Hospitals will not experience an additional reporting burden under this model for such measures. In addition, while we are including testing of a voluntary patient-reported outcomes measures, as discussed in section III.C.5.b.2. of this final rule, reporting of this measure will be voluntary. We do not believe there is any required additional burden on participant hospitals to report quality data.

Given the success of participants in a similar model, the possibility to achieve reconciliation payments with relatively low investment approaches, and the lack of required additional quality reporting burden, we will not make additional upfront payments through mechanisms such as per-beneficiary-per-month payments or additional payments per episode.

Final Decision: After consideration of the public comments we received, we are modifying our proposal to use a composite score methodology to link quality and payment in the CJR model. With this composite score methodology, a participant hospital may qualify for a reconciliation payment and for different effective discount factors depending on its quality performance. We refer readers to section III.C.5. of this final rule more details on how quality and payment will be linked.

[40] Medicare FFS Parts A and B claims, CJR episodes, as proposed in this rule, between October 2013 and September 2014.

c. Approach To Combine Pricing Features

In section III.C.4.(b) of the proposed rule we discuss the various features we proposed to incorporate into our approach to set target prices. We refer readers to that section for more information on rationale and alternatives considered for each feature. In this section we discuss how the different pricing features, as well as the episode definition (section III.B. of the proposed rule) and adjustments to payments included in the episodes (section III.C.3. of the proposed rule), would fit together and be sequenced to calculate CJR episode target prices for participant hospitals. The following steps would be used to calculate MS–DRG 469 and 470 anchored episode target prices for both January 1 through September 30 and October 1 through December 31 each performance year. The output of each step would be used as the input for the subsequent step, unless otherwise noted.

- (1) Calculate historical CJR episode payments for episodes that were initiated during the 3-historical-years (section III.C.4.b.(2) of the proposed rule) for all CJR eligible hospitals for all Medicare Part A and B services included in the episode. We note that specific Per Beneficiary Per Month (PBPM) payments may be excluded from historical episode payment calculations as discussed in section III.C.7.d. of the proposed rule.
- (2) Remove effects of special payment provisions (section III.C.3.a. of the proposed rule).
- (3) Prorate Medicare payments for included episode services that span a period of care that extends beyond the episode (section III.C.3.b of the proposed rule.).
- (4) Normalize for hospital-specific wage adjustment variation by dividing the episodes outputted in step (3) by the hospital's corresponding wage normalization factor described in section III.C.4.b.(7) of the proposed rule.
- (5) Trend forward 2 oldest historical years of data to the most recent year of historical data. As discussed in section III.C.4.b.(3) of the proposed rule, separate national trend factors would be applied to episodes anchored by MS–DRG 469 versus MS–DRG 470.
- (6) Cap high episode payment episodes with a region and MS–DRG anchor-specific high payment ceiling as discussed in section III.C.3.c. of the proposed rule, using the episode output from the previous step. We have posted region-specific historical average episode payments on the CJR Web site at *http://innovation.cms.gov/initiatives/CJR/*. Note that these historical average episode payments were based on our proposed policies and do not represent actual target prices or the regional portion of actual target prices under the model.
- (7) Calculate anchor factor and participant hospital-specific weights (section III.C.4.b.(8) of the proposed rule) using the episode output from the previous step to pool together MS–DRG 469 and 470 anchored episodes, resulting in participant hospital-specific pooled historical average episode payments. Similarly, calculate region-specific weights to calculate region-specific pooled historical average episode payments.
- (8) Calculate participant hospital-specific and region-specific weighted update factors as described in section III.C.4.b.(4) of the proposed rule. Multiply each participant hospital-specific and region-specific pooled historical average episode payment by its corresponding participant hospital-specific and region-specific weighted update factors to calculate participant hospital-specific and region-specific updated, pooled, historical average episode payments.
- (9) Blend together each participant hospital-specific updated, pooled, historical average episode payment with the corresponding region-specific updated, pooled, historical average episode payment according to the proportions described in section III.C.4.b.(5) of the proposed rule. Participant hospitals that do not have the minimum episode volume across the historical 3 years would use 0.0 percent and 100 percent as the proportions for hospital and region, respectively.
- (10) Reintroduce hospital-specific wage variations by multiplying the participant hospital-specific blended, updated, and pooled historical average episode payments by the corresponding hospital-specific wage normalization factor, using the hospital's IPPS wage index that applies to the hospital during the period for which target prices are being calculated (section III.C.4.b.(7) of the proposed rule).
- (11) Multiply the appropriate discount factor, as discussed in section III.C.4.b.(9) of the proposed rule to each participant hospital's wage-adjusted, blended, updated, and pooled historical

average episode payment. For performance years 1, 3, 4, and 5, two discount factors would be used, one if the hospital successfully submits data on the patient-reported outcomes measure proposed in section III.C.5. of the proposed rule, and one if the hospital does not successfully submit the data. For performance year 2, 4 discount factors would be used to account for the 4 combinations of the following: (a) Whether or not the hospital successfully submits data on the patient-reported outcomes measure; and (b) for the different discount factors proposed for purposes of calculating reconciliation payments vs. calculating repayment amounts. The result of this calculation would be the participant hospital-specific target prices for MS–DRG 470 anchored episodes.

• (12) Multiply participant hospitals' target prices for MS–DRG 470 anchored episodes by the anchor factor (section III.C.4.b.(8) of the proposed rule) to calculate hospitals' target prices for MS–DRG 469 anchored episodes.

The previously stated twelve steps would be used to calculate target prices for episodes that begin between January 1 and September 30, as well as for episodes that begin between October 1 and December 31, for each performance year. The target price calculations for the two different time periods each performance year would differ by the IPPS wage index used in step (11) and the update factors used in step (8). By following these twelve steps, we would calculate target prices for each participant hospital for each performance year. We refer readers to section III.C.4.b. of the proposed rule for further details on each of the specific steps.

We sought comment on the proposed approach to sequence and fit together the different pricing features, the episode definition (section III.B. of the proposed rule), and adjustments to payments included in the episodes (section III.C.3. of the proposed rule) to calculate CJR episode target prices for participant hospitals.

The following is a summary of the comments received and our responses.

Comment: Many commenters requested for risk adjustment based on patients' hip fracture status, among other clinical and demographic dimensions. Commenters also recommended that we modify the definition of ''CJR eligible hospitals'', the term used to identify hospitals included in calculations for the regional component of target prices, to not exclude hospitals that are participating in BPCI.

Response: We refer readers to comments and responses to comments in sections III.C.4.b.(1) and III.C.4.b.(4) of the final rule for further discussion on risk stratification and CJR eligible hospitals, respectively. We reference them here because changes to risk stratification and CJR eligible hospitals would impact how we would combine CJR pricing features. Given the changes to the proposed rule described in sections III.C.3, III.C.4.b, and III.C.5, we are modifying the different pricing features would fit together and be sequenced to calculate CJR episode target prices for participant hospitals. The following steps would be used to calculate different target prices in each performance year for each combination of anchor MS–DRG (469 vs. 470), hip fracture status (with hip fracture vs. without hip fracture), and period during which target prices are applicable within a performance year (episodes initiated January 1 through September 30 vs. October 1 through December 31 each performance year). The output of each step would be used as the input for the subsequent step, unless otherwise noted.

• (1) Calculate historical CJR episode payments for episodes that were initiated during the 3-historical-years (section III.C.4.b.(2) of this final rule) for all CJR eligible hospitals for all Medicare Part A and B services included in the episode. We note that specific PBPM payments may be excluded from historical episode payment calculations as discussed in section III.C.7.d. of this final rule.

• (2) Remove effects of special payment provisions (section III.C.3.a. of this final rule) and normalize for wage index differences (section III.C.4.b.(7) of this final rule) by standardizing Medicare FFS payments at the claim-level.

• (3) Prorate Medicare payments for included episode services that span a period of care that extends beyond the episode (section III.C.3.b of this final rule.).

• (4) Trend forward 2 oldest historical years of data to the most recent year of historical data. As discussed in section III.C.4.b.(3) of this final rule, separate national trend factors would be applied for each combination of anchor MS–DRG (469 vs. 470) and hip fracture status (with hip fracture vs. no hip fracture).

• (5) Cap high episode payment episodes with a region and MS DRG anchor specific high payment ceiling as discussed in section III.C.3.c. of this final rule, using the episode output from the previous step. We have posted region specific historical average episode payments on the CJR final rule Web site at *http://innovation.cms.gov/initiatives/CJR/*.

• (6) Calculate anchor factor and participant hospital specific weights (section III.C.4.b.(8) of this final rule) using the episode output from the previous step to pool together MS DRG 469 and 470 anchored episodes with and without hip fracture, resulting in participant hospital specific pooled historical average episode payments. Similarly, calculate region specific weights to calculate region specific pooled historical average episode payments.

• (7) Calculate participant hospital specific and region specific weighted update factors as described in section III.C.4.b.(4) of this final rule. Multiply each participant hospital specific and region specific pooled historical average episode payment by its corresponding participant hospital specific and region specific weighted update factors to calculate participant hospital specific and region specific updated, pooled, historical average episode payments.

• (8) Blend together each participant hospital specific updated, pooled, historical average episode payment with the corresponding region specific updated, pooled, historical average episode payment according to the proportions described in section III.C.4.b.(5) of this final rule. Participant hospitals that do not have the minimum episode volume across the historical 3 years would use 0.0 percent and 100 percent as the proportions for hospital and region, respectively. For purposes of this final rule, we will define the output of this step as the pre-discount target price for MS DRG 470 anchored episodes without hip fracture.

• (9) Multiply the output of step (8) by the appropriate anchor factors (step (6) of this target price calculation process and detailed in section III.C.4.b.(8) of this final rule) for MS DRG 469 anchored episodes with hip fracture, MS DRG 469 anchored episodes without hip fracture, and MS DRG 470 anchored episodes with hip fracture. For purposes of this final rule, we will define the outputs of this step as the pre-discount target prices for MS DRG 469 anchored episodes with hip fracture, MS DRG 469 anchored episodes without hip fracture, and MS DRG 470 anchored episodes with hip fracture.

• (10) Multiply the pre-discount target prices for MS DRGs 469 and 470 episodes with and without hip fracture by the appropriate effective discount factor that incorporates any quality incentive payment, as briefly described in section III.C.4.b.(9) of this final rule

and more specifically detailed in the response to comments in section III.C.5. of this final rule and Tables 19, 20, and 21. The results of these calculations will be participant hospitals' target prices for MS DRG 469 anchored episodes with hip fracture, MS DRG 469 anchored episodes without hip fracture, MS DRG 470 anchored episodes with hip fracture, and MS DRG 470 anchored episodes without hip fracture.

The previously stated 10 steps will be used to calculate target prices for episodes that begin between January 1 and September 30 (between April 1 and September 30 for performance year 1), as well as for episodes that begin between October 1 and December 31, for each performance year. The target price calculations for the two different time periods each performance year will differ by the update factors used in the seventh step. By following these ten steps, we will calculate target prices for each participant hospital for each performance year. We refer readers to section III.C.4.b. of this final rule for further details on each of the specific steps.

Final Decision: After consideration of the public comments we received, we are modifying our proposal to incorporate changes described in sections III.C.3, III.C.4.b, and III.C.5 of this final rule when fitting together and sequencing episode target price features used to calculate CJR episode target prices for participant hospitals.

These final policies are set forth at § 510.300 and § 510.305.

5. Use of Quality Performance in the Payment Methodology

a. Background

Over the past several years Medicare payment policy has moved away from FFS payments unlinked to quality and towards payments that are linked to quality of care. Through the Affordable Care Act, we have implemented specific IPPS programs like the HVBP program (subsection (o) of section 1886 of the Act), the Hospital Acquired Condition Reduction Program (HACRP) (subsection (q) of section 1886) and the HRRP (subsection (p) of section 1886), where quality of care is linked with payment. We have also implemented the Shared Savings Program, an ACO program that links shared savings payment to quality performance. Since the implementation of the HRRP in October 2012, readmission rates for various medical conditions like THA and TKA (THA/TKA) have improved. Trend analyses show a decrease in readmission rates and specifically with THA/TKA risk-standardized readmissions rates (RSRR) from 5.4 percent (July 2010–June 2011) to 4.8 percent (July 2012–June 2013).[41] Additionally, hospital THA/TKA RSCR decreased from 3.4 percent (April 2010 through March 2011) to 3.1 percent (April 2012 through March 2013). Despite the downward trend of THA/TKA RSRRs and RSCRs, the wide dispersion in these readmission rates suggests there is still room for hospitals to improve their performance on these measures as illustrated by a THA/TKA RSRR distribution of 2.8 to 9.4 percent (July 2010–June 2013) and a THA/TKA RSCR distribution of 1.5 to 6.4 percent (April 2010–March 2013). In the proposed rule, we stated our belief that the CJR model would provide another mechanism for hospitals to improve quality of care, while also achieving cost efficiency. Incentivizing high-value care through episode-based payments for LEJR procedures is a primary objective of CJR. Therefore, incorporating quality performance into the episode payment structure is an essential component of the CJR model. We also stated our belief that the financial opportunity discussed in section III.C.2. of the proposed rule would provide the appropriate incentives necessary to reward a participant hospital's achievement of episode savings when the savings are greater than the discounted target price. For the reasons stated previously, we discussed our belief that it would be important for the CJR model to link the financial reward opportunity with achievement in quality of care for Medicare beneficiaries undergoing LEJR.

As discussed in section III.C. of this final rule, which outlines the payment structure proposed for the CJR model, each participant hospital would have target prices calculated for MS–DRG 469 and 470 anchored episodes; each anchored episode would include an anchor hospitalization for an LEJR procedure and a 90–day period after the date of discharge from the anchor hospitalization. These episode target prices represent expected spending for all related Part A and Part B spending for such episodes, with a discount applied. Hospitals who achieve actual episode spending below a target price for a given performance period would be eligible for a reconciliation payment from CMS, subject to the proposed stop-gain limit policy as discussed in section III.C.8. of this final rule.

In the proposed rule, we proposed quality performance standards that must also be met in order for a hospital to be eligible to receive a reconciliation payment under CJR. Specifically, we described our proposal to include a performance measure result threshold on select outcomes-based quality measures as a requirement for participants to receive a reconciliation payment if actual episode spending is less than the target price under CJR in a performance year, in addition to a payment adjustment for successful reporting of a voluntary measure in development. Beginning in performance year one and continuing throughout the duration of the model, we proposed to make reconciliation payments only to those CJR hospital participants that met or exceeded a minimum measure result threshold. We also discussed an alternative approach to determining CJR reconciliation payment eligibility and adjusting payment based on a quality score developed from performance on three outcomes-based quality measures and success in reporting the voluntary measurement in development.

b. Implementation of Quality Measures in the Payment Methodology

In section III.D. of the proposed rule, we proposed three measures to assess quality of care of the hospitals participating in the CJR model. We also proposed voluntary data submission for a patient-reported outcome measure in development. In section III.C.5. of the proposed rule, we proposed using three measures to determine eligibility for a reconciliation payment, as well as proposed rewarding hospitals that voluntarily submit data for the patient-reported outcome measure. We also discussed an alternative approach to determining reconciliation payment eligibility and adjusting payment based on a composite quality score calculated from the three required outcome measures and success on reporting voluntary data on the patient-reported outcome measure.

(1) General Selection of Quality Measures

The CJR model is designed to provide financial incentives to improve coordination of care for beneficiaries that we expect to lead to avoidance of post-surgical complications and hospital readmissions, as well as to improve patient experience through care redesign and coordination. Furthermore, we acknowledge that achievement of savings while ensuring high-quality care for Medicare FFS beneficiaries in LEJR episodes would require close collaboration among hospitals,

[41] Hospital Quality Initiatives. CMS Hospital Quality Chartbook 2014. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf.* Accessed April 21, 2015.

physicians, PAC providers, and other providers and suppliers. In order to encourage care collaboration among multiple providers of patients undergoing THA and TKA, we proposed three measures, as described in detail in section III.D.2. of this final rule, to determine hospital quality of care and to determine eligibility for a reconciliation payment under the CJR model. The measures we proposed are as follows:

- Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (National Quality Forum (NQF)#1551), an administrative claims-based measure.
- Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550), an administrative claims-based measure.
- HCAHPS Survey measure (NQF #0166).

Beginning in performance year 1 and continuing throughout the duration of the model, we proposed to make reconciliation payments only to those CJR participant hospitals that met or exceeded a minimum performance threshold on the measures previously listed. We proposed that hospitals must meet or exceed the measure reporting thresholds and other requirements described in section III.C.5 and III.D. of this final rule on all three measures in order to be eligible for a reconciliation payment.

These three outcome measures were chosen due to their: (1) Alignment with the goals of the CJR model; (2) hospitals' familiarity with the measures due to their use in other CMS hospital quality programs, including programs that tie payment to performance such as HVBP and HRRP; and (3) assessment of CMS priorities to improve the rate of LEJR complications and readmissions, while improving patient experience. In the proposed rule, we stated our belief that the three quality measures we proposed for reconciliation payment eligibility reflected these goals and accurately measured hospitals' level of achievement on such goals.

(2) Adjustment to the Payment Methodology for Voluntary Submission of Data for Patient-Reported Outcome (PRO) Measure

During our consideration of quality metrics for the CJR model, we examined the feasibility of linking voluntary data submission of patient-reported outcomes, beyond the current three required measures discussed in section III.D.2. of this final rule for use in the model, with the possibility of incentivizing participant hospitals under the episode payment model to participate in this voluntary submission of data. We specifically examined potential patient-reported outcome measures since this type of outcome measure aligns with the CJR model goal of improving LEJR episode quality of care, including a heightened emphasis on patient-centered care where patients provide meaningful input to their care. Furthermore, the availability of patient reported outcome data would provide additional information on a participant hospital's quality performance, especially with respect to a patient's functional status, beyond the current three required measures discussed in section III.D.2. of this final rule for use in the model. We noted that we have a measure in development, the Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary THA or TKA measure or both (hence forth referred to as ''THA/TKA patient-reported outcome-based measure''), that would support the National Quality Strategy domain of patient and family engagement, and could capture meaningful information that would not otherwise be available on patient outcomes that are related to the quality of LEJR episodes under CJR. In the proposed rule, we stated our belief that incorporating this measure into CJR by adjusting the payment methodology for successful voluntary data submission on the THA/TKA patient-reported outcome-based measure (henceforth referred to as ''THA/TKA voluntary data'') would provide participant hospitals with valuable information on functional outcomes that would assist them in assessing an important patient-centered outcome, engaging other providers and suppliers in care redesign for LEJR episodes, as well as provide them with the potential for greater financial benefit from improved LEJR episode efficiencies. We did not believe it would be appropriate at this time to hold any participant hospitals financially accountable for their actual THA/TKA voluntary data, as we proposed to require for the three measures described in section III.C.5.b.(5) of this final rule.

Instead, we proposed to adjust the episode payment methodology for participant hospitals that successfully submit THA/TKA voluntary data by reducing the discount percentage used to set the target price from 2.0 percent to 1.7 percent of expected episode spending based on historical CJR episode data, hereinafter referred to as the voluntary reporting payment adjustment. The proposed payment policies with respect to reconciliation payment eligibility and the discount percentage based on hospital voluntary data submission are summarized in Table 10 for performance years 3 through 5 where we proposed that hospitals have full repayment responsibility. The proposed specific percentages that would apply for purposes of the repayment amount and reconciliation payment are outlined for performance years 1 and 2 in the discussion that follows.

TABLE 10—PROPOSED RECONCILIATION PAYMENT ELIGIBILITY AND DISCOUNT PERCENTAGE INCLUDED IN THE TARGET PRICE FOR EACH PARTICIPANT HOSPITAL BASED ON QUALITY PERFORMANCE IN PERFORMANCE YEARS 3 THROUGH 5

Discount percentage included in target price/reconciliation payment eligibility	Meets thresholds for all 3 required quality measures	Does not meet thresholds for one or more of 3 required quality measures
Successfully submits THA/TKA voluntary data	1.7%/eligible	1.7%/ineligible.
Does not successfully submit THA/TKA voluntary data	2.0%/eligible	2.0%/ineligible.

We refer readers to section III.D.3.a. of this final rule for further discussion of the THA/TKA patient-reported outcome-based measure and our proposed definition of successful reporting. In addition, we refer readers to section III.C.4.b.(9) of this final rule for discussion of the proposed discount of 2.0 percent (without the voluntary reporting payment adjustment) to establish the target price. In the proposed rule, we stated our belief that a voluntary reporting payment adjustment of 0.3 percent of expected episode spending would, on average, cover the participant hospitals' additional administrative costs of voluntarily reporting patient risk variables and patient-reported reported function for outcome calculation. We estimated the value of this discount

reduction, on average, to be about $75 per LEJR episode at a participant hospital, which we believed would be sufficient to pay hospitals for the resources required to survey beneficiaries pre- and post-operatively about functional status and report this information required for measure development to CMS. We also believed that voluntary reporting on this patient-reported outcome measure would be integral to implementation of the CJR model, as it would allow us to further develop and evaluate the measure for potential use in this model in the future as a measure of quality that is important and not captured in any other available measures.

We proposed that the voluntary reporting payment adjustment would be available for all years of the model, unless we find the measure to be unfeasible or have adequately developed the measure such that continued voluntary data collection is no longer needed for measure development during the course of the model. In those situations, we would notify participant hospitals that the voluntary reporting payment adjustment was no longer available as we would cease collecting the data.

We proposed that when we provide the episode target price to each participant hospital at 2 times during the performance year, we would provide different target prices reflecting the 2.0 percent and 1.7 percent discounts. At the time of reconciliation for the performance year, we would determine which participant hospitals successfully reported the THA/TKA voluntary data for that performance year. The effects of this voluntary reporting payment adjustment would vary for each year of the model, depending on the proposed reconciliation payment and repayment policies for that performance year. For hospitals that achieved successful reporting of the THA/TKA voluntary data in performance year 3, 4, or 5, we would use the target price reflecting the 1.7 percent discount (compared with the 2.0 percent discount for nonreporting or unsuccessfully reporting hospitals) to calculate the hospital's reconciliation payment or repayment amount. Based on this comparison, consistent with the proposal described in section III.C.6. of this final rule, we would make a reconciliation payment if actual episode spending was less than the target price (and the thresholds for reconciliation payment eligibility are met for the three required quality measures) or make participant hospitals responsible for repaying Medicare if actual episode spending exceeded the target price. For performance year 2, when we proposed that repayment responsibility would be phased-in, for participant hospitals with successful THA/TKA voluntary data reporting, we would use a target price reflecting the 1.7 percent discount (compared with the 2.0 percent discount for nonreporting or unsuccessfully reporting hospitals) to determine if actual episode spending was below the target price, whereupon the participant hospital would receive a reconciliation payment if the quality thresholds on the three required measures were met. In order to help hospitals transition to taking on repayment responsibility, we proposed to apply a reduced discount of 0.7 percent for successful THA/TKA voluntary data reporting hospitals (compared with 1.0 percent for nonreporting or unsuccessfully reporting hospitals) in performance year 2 for purposes of determining the hospital's repayment responsibility for excess episode spending. For performance year 1, when we proposed that there would be no repayment responsibility, for participant hospitals with successful THA/TKA voluntary data reporting, we would use a target price reflecting the 1.7 percent discount (compared with the 2.0 percent discount for nonreporting or unsuccessfully reporting hospitals) to determine if actual episode spending was below the target price, whereupon the participant hospital would receive a reconciliation payment if the quality thresholds on the three required measures were met. In the proposed rule, we stated our belief that this proposed voluntary reporting payment adjustment would provide the potential for increased financial benefit for participant hospitals due to a higher target price (that reflects a lower discount percentage) that successfully report the measure. Participant hospitals that successfully reported the voluntary data would be subject to a lower repayment amount (except for performance year 1 when hospitals have no repayment responsibility) or a higher reconciliation payment (assuming the thresholds are met on the three required measures for reconciliation payment eligibility), than hospitals that did not successfully report the voluntary data.

In general, we proposed that participant hospitals that met the performance thresholds for the three required quality measures and reduced actual episode spending below the target price, as well as successfully reported the THA/TKA voluntary data, would be eligible to retain an additional 0.3 percent of the reduced episode expenditures relative to participant hospitals that successfully reported the three required quality measures but did not report voluntary data, funds which would offset additional administrative costs that the participant hospitals would incur in reporting on the measure. Additionally, for performance years 2–5 where we proposed that participant hospitals would have payment responsibility, participant hospitals with increased actual episode spending above the target price would not be required to repay 0.3 percent of the increased episode expenditures (relative to participant hospitals that do not report voluntary data), funds that would offset additional administrative costs that the participant hospitals would incur in reporting on the measure. These costs would include the hospital staff time required for training on the measure, as well as then gathering and reporting on multiple patient risk variables from LEJR episode beneficiaries' medical records and locating beneficiaries and administering via phone survey questions on functional status, which would also then be reported to CMS. Thus, we expected that the proposal would encourage reporting by a number of participant hospitals, and it would have the potential to benefit those hospitals that successfully reported on the measure. Therefore, this proposal could financially benefit reporting hospitals that would also collect valuable information on patient functional outcomes that could inform their LEJR care redesign. While this measure remains in development from our perspective to ensure translation of data across care settings and the respective hospital communities during the 90-day post-discharge episode of care, participant hospitals would gain anecdotal, locally relevant information regarding the patient-reported outcomes of their own patients that could inform participant hospitals' continuous quality improvement efforts.

We considered two alternative options to adjust the CJR payment methodology by modifying the required quality measure thresholds for reconciliation payment eligibility for those participant hospitals that successfully submit the THA/TKA voluntary data. First, we considered adjusting the threshold that hospitals must meet on the three required quality measures for reconciliation payment eligibility if reduced episode spending was achieved from the unadjusted 30th percentile threshold to the adjusted 20th percentile threshold for performance years 1, 2, and 3, and from the unadjusted 40th percentile to the adjusted 30th percentile for performance years 4 and 5. Second, we

considered only requiring hospitals to meet the 30th percentile threshold on two of three outcome measures for performance years 1, 2, and 3, and the 40th percentile threshold on two of three outcome measures for performance years 4 and 5. These options would provide the opportunity for some participant hospitals, specifically those that missed the unadjusted percentile for one or more of the three required quality measures by a specified margin, to receive reconciliation payments if actual episode spending was less than the target price. However, these options could benefit only a subset of participant hospitals that successfully reported the THA/TKA voluntary data. For the majority of participant hospitals that we expect would meet the unadjusted thresholds for all three required measures, these options would not provide any incentive to voluntarily report the data because the hospitals would not benefit from voluntarily reporting the additional measure. We decided not to propose either of these options to adjust the CJR payment methodology for participant hospitals that voluntarily report data on the new measure because the limited benefit could result in few hospitals choosing to report on the measure, thereby limiting our progress in developing the measure. We noted that these two considered options and our proposal were not mutually exclusive.

We sought comment on the proposed voluntary reporting payment adjustment of reducing the discount percentage from 2.0 percent to 1.7 percent for CJR participant hospitals that voluntarily and successfully report on the THA/TKA voluntary data. Given our interest in robust hospital participation in reporting on the THA/TKA voluntary data under CJR, we were specifically interested in information on the additional resources and their associated costs that hospitals would incur to report THA/TKA voluntary data, as well as the relationship of these costs to the potential financial benefit participant hospitals could receive from the proposed reduced discount of 1.7 percent. Based on such information, we would consider whether a change from the proposed discount factor reduction due to successful voluntary data submission would be appropriate. We also sought comment on whether the alternative payment methodology adjustments considered, or combination of adjustments, would more appropriately incentivize CJR participant hospitals to submit THA/TKA voluntary data. In the proposed rule, we stated our belief that development of the THA/TKA patient-reported outcome measure would benefit from reporting by a broad array of participant hospitals, including those that currently deliver high quality, efficient LEJR episode care and those that have substantial room for improvement on quality and or cost-efficiency.

We summarize the public comments we received on the proposed voluntary reporting payment adjustment and provide our responses in section III.C.5.b.(5)(c)(iii) of this final rule. We did not receive public comments on the alternative payment methodology adjustments that we discussed in the proposed rule. Furthermore, in light of our interest in encouraging CJR participant hospital THA/TKA voluntary data reporting, we also considered alternative approaches to collect this information or provide hospitals with funds to help cover their associated administrative costs other than adjustments to the CJR model payment methodology. One alternative would be for hospitals to collect and report on patient pre-operative information collected 0 to 90 days before surgery, while CMS would engage a contractor to collect and report the post-operative information collected 9 to 12 months after surgery. This approach would reduce some of the administrative burden of collection and reporting on hospitals, although participant hospitals would need to provide CMS with certain beneficiary information, including contact information that would be needed for a CMS contractor to contact the beneficiary at a later date. We sought comment on this alternative, including whether hospitals would incur significant additional administrative costs to report on the data prior to surgery and how CMS could best provide funds to offset some of those costs, through an adjustment to the CJR payment methodology or other means. We also sought comment on the information participant hospitals would need to provide to CMS so that a CMS contractor could collect and report the post-operative data, and the most efficient ways for hospitals to provide this information to us. Finally, we considered an approach that would provide hospitals with separate payment outside of an adjustment to the CJR payment methodology to specifically assist in covering their administrative costs of reporting THA/TKA voluntary data, in order to achieve robust hospital participation in reporting. We sought comment on the hospital administrative costs that would be incurred for reporting, as well as on approaches we could take to ensure that hospitals achieved successful reporting under such an approach if separate payment was made. Finally, we expressed our interest in comments regarding the comparative strength of these various alternatives in encouraging hospitals to participate in reporting THA/TKA voluntary data.

We did not receive any public comments on the alternatives we discussed other than adjustments to the payment methodology to collect THA/TKA voluntary data and provide hospitals with funds to cover the required resources. We summarize these comments we received in section III.C.5.b.(5)(c)(iii) of this final rule and provide our responses.

(3) Measure Risk-Adjustment and Calculations

All three proposed outcome measures are risk-adjusted, and we refer readers to section III.D.2. of this final rule for a full discussion of these measures and risk-adjustment methodologies. We believed that risk-adjustment for patient case-mix is important when assessing hospital performance based on patient outcomes and experience and understanding how a given hospital's performance compares to the performance of other hospitals with similar case-mix.

(4) Applicable Time Period

We proposed to use a 3-year rolling performance or applicable period for the Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551) and the Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550) measures. We also specifically proposed to align with the HIQR Program's 3-year rolling performance period for the RSRR and RSCR measures since we believed that a 3-year performance period yields the most consistently reliable and valid measure results (FY 2015 IPPS/LTCH final rule, 79 FR 50208 through 50209). For the HCAHPS Survey measure, we proposed to follow the same performance period as in the HIQR Program (FY 2015 IPPS/LTCH final rule, 79 FR 50259). HCAHPS scores are created from 4 consecutive quarters of survey data; publicly reported HCAHPS results are also based on 4 quarters of data. For the voluntary data collection for the proposed THA/TKA patient-reported outcome-based performance measure, the optimal reporting time period had not been determined at the time of issuance of the CJR model proposed rule. Therefore, we proposed defining the applicable time period as

12 month intervals that may begin between July 1, 2016 and December 31, 2016, and continue in subsequent performance years for a total of four or fewer performance periods. Participant hospitals will submit required data to CMS in a mechanism similar to the data submission process for the HIQR Program within sixty days of the end of each 12 month period. As described in section III.C.5.b.(2) of the proposed rule, the proposed voluntary reporting payment adjustment of reducing the discount percentage from 2.0 percent to 1.7 percent for CJR participant hospitals that successfully report on the THA/TKA voluntary data would begin in year 2 and also apply to subsequent years of the model. We are not finalizing the proposed voluntary reporting payment adjustment, as discussed further in section III.C.5.b.(5)(c)(iii) of this final rule. We note that we summarize the public comments we received on the proposed applicable time period and provide our responses in section III.D.3.d. of this final rule, and we summarize the public comments we received on the reporting time period for the THA/TKA patient-reported outcome and limited risk variable data and provide our responses in section III.D.3.a.(9) of this final rule.

(5) Criteria for Applicable Hospitals and Performance Scoring

(a) Identification of Participant Hospitals for the CJR Model

As discussed in section III.A.2. of this final rule, all CJR participant hospitals will be IPPS hospitals.

(b) Methodology To Determine Performance on the Quality Measures

To determine performance on the quality measures, we proposed to calculate measure results for all three measures as outlined in the Quality Measures section III.D.2. of this final rule. Performance on the three measures for the CJR model participant hospitals would be compared to the national distribution of measure results for each of these measures obtained through the HIQR Program. The HIQR Program is an IPPS program in which public reporting is a focus of the program for the nation's acute care hospitals, and we proposed using the absolute value of the CJR model participant hospital's result to determine if that participant hospital was eligible for a reconciliation payment. In essence, we intended to take the HIQR Program measure results (also posted publicly) for the proposed measures, identify the proposed threshold, and apply the thresholds as outlined in section III.C.5.b.(5)(c)(iii) of this final rule. In the proposed rule, we stated our belief that it would be reasonable to use the HIQR Program distribution of measure results to identify a measure result threshold because—(1) The hospitals in the HIQR Program represent most acute care hospitals in the nation; (2) the CJR model participant hospitals are a subset of the hospitals in the HIQR Program; and (3) the expectation that the CJR model participant hospitals meet a measure result threshold based on a national distribution of measure results would encourage the CJR model participant hospitals to strive to attain measure results consistent with or better than hospitals across the nation. For a detailed description of how we proposed to determine the measure result thresholds for consideration of a reconciliation payment adjustment, see section III.C.5.b.(3) and III.C.5.b.(5)(c) of this final rule. We would not want to encourage CJR model participant hospitals to strive for measure results or quality of care performance that may be lower than the national measure results. Given that the CJR participant hospitals are a subset of the HIQR Program participant hospitals, they are familiar with these three measures and may have put into place processes that will help to improve quality of care in the LEJR patient population. Finally, once the measure results were calculated, we proposed to use these results to determine eligibility for reconciliation payment, which is discussed in detail in the next section.

We summarize the public comments we received on the proposed calculation of the measure results and application of performance thresholds and provide our responses in sections III.D.2 and III.C.5.b.(5)(c)(iii) of this final rule, respectively.

To be considered to have successfully reported the voluntary data collection and submission for the THA/TKA voluntary data, we proposed that successfully reporting would mean participant hospitals must meet all of the following:

- Submit the data elements listed in section III.D.3.a.(2) of this final rule.
- Data elements listed in section III.D.3.a.(3) of this final rule must be submitted on at least 80 percent of their eligible elective primary THA/TKA patients (patients eligible for pre-operative THA/TKA voluntary data submission are those described in section III.D.3.a.(3) of this final rule); patients eligible for post-operative THA/TKA voluntary data submission are those described in section III.D.3.a.(3) of this final rule and also having a THA/TKA procedure date during the anchor hospitalization at least 366 days prior to the end of the data collection period. Therefore, participant hospitals would not be expected to collect and submit post-operative THA/TKA voluntary data on patients who are fewer than 366 days from the date of surgery.
- THA/TKA voluntary data submission must occur within 60 days of the end of the most recent performance period.

Hospitals that meet these three standards and successfully submit THA/TKA voluntary data would be eligible for the proposed voluntary reporting payment adjustment of reducing the discount percentage from 2.0 percent to 1.7 percent for CJR participant hospitals that voluntarily and successfully report on the THA/TKA voluntary data. We note that we are not finalizing this voluntary reporting payment adjustment proposal as discussed in section III.C.5.b.(5)(c)(iii) of this final rule. However, we continue to believe that encouraging collection and submission of the THA/TKA voluntary data through the CJR model would increase availability of patient-reported outcomes to both participant hospitals that collect and submit data on their own patients in the model (and their patients as well); further development of an outcomes measure that provides meaningful information on patient-reported outcomes for THA/TKA procedures that are commonly furnished to Medicare beneficiaries; provide another quality measure that may be incorporated into the CJR model policy linking quality to payment in future performance years, pending successful development of the measure; and inform the quality strategy of future payment models. Collecting data on at least 80 percent of hospital's eligible THA/TKA patients would provide sufficiently representative data to allow for development and testing of the THA/TKA patient-reported outcome-based performance measure.

We invited public comment on the proposal to calculate measure results for all three measures as outlined in the Quality Measures section III.D.2. of this final rule. We also sought public comment on our proposal for hospitals to meet three requirements, previously outlined, in order to be considered as successfully submitting THA/TKA voluntary data.

We summarize the public comments on the proposals to calculate measure results and determine measure result thresholds and provide our responses in sections III.D.2. and III.C.5.b.(5)(c)(iii) of this final rule, respectively. We summarize the public comments on the proposals for successful THA/TKA

voluntary data submission and provide our responses in section III.D.3.a. of this final rule.

(c) Methodology To Link Quality and Payment

(i) Background

In proposing a methodology for linking payment for LEJR episodes to quality under this model, we considered several alternatives. Specifically, we considered making reconciliation payments to hospitals tied to achievement and improvement in quality performance or, alternatively, establishing minimum quality performance thresholds for selected quality measures from the beginning of the model or a later year, which would reward achievement but not necessarily improvement. While we proposed as discussed section III.C.5.b.(5)(c) of this final rule to establish minimum thresholds for participant hospital performance on three selected quality measures for reconciliation payment eligibility each performance year from the beginning of the model, we also discussed in detail an alternative we considered, which would make quality incentive payments related to hospital achievement and improvement on the basis of a composite quality score developed for each performance year. The composite quality score would affect reconciliation payment eligibility and change the effective discount included in the target price experienced by a participant hospital at reconciliation.

Similar to the proposal described in section III.C.5.b.(5)(c) of this final rule, the alternatives considered would require a determination of participant hospital performance on all three proposed required quality measures, described in section III.D.2. of this final rule, based on the national distribution of hospital measure result performance, but instead of identifying the participant hospital's performance percentile for comparison with a threshold requirement, we would do so for purposes of assigning points toward a hospital composite quality score. Both the hospital-level 30-day, all cause Risk-Standardized Readmission Rate (RSRR) following elective primary THA and/or TKA (NQF #1551) measure and the hospital-level Risk-Standardized Complication Rate (RSCR) following elective primary THA and/or TKA (NQF #1550) measure directly yield rates for which a participant hospital performance percentile could be determined and compared to the national distribution in a straightforward manner. As discussed in section III.D.2.c. of this final rule, we proposed to use the HCAHPS Linear Mean Roll Up (HLMR) score calculated using the HCAHPS Survey measure (NQF #0166). Once the HLMR scores are calculated, the participant hospital performance percentile could also be determined and compared to the national distribution in a straightforward manner. In addition, the alternatives considered would account for the successful submission of voluntary THA/TKA data on the patient-reported outcome measure, as discussed in section III.C.5.b.(2) of this final rule, in the calculation of the composite quality score.

(ii) Alternatives Considered To Link Quality and Payment

We considered assigning each participant hospital a composite quality score, developed as the sum of the individual quality measure scores described later in this section, which were set to reflect the intended weights for each of the quality measures and the successful submission of THA/TKA voluntary data in the composite quality score. The participant hospital's composite quality score would affect reconciliation payment eligibility and could also provide the opportunity for quality incentive payments under the CJR model. Each quality measure would be assigned a weight in the composite quality score and possible scores for the measures would be set to reflect those weights. A composite quality score for each performance year would be calculated for each participant hospital based on its own performance that would affect reconciliation payment eligibility and the hospital's opportunity to receive quality incentive payments under the model. The composite quality score would also change the effective discount included in the target price experienced by the hospital at reconciliation for that performance year. We would weigh participant hospital performance on each of the three measures and successful submission of voluntary THA/TKA data according to the measure weights displayed in Table 11.

TABLE 11—QUALITY MEASURE WEIGHTS UNDER THE COMPOSITE QUALITY SCORE ALTERNATIVE CONSIDERED IN THE PROPOSED RULE

Quality measure	Weight in composite quality score (%)
Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551)	20
Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550)	40
HCAHPS Survey (NQF #0166)	30
Voluntary THA/TKA data submission on patient-reported outcome measure	10

We would assign the lowest weight of 10 percent to the successful submission of THA/TKA data on the patient-reported outcome measure because these data represent a hospital's meaningful participation in advancing the quality measurement of LEJR patient-reported outcomes but not actual outcome performance for LEJR episodes under the CJR model. In the proposed rule, we stated our belief the three required measures that represent LEJR outcomes deserve higher weights in the composite quality score. We would assign a modest weight of 20 percent to the readmissions measure because, while we believed that readmissions are an important quality measure for LEJR episodes, the episode payment methodology under the model already provides a strong financial incentive to reduce readmissions that otherwise would contribute significantly to greater actual episode payments. Furthermore, hospitals generally have already made significant strides over the past several years in reducing readmissions due to the inclusion of this measure in other CMS hospital programs that make payment adjustments based on performance on this measure. We believed that a higher weight than 20 percent would overvalue the contribution of readmissions performance as an indicator of LEJR episode quality in calculating the composite quality score. Furthermore, other CMS hospital programs may also make a payment adjustment based on hospital performance on the readmissions measure, so we would not want this measure to also strongly influence reconciliation payment eligibility and the opportunity for quality incentive payments under the

CJR model. We would assign a higher weight of 30 percent to the HCAHPS Survey measure because we believed that incorporating this quality measure, which reflects performance regarding patients' perspectives on care, including communication, care transitions, and discharge information, is a highly meaningful outcome measure of LEJR episode quality under the CJR model. However, we did not believe it would be appropriate assign the HCAHPS Survey measure the highest weight of the four measures, as the measure is not specific to LEJR episode care, but rather to all clinical conditions treated by participant hospitals. Finally, we would assign the highest weight, 40 percent, to the complications measure. We believed this measure should be weighted the most because it is specific to meaningful outcomes for primary THA and TKA that are the major procedures included in LEJR episodes under the CJR model. The measure includes important complications of LEJR episodes, such as myocardial infarction, pneumonia, surgical site bleeding, pulmonary embolism, death, mechanical joint complications, and joint infections occurring within various periods of time during the LEJR episode. LEJR episodes under the CJR model are broadly defined so that reducing complications should be a major focus of care redesign that improves quality and efficiency under this model, yet because complications may not be as costly as readmissions, the payment incentives under the model would not as strongly target reducing complications as reducing readmissions. We sought comment on this weighting of the individual quality scores in developing a composite quality score for each participant hospital.

Under such an approach, we would first score individually each participant hospital on the Hospital-level 30-day, all-cause RSRR using the elective primary THA and/or TKA (NQF #1551) measure; Hospital-level RSCR following using the elective primary THA and/or TKA measure (NQF #1550); and HCAHPS Survey measure (NQF #0166) based on the participant hospital's performance percentile as compared to the national distribution of hospitals' measure performance, assigning scores according to the point values displayed in Table 12. These individual measure scores were set to reflect the measure weights included in Table 11 so they could ultimately be summed without adjustment in calculating the composite quality score.

TABLE 12—INDIVIDUAL SCORING UNDER THE COMPOSITE QUALITY SCORE ALTERNATIVE CONSIDERED FOR THREE REQUIRED QUALITY MEASURES IN THE PROPOSED RULE

Performance percentile	Complications measure quality score (points)	HCAHPS survey quality score (points)	Readmissions measure quality score (points)
≥90th	8.00	6.00	4.00
≥80th and <90th	7.40	5.55	3.70
≥70th and <80th	6.80	5.10	3.40
≥60th and <70th	6.20	4.65	3.10
≥50th and <60th	5.60	4.20	2.80
≥40th and <50th	5.00	3.75	2.50
≥30th and <40th	4.40	3.30	2.20
<30th	0.00	0.00	0.00

Given the current national distribution of hospital performance on these measures, in the proposed rule we stated our belief that small point increments related to higher measure performance deciles would be the most appropriate way to assign more points to reflect meaningfully higher quality performance on the measures. The absolute differences for each decile among the three measures reflect the intended weight of the measure in the composite quality score. We would assign any low volume participant hospital without a reportable value for the measure to the 50th performance percentile of the measure, so as not to disadvantage a participant hospital based on its low volume alone because that hospital may in actuality provide high quality care. These three measures are well-established measures in use under CMS hospital programs, so we did not believe that scores below the 30th percentile reflect quality performance such that they should be assigned any individual quality measure score points for LEJR episodes under CJR. However, we also considered reducing scores incrementally across the bottom three deciles in order to provide greater incentives for quality improvement for hospitals that may not believe they can attain the 30th performance percentile on one or more of the three measures and to avoid creating a ''cliff'' at the 30th performance percentile. We sought comment on this scoring approach to the three required quality measures.

Additionally, we would assign a measure quality score of one point for participant hospitals that successfully submit THA/TKA voluntary data and 0 points for participant hospitals that do not successfully submit these data. Because we would not use the actual THA/TKA voluntary data on the patient-reported outcome measure in assessing LEJR episode quality performance under the model, we believed this straightforward binary approach to scoring the submission of THA/TKA voluntary data for the patient-reported outcome measure development would be appropriate.

We note that the Shared Savings Program utilizes a similar scoring and weighting methodology, which is described in detail in the CY2011 Shared Savings Program Final Rule (see § 425.502). The HVBP and HACRP programs also utilize a similar scoring methodology, which applies weights to various measures and assigns an overall score to a hospital (79 FR 50049 and 50102).

We would sum the score on the three quality measures and the score on successful submission of THA/TKA voluntary data to calculate a composite quality score for each participant hospital. Then we would incorporate this score in the model payment methodology by first, requiring a minimum composite quality score for reconciliation payment eligibility if the participant hospital's actual episode spending is less than the target price and second, by making quality incentive payments that change the effective discount percentage included in the target price experienced by the hospital in the reconciliation process. The payment policies we would apply are displayed in Tables 13, 14, and 15 for the performance years of the model.

Under the CJR model as proposed, there would be no participant hospital repayment responsibility in performance year 1 and this responsibility would begin to be phased-in in performance year 2, with full implementation in performance year 3.

TABLE 13—PERFORMANCE YEAR 1: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION UNDER THE COMPOSITE QUALITY SCORE ALTERNATIVE CONSIDERED IN THE PROPOSED RULE

Composite quality score	Eligible for reconciliation payment	Eligible for quality incentive payment	Effective discount percentage for reconciliation payment (%)	Effective discount percentage for repayment amount
≤5.00	No	No	3.0	Not applicable.
>5.00 and ≤9.25	Yes	No	3.0	Not applicable.
>9.25 and ≤15.20	Yes	Yes	2.0	Not applicable.
>15.20	Yes	Yes	1.5	Not applicable.

TABLE 14—PERFORMANCE YEAR 2: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION UNDER THE COMPOSITE QUALITY SCORE ALTERNATIVE CONSIDERED IN THE PROPOSED RULE

Composite quality score	Eligible for reconciliation payment	Eligible for quality incentive payment	Effective discount percentage for reconciliation payment (%)	Effective discount percentage for repayment amount (%)
≤5.00	No	No	3.0	2.0
>5.00 and ≤ 9.25	Yes	No	3.0	2.0
>9.25 and ≤ 15.20	Yes	Yes	2.0	1.0
>15.20	Yes	Yes	1.5	0.5

TABLE 15—PERFORMANCE YEARS 3–5: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION UNDER THE COMPOSITE QUALITY SCORE ALTERNATIVE CONSIDERED IN THE PROPOSED RULE

Composite quality score	Eligible for reconciliation payment	Eligible for quality incentive payment	Effective discount percentage for reconciliation payment (%)	Effective discount percentage for repayment amount (%)
≤5.00	No	No	3.0	3.0
>5.00 and ≤ 9.25	Yes	No	3.0	3.0
>9.25 and ≤ 15.20	Yes	Yes	2.0	2.0
>15.20	Yes	Yes	1.5	1.5

Under this approach, the CJR model discount included in the target price without consideration of the composite quality score would be 3.0 percent, not the 2.0 percent described under our payment proposal in section III.C.4.b.(9) of this final rule. In the proposed rule, we stated our belief that a discount percentage of 3.0 percent without explicit consideration of episode quality is reasonable as it is within the range of discount percentages included in the ACE demonstration and it is the Model 2 BPCI discount factor for 30 and 60 day episodes, where a number of BPCI participants are testing LEJR episodes subject to the 3.0 percent discount factor. Hospitals that provide high quality episode care would have the opportunity to receive quality incentive payments that would reduce the effective discount percentage as displayed in Tables 13, 14, and 15. Depending on the participant hospital's actual composite quality score, quality incentive payments could be valued at 1.0 percent to 1.5 percent of the hospital's benchmark episode price (that is, of the expected episode spending prior to application of the discount factor to calculate a target price).

Under this methodology, we would require hospitals to achieve a minimum composite quality score of greater than 5.00 to be eligible for a reconciliation payment if actual episode spending was less than the target price. Participant hospitals with below acceptable quality performance reflected in a composite quality score less than or equal to 5.00 would not be eligible for a reconciliation payment if actual episode spending was less than the target price. A level of quality performance that is below acceptable would not affect participant hospitals' repayment responsibility if actual episode spending exceeds the target price. We believed that excessive reductions in utilization that lead to low actual episode spending and that could result from the financial incentives of an episode payment model would be limited by a requirement that this minimum level of LEJR episode quality be achieved for reconciliation payments to be made. This policy would encourage hospitals to focus on appropriate reductions or changes in utilization to achieve high quality care in a more efficient manner. Therefore, these hospitals would be ineligible to

receive a reconciliation payment if actual episode spending was less than the target price.

For hospitals with composite quality scores of less than or equal to 5.00, we also considered a potential alternative approach. Under this approach, we would still permit this group of hospitals to receive reconciliation payments but would impose a quality penalty that would increase their effective discount percentage to 4.0 percent for purposes of calculating the reconciliation payment or recoupment amount in performance years 3 through 5, 4.0 percent for calculating the reconciliation payment and 3.0 percent for calculating the repayment amount in performance year 2, and 4.0 percent for calculating the reconciliation payment in performance year 1 where participant hospitals have no repayment responsibility. A potential advantage of this approach is that it would provide stronger incentives for quality improvement for participant hospitals with low performance on quality, even if they did not expect to be able to reduce actual episode spending below the target price. In addition, this approach would provide financial incentives to improve the efficiency of care even for hospitals that did not expect to meet the minimum quality score for reconciliation payment eligibility, while still providing strong incentives to provide high-quality care. The disadvantage of this approach is that it could provide reconciliation payments even to hospitals that did not achieve acceptable quality performance.

Participant hospitals with an acceptable composite quality score of >5.00 and ≤9.25 would be eligible for a reconciliation payment if actual episode spending was less than the target price because their quality performance was at the acceptable level established for the CJR model. They would not be eligible for a quality incentive payment at reconciliation because their episode quality performance, while acceptable, was not good or excellent. Therefore, these hospitals would be eligible to receive a reconciliation payment if actual episode spending was less than the target price.

Participant hospitals with a good composite quality score of >9.25 and ≤15.20 would be eligible for a quality incentive payment at reconciliation if actual episode spending was less than the target price because their quality performance exceeded the acceptable level required for reconciliation payment eligibility under the CJR model. In addition, they would be eligible for a quality incentive payment at reconciliation for good quality performance that equals 1.0 percent of the participant hospital's benchmark price, thereby changing the effective discount percentage included in the target price experienced by the hospital at reconciliation. Thus, participant hospitals achieving this level of quality for LEJR episodes under CJR would either have less repayment responsibility (that is, the quality incentive payment would offset a portion of their repayment responsibility) or receive a higher payment (that is, the quality incentive payment would add to the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual episode spending to the target price that reflects a 3.0 percent discount. Therefore, these hospitals would be eligible to receive a reconciliation payment if actual episode spending was less than the target price and would also receive a quality incentive payment.

Finally, hospitals with an excellent composite score quality score of >15.20 would be eligible to receive a reconciliation payment if actual episode spending was less than the target price because their quality performance exceeded the acceptable level required for reconciliation payment eligibility under the CJR model. In addition, they would be eligible for a higher quality incentive payment at reconciliation for excellent quality performance that equals 1.5 percent of the participant hospital's benchmark price, thereby changing the effective discount percentage included in the target price experienced by the hospital at reconciliation. Thus, participant hospitals achieving this level of quality for LEJR episodes under CJR would either have less repayment responsibility (that is, the quality incentive payment would offset a portion of their repayment responsibility) or receive a higher payment (that is, the quality incentive payment would add to the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual episode spending to the target price that reflects a 3.0 percent discount. Therefore, these hospitals would be eligible to receive a reconciliation payment if actual episode spending was less than the target price and would also receive a quality incentive payment.

Under this methodology, the proposed stop-loss and stop-gain limits discussed in section III.C.8. of this final rule would not change. We believed this approach to quality incentive payments based on the composite quality score could have the effect of increasing the alignment of the financial and quality performance incentives under the CJR model to the potential benefit of participant hospitals and their collaborators as well as CMS, although it would substantially increase the complexity of the methodology to link quality and payment. We sought comment on this alternative approach to basing reconciliation payment eligibility and quality incentive payments on the participant hospital's composite quality score under the CJR model, as well as the composite quality scoring ranges applicable to the respective payment policies.

While we described in detail this alternative considered to link quality to payment under CJR, we did not propose this methodology for several reasons. First, the Shared Savings Program and HVBP program utilize many more measures than we proposed for the CJR model. For example, the Shared Savings Program initially incorporated thirty-three measures across four quality domains (79 FR 67916 and 67917). The range of measures in the Shared Savings Program and the HVBP program lends itself to a scoring approach, which can account for many measures and allows providers to achieve a high score despite performing well on some measures but achieving lower performance on others. There is a detailed description of the Shared Savings Program scoring methodology on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Quality_Measures_Standards.html*. We believed that given the more limited set of measures chosen for the CJR model, a scoring approach such as the alternative described in this section could diminish the importance of each measure. Use of a scoring approach would not allow hospital performance on two different outcomes to be easily reviewed and understood with respect to the impact of individual measure performance on Medicare's actual payment for the episode under the model. Second, we believed the measures proposed for this model represent goals of clinical care that should be achievable by all hospitals participating in the model that heighten their focus on these measures, especially the readmissions and complications measures, for LEJR episodes based on the financial incentives in the model. Finally, we believed that a methodology that assesses performance based on absolute values of a specific set of measures that

are already in use, as we proposed for the CJR model, would be the most appropriate methodology to provide achievable and predictable quality targets for participant hospitals on measures that monitor the most meaningful quality of care outcomes in a model where some acute care hospitals that might not choose to participate in a voluntary model are also included. Our proposed method as discussed in the next section reflected our expectation that hospitals achieve a certain level of performance on measures to ensure that hospitals provide high-quality care under the model.

Finally, we also considered an approach whereby participant hospitals would not be penalized with regard to their eligibility for reconciliation payments in CJR for failure to meet the specified thresholds for the quality measures in performance year 1 of the model; in other words, we would delay the proposal described in the next section to performance year 2 rather than beginning in performance year 1. We considered calculating participant hospital performance on the required measures for the model, and, if actual episode spending was less than the target price, the participant hospital would receive a full reconciliation payment of savings achieved beyond the target price, regardless of performance on the quality measures. However, we did not believe this would be appropriate for the CJR model, given that two of the measures are administrative claims-based and thus impose no additional reporting burden on hospitals; rather, these two measures are established measures in existing CMS quality programs, and a central goal of the model is improving care for Medicare beneficiaries in LEJR episodes. We noted that the HCAHPS Survey measure (NQF #0166) is also an established measure in the HIQR Program and would not impose additional reporting burden on hospitals.

We summarize the public comments we received on these alternatives considered to link quality and payment and provide our responses in section III.C.5.b.(5)(c)(iii) of this final rule. We note that we will be adopting the composite score methodology for the CJR model, as discussed in our responses to comments in section III.C.5.b.(5)(c)(iii) of this final rule.

(iii) Threshold Methodology and Final Policy To Link Quality and Payment

For the reasons outlined in the previous section, we did not propose to use similar methodologies to other CMS programs that would tie CJR episode reconciliation payment eligibility and reconciliation payment and Medicare repayment amounts to a composite quality score on specified quality measures, but as discussed later in this section, we instead proposed to simply assess performance or achievement on a quality measure by setting a measure result threshold for each measure beginning in performance year 1 of the model.

We proposed that the CJR measure result threshold would be based on the measure results from the HIQR Program, a nationally-established program, and would use its national distribution of measure results. These are the same measure results posted on *Hospital Compare* or in the *Hospital Compare* downloadable database (*https://data.medicare.gov/data/hospital-compare*) for the HIQR Program. We refer readers to the earlier discussion of the HIQR Program, which utilizes measures to assess most acute care hospitals in the nation. Determining the CJR model target thresholds are discussed in the next section.

As previously described, we proposed for the CJR model the following three required measures to assess LEJR episode quality of care:

- Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551).
- Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550).
- HCAHPS Survey (NQF #0166).

We also proposed to make a voluntary reporting payment adjustment for CJR participant hospitals who successfully and voluntarily submit data for the THA/TKA patient-reported outcome-based performance measure (henceforth referred to as ''THA/TKA voluntary data'') as described in sections III.C.5.b.(2) and III.D.3.a. of this final rule. We proposed that participant CJR hospitals must meet or surpass a specified threshold for each required measure beginning for performance year 1 of the model in order to be eligible for a reconciliation payment if actual episode payments are less than the target price. The calculation of the HCAHPS Survey measure is described in section III.D.2.c. of this final rule. We proposed to use the individual measure results calculated as specified in section III.D. of this final rule for the three required measures to determine hospital eligibility for reconciliation payment for each performance year of the CJR model. Also, as discussed in section III.C.4. of this final rule, which outlines the proposed pricing structure for the CJR model, target prices for MS–DRG 470-anchored episodes and for MS–DRG 469-anchored episodes would be calculated for hospitals participating in the model for an episode of care extending 90 days after discharge from the anchor hospitalization. Participant hospitals that achieve actual episode payment below the specified target price for a given performance period would be eligible for a reconciliation payment, provided that the participant hospital also met episode quality thresholds on the three required measures for the performance period.

We proposed to use the following quality criterion to determine if a participant hospital qualifies for a reconciliation payment based on the episode quality thresholds on the three required measures:

The hospital's measure result is at or above the 30th percentile of the national hospital measure results calculated for all HIQR-Program participant hospitals for each of the three required measures for each performance period (for a detailed description of how we determined the performance period and reconciliation payment eligibility, see section III.C.5. of this final rule).

Using HIQR Program's 3 year rolling period as outlined in section III.D.2.d. (Applicable Time Period) of this final rule, if a participant hospital performed at or above the 30th percentile of all HIQR Program hospitals for each of the three required measures and if actual episode payment was less than the target price for the specified performance year, we would make a reconciliation payment to the hospital. Failure to achieve the threshold on one or more measures would result in the participant hospital not receiving a reconciliation payment regardless of whether the actual episode payment was less than the target price for that performance period. We proposed that for hospitals with insufficient volume to determine performance on an individual measure, these hospitals would be considered to be performing at the threshold level and their results would be publicly posted with all other participant hospitals' measure results (for a detailed summary of public reporting, see section III.D.5. of this final rule). We did not believe it would be appropriate to potentially penalize high quality, efficient hospitals due to their low volume, given that meeting the required quality measure thresholds would be required for reconciliation payment eligibility.

We also proposed for performance years 4 and 5 to increase the measure result threshold to the 40th percentile. We believed that increasing the measure result threshold to the 40th percentile

would encourage participants to strive for continued quality improvement throughout the 5 performance years of the model. We sought comment on our proposal to make a reconciliation payment to a participant hospital that achieves actual episode spending below the target price for a performance year and performs at or above the 30th percentile of HIQR program participant hospitals for all three required quality measures in performance years 1 through 3 or the 40th percentile in performance years 4 and 5, as well as our proposal to consider low volume hospitals to be performing at the threshold level.

We proposed to require hospitals to meet the threshold for all three measures for the following reasons. The measures proposed for this model are fully developed, NQF-endorsed, and implemented measures in CMS IPPS programs. These measures are also publicly reported on the *Hospital Compare* Web site. Hospitals are familiar with the complications and readmissions quality measures and with the HCAHPS Survey, as they are currently included in the HIQR Program, HVBP program, and HRRP (79 FR 50031, 50062, 50208, 50209 and 50259), and we believed that there would be minimal additional administrative burden for hospitals. All three measures are widely utilized nationally; thus, a nationally-based threshold would be an appropriate benchmark. In addition, the goal of the CJR model is LEJR episode care redesign that includes effective care coordination and management of care transitions. Strategies to prevent and efficiently manage post-procedure complications and hospital readmissions following an LEJR procedure are consistent with the goals of the model; a hospital cannot succeed in this model without engaging in care redesign efforts that would address aspects of care included in these measures. Failure to perform successfully on these key quality measures (defined by meeting the minimum thresholds) would indicate that hospitals are not achieving quality consistent with the goals of the model to specifically incentivize greater improvement on these measures than hospitals not participating in the CJR model, and should not be eligible to receive a reconciliation payment from Medicare even if reduced episode spending is achieved. Finally, the approach we proposed is consistent with CMS' goal of moving hospitals and other providers to value-based payment that ties payment to quality. In the 5 performance years of this model, performance on quality measures would only be applied to determining eligibility for a reconciliation payment; quality measures would not be used to determine participant hospitals' financial responsibility, except for the proposed voluntary reporting payment adjustment described in described in section III.C.5.b.(3) of this final rule. In essence, participant hospitals' responsibility to repay Medicare the difference between their target price and their actual episode payment, should actual episode payments exceed the target price, would not be impacted by performance on quality measures.

Finally, we proposed to increase the measure result thresholds for the final 2 performance years of the model, to ensure that CJR participant hospitals continue to maintain a high level of quality performance or improve performance on these measures as they gain experience with implementation of this payment model. More specifically, we proposed that in order for a participant hospital to receive a reconciliation payment for actual episode spending that is less than the target price for performance years 4 and 5, the participant hospital's measure result must be at or above the 40th percentile of the national hospital measure results calculated for all HIQR-Program participant hospitals for each of the three required measures for each performance period. As previously noted, we proposed to use the most recently available HCAHPS 4-quarter roll-up to calculate the HLMR. In the proposed rule, we stated our belief that holding the participant hospitals to a set measure result threshold for the first 3 years, and increasing this threshold for performance years 4 and 5, would emphasize the need to maintain and improve quality of care while cost efficiencies are pursued. We sought comment on our proposed approach to incorporating quality performance into eligibility for reconciliation payments under the CJR model for participant hospitals.

Table 16 displays the proposed thresholds that participant hospitals must meet on the various measures over the 5 model performance years.

TABLE 16—PROPOSED THRESHOLDS FOR REQUIRED QUALITY MEASURES TO DETERMINE PARTICIPANT HOSPITAL RECONCILIATION PAYMENT ELIGIBILITY OVER 5 YEARS

Measure	PY1 Threshold	PY2 Threshold	PY3 Threshold	PY4 Threshold	PY5 Threshold
Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551).	30th percentile	30th percentile	30th percentile	40th percentile	40th percentile.
Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550).	30th percentile	30th percentile	30th percentile	40th percentile	40th percentile.
HCAHPS Survey (NQF #0166)	30th percentile	30th percentile	30th percentile	40th percentile	40th percentile.

We sought comment on our proposed methodology to utilize quality measure performance in the payment methodology for CJR, as well as the proposed thresholds for participant hospital reconciliation payment eligibility over the performance years of the model.

As discussed in section III.C.5.b.(2) of this final rule, we stated our belief that hospitals that choose to submit THA/TKA voluntary data should have the potential to benefit financially through an adjustment to the payment methodology of the model. We proposed a voluntary reporting payment adjustment for hospitals that successfully submit the THA/TKA voluntary data by reducing the discount percentage incorporated into the target price from 2.0 percent to 1.7 percent. This voluntary reporting payment adjustment would start in performance year 1 and would be available through performance year 5 of the model for each year that the hospital successfully reports THA/TKA voluntary data. As proposed, reporting THA/TKA voluntary data would not affect eligibility for a reconciliation payment if actual episode payments are less than the target price. Participant hospitals would still need to meet the 30th or 40th percentile threshold, as applicable to the given performance year, on all

three required quality measures (Table 16).

We considered, but did not propose, two other alternatives to adjust the payment methodology for participant hospitals that successfully report the THA/TKA voluntary data as described in section III.C.5.b.(2) of this final rule. These alternatives would change the threshold percentile for the three required quality measures or, alternatively, reduce the number of required measures in which the threshold must be met provided that successful THA/TKA voluntary data were reported for a performance year. First, we considered reducing the threshold for reconciliation payment eligibility that participant hospitals must meet on the three required quality measures from the 30th percentile threshold to the 20th percentile threshold for performance years 1, 2, and 3, and from the 40th percentile to the 30th percentile for performance year. Second, we considered only requiring hospitals to meet the 30th percentile threshold on two of three outcome measures for performance years 1, 2, and 3, and the 40th percentile threshold on two of three outcome measures in performance years 4 and 5. Under both of these alternatives, the eligibility for reconciliation payments could change based on the THA/TKA voluntary data. We sought comment on these alternative payment methodology adjustments that could impact reconciliation payment eligibility, unlike the proposed voluntary reporting payment adjustment. We note that the other alternative approaches to encouraging THA/TKA voluntary data reporting for CJR beneficiaries as discussed in section III.C.5.b.(2) of this final rule that would not require adjustments to the CJR payment methodology would also not affect reconciliation payment eligibility.

The following is a summary of the comments received and our responses on the proposals and alternatives discussed in section III.C.5. of the proposed rule, including the proposed threshold methodology for reconciliation payment eligibility, as well as the alternatives considered that would change the proposed threshold requirements for participant hospitals that successfully report voluntary THA/TKA data. As cross-referenced several times earlier in this section, these comments and our responses also discuss a number of other proposals, alternatives considered, and other topics related to linking quality and payment under the CJR model for which we sought public comment.

Comment: Some commenters questioned the rationale for linking quality to episode payment for participant hospitals under the CJR model, arguing that the model should not be focused on individual hospital performance but on the overall performance of hospitals within the model, with respect to both the cost and quality of LEJR episode performance. The commenters observed that BPCI, a bundled payment model that includes LEJR as the most commonly selected episode and shares many features with the proposed CJR model, does not tie payment to quality, although BPCI has quality reporting requirements. They claimed that CMS, hospitals, and other providers lack experience with pay-for-performance in a bundled payment context and, therefore, that the level of performance that should be expected from providers under bundled payment is not yet understood. A commenter urged CMS to focus on the big picture in the CJR model, specifically changes in critical aspects of performance versus the national average for all hospitals along the continuum, potential changes in the types or nature of services to beneficiaries undergoing LEJR procedures, and aggregate changes in patient outcomes. Commenters asserted that tying a hospital's payment to performance on quality measures was not the only or the best way to make maintaining or improving LEJR episode quality performance central to the CJR model. Several commenters stated that implementing pay-for-performance in an episode payment model was premature, and recommended that CMS, at most, adopt a pay-for-reporting methodology while quality data are being collected and analyzed to determine the appropriate level of quality performance that should be specifically rewarded.

Several commenters urged CMS to delay implementing the proposed quality performance thresholds for reconciliation payment eligibility until performance year 2, or later, where the performance period for measure data would correspond more fully or completely to performance years under the model. They recommended that the first year or two of the CJR model should be pay-for-reporting and, because the proposed THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) are claims-based measures and the HCAHPS Survey measure (NQF #0166) is currently administered by hospitals, all participant hospitals would be expected to meet the CJR model quality performance requirements, which would only require public reporting in performance year 1 and possibly performance year 2. Several commenters in favor of pay-for-reporting in the first performance year asserted that such an approach would be consistent with other CMS value-based initiatives. A commenter also claimed that a year of pay-for-reporting would allow participant hospitals the time to establish internal systems for analyzing quarterly claims data and provide them with maximal opportunity to achieve savings that could be invested in these systems.

Response: We note that we currently have broad experience with pay-for-performance in Medicare programs, including the HRRP, HVBP Program, HAC Reduction Program, and the Shared Savings Program. These pay-for-performance programs have improved the quality of care for Medicare beneficiaries. For example, since the implementation of HRRP in 2012, readmission and complications rates for various medical conditions such as elective THA/TKA have been significantly reduced, thereby resulting in improvements in the quality of care for Medicare beneficiaries undergoing LEJR procedures. Furthermore, pay-for-performance is a feature of a number of Innovation Center models currently in testing. We refer readers to section III.D.5. of this final rule for further discussion of public reporting of pay-for-performance data during performance year 1 of the model.

While the current BPCI models do not specifically link payment to quality, the Request for Applications describing the BPCI model design features was released over 4 years ago, in August 2011. We now have two years of experience with BPCI Model 2 Awardees, the model that most closely resembles the CJR model, in the risk-bearing period, and the year 1 BPCI annual evaluation and monitoring report from February 2015 is publicly available on the CMS Web site at: *https://innovation.cms.gov/Files/reports/BPCI-EvalRpt1.pdf*. We have developed and adopted a variety of new quality measures in programs and models since 2011, as well as gained experience with pay-for-reporting and pay-for-performance in a variety of models and programs involving a wide range of health care providers and clinical conditions. Given our extensive experience over the past several years with pay-for-performance approaches, the availability of existing measures that reflect the quality of care for elective THA/TKA episodes, and the breadth of the CJR model, which reaches

substantially all IPPS hospitals in the selected MSAs, including those hospitals who otherwise would not participate in a voluntary payment model, we believe that a pay-for performance approach is necessary and appropriate beginning in the model's first performance year. IPPS hospitals have substantial experience over multiple years with CMS programs that include pay-for-performance and we believe, given the proposed quality measures for the CJR model, that CJR pay-for-performance in an episode payment model is a natural extension to bundled payment of pay-for-performance measures used in current CMS programs. While we acknowledge that pay-for-performance is not the only way for a model to heighten a focus on maintaining or improving the quality of LEJR episode care, we believe that the CJR model, like other Innovation Center models, should target both improved quality and reduced costs. Based on our experience in other programs and models, we believe that pay-for-performance under the CJR model shows great promise in moving participant hospitals toward greater efficiency and higher quality of LEJR episodes. In view of successful implementation of pay-for-performance in other CMS hospital programs using similar quality measures that has resulted in significant improvements in the quality of care, we believe IPPS hospitals have sufficient experience to be ready for pay-for-performance under the CJR model. We expect that other features of the model design, including our plans for data sharing, will help participant hospitals committed to care redesign toward these goals achieve success on both quality and cost performance for episodes.

We note that the quality measures finalized for the model as discussed in section III.D.2. of this final rule rely upon data that hospitals are already submitting and which are already analyzed by CMS for other programs, so we see no reason to adopt a period of pay-for-reporting for the first performance year of the model or longer. In the proposed rule, we considered a similar policy that would not penalize hospitals with regard to their eligibility for reconciliation payments for failure to meet the proposed quality measure thresholds in performance year 1. However, we continue to believe that adopting pay-for-reporting and not pay-for-performance in performance year 1 or longer would be inappropriate given that two of the proposed quality measures are administrative claims-based measures and impose no additional reporting burden on hospitals, the proposed measures are all established measures in existing CMS quality programs, and a central goal of the CJR model is improving care for Medicare beneficiaries in LEJR episodes. In this regard, the CJR model is different from some other CMS value-based initiatives where the data for some measures were newly submitted by providers or newly analyzed by CMS early in the initiative. Furthermore, we do not believe that participant hospitals need a year of pay-for-reporting to develop systems for analyzing episode claims under the model, as we expect hospitals to already be focused on improving their performance on these measures. The two measures finalized for the CJR model are aligned with the goals of the CJR model, are familiar to hospitals based on their use in other CMS hospital programs, and are aligned with CMS priorities to reduce LEJR complications while improving the patient experience. Because the measures reflect these goals and accurately measure hospitals' level of achievement and improvement on quality outcomes that are important to beneficiaries undergoing LEJR procedures, we are finalizing our proposal to implement a pay-for-performance approach in the CJR model in the first performance year by using quality performance in the episode payment methodology.

Comment: Some commenters supported the proposed strategy to link quality to payment through performance thresholds for quality measures that would result in reconciliation payment eligibility if the thresholds were met. Several commenters further reasoned that there should be no need to increase thresholds for reconciliation payment eligibility over the performance years of the model as CMS had proposed because the possibility of reconciliation payment provides an adequate quality improvement incentive. A commenter in favor of the proposed threshold approach recommended that CMS make the proposed THA/TKA voluntary patient-reported outcome (PRO) data submission mandatory and significantly increase incentives around their collection.

A number of commenters estimated that under CMS' proposal, more than half of the participant hospitals would be ineligible for reconciliation payments based on their current quality measure performance, even if episode savings were achieved during a performance year. The commenters stated that CMS should not use performance percentiles that would always exclude a predetermined number of participant hospitals from reconciliation payments, and hold hospitals to multiple quality performance standards for the same measure performance under different CMS models and programs. They contended that performance percentiles, as measures of relative performance, do not reflect best practices and, therefore, recommended that CMS require a level of absolute measure performance rather than relative performance when incorporating quality performance into the payment methodology under the CJR model. The commenters did not describe the absolute levels of performance that they would recommend on the quality measures for the CJR model. Several commenters claimed that the use of thresholds for reconciliation eligibility disadvantages small hospitals because only one or two patient instances could change the participant hospital's performance percentile and, therefore, affect the hospital's eligibility for reconciliation payments. Other commenters pointed out that the Shared Savings Program uses quality thresholds, but the methodology accounts for improvement and the program is voluntary, while hospital participation would be required in the CJR model and improvement was not considered in the pay-for-performance methodology CMS proposed.

Other commenters asserted that CMS' proposal linking quality measure performance to eligibility for reconciliation payments failed to reflect the quality of care delivered in the context of the model due to flaws in the proposed approach to determining participant hospital performance in relation to the thresholds. The commenters contended that the proposed methodology to determine performance on quality measures and link performance to reconciliation payment eligibility uses arbitrary distinctions in performance among hospitals that are not borne out by the data or even by CMS's own method of assigning ratings of performance on the *Hospital Compare* Web site. They stated that use of measure result point estimates to determine performance percentiles under CMS' proposal for performance thresholds for reconciliation payment eligibility may not be appropriate because: (1) The THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) are a ratio comparing observed to expected outcome, where expected is based on the national performance, so an individual hospital's performance

should be assessed within confidence intervals as the measure was originally specified, tested, and endorsed by the NQF; and (2) there may not be a clinically and statistically significant difference in the performance of hospitals immediately above and below the 30th percentile. The commenters observed that while the HRRP uses measure result point estimates (the same measure results proposed in section III.C.5.b.(5)(b) of the proposed rule, which proposed to use the absolute values of the CJR model participant hospital measure results) in calculating the excess readmission ratio in accordance with the statutory provision that defines this ratio, they stated that CMS has the flexibility under the statutory authority for the CJR model to use confidence intervals in determining outcome measure results for use in the payment methodology.

A number of commenters recommended that CMS adopt a threshold methodology that would utilize the confidence intervals used on the *Hospital Compare* Web site that distinguishes performance based on the three categories of comparison to the national rate on the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) to determine if a participant hospital is eligible for reconciliation payment. On *Hospital Compare,* hospitals are grouped into ''no different than national rate,'' ''better than national rate,'' or ''worse than national rate'' for each measure. The commenters recommending this methodology recommended against use of the HCAHPS Survey measure (NQF #0166).

Therefore, the commenters maintained that CMS should modify its proposal and set the quality performance thresholds for reconciliation payment eligibility at ''worse than national rate,'' rather than at the 30th percentile or above compared to the national rate. Specifically, the commenters suggested if performance on both the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) is statistically ''worse than national rate,'' then a participant hospital should not be eligible for reconciliation payment. Those hospitals that are deemed ''no different than national rate'' or ''better than national rate'' on both measures should automatically be deemed eligible for any potential reconciliation payment. Some commenters further urged CMS to also allow participant hospitals performing ''worse than national rate'' on one or both quality measures to receive reconciliation payments if CJR model episode savings were achieved as long as the hospital submits a corrective action plan to CMS describing their future strategies to improve quality of care, including contributing a portion of the reconciliation payment to quality performance improvement strategies. These commenters asserted that the quality performance thresholds should provide equal financial opportunity and incentives to all hospital participants.

The commenters claimed that setting quality performance thresholds at the level of ''worse than national rate'' as displayed on the *Hospital Compare* Web site would reduce confusion among the public with an interest in hospital performance under the CJR model, and strike an appropriate balance between encouraging hospital to focus on quality performance and providing hospitals with a fair opportunity to receive reconciliation payments if episode savings are achieved. A commenter reported that nationally there are 22 hospitals with performance on the THA/TKA Complications measure (NQF #1550) or the THA/TKA Readmissions measure (NQF #1551) that is ''worse than national rate,'' and only one hospital that is ''worse than national rate'' on both measures.

Response: We appreciate the support of some commenters for our proposal to set performance thresholds for reconciliation payment eligibility at the 30th percentile based on the national distribution of measure results, as well as the concerns expressed by some commenters about using relative performance to assess participant hospital episode quality performance in the CJR model. We continue to believe that relative measure performance is the most appropriate way to incorporate quality performance into the CJR model because we do not have sufficient information about hospital performance to set and use an absolute performance result on each measure. We believe that hospitals nationally are working to improve their performance on the quality measures proposed for the CJR model on an ongoing basis and, thus, while we expect that CJR participant hospitals will have a heightened focus on improvement on these measures as a result of the financial incentives resulting from episode payment, we are not yet certain in this model test what performance outcomes can be achieved under best practices. Therefore, we will not set absolute performance results as quality thresholds for reconciliation payment eligibility under the CJR model. We continue to believe that relative measures of quality performance are most appropriate for the CJR model as hospitals continue to make progress nationally on improving patient outcomes.

Furthermore, we will not make THA/TKA voluntary PRO and limited risk variable data submission mandatory and increase the incentives around their collection in the CJR pay-for-performance methodology as recommended by a commenter. This measure remains under development, and we want to encourage robust hospital reporting to speed measure development, but the measure is not yet ready to have its results incorporated in the CJR model methodology in the manner recommended by the commenter. We refer readers to section III.D.3.a. of this final rule for further discussion of our future plans to incorporate PRO measure results in the CJR pay-for-performance methodology.

We appreciate the suggestions of many commenters that we utilize outcome measure thresholds of ''worse than national rate'' as displayed on the Hospital Compare Web site to set the thresholds for reconciliation payment eligibility. For purposes of the *Hospital Compare* Web site, we made a specific choice around categorizing hospitals to performance categories for public display of hospital measure results in order to display a high level of statistical certainty about differences in hospital quality performance that would be reviewed by beneficiaries and other members of the public. Specifically for the *Hospital Compare* Web site, to assign hospitals to performance categories, the hospital's interval measure estimate is compared to the national rate. If the 95 percent interval estimate includes the national observed rate for that measure, the hospital's performance is in the ''no different than national rate'' category. If the entire 95 percent interval estimate is below the national observed rate for that measure, then the hospital is performing ''better than national rate.'' Finally, if the entire 95 percent interval estimate for the hospital is above the national observed rate for that measure, the hospital's performance is ''worse than national rate.''

Regarding the commenter who suggested that an individual hospital's performance on a measure should be assessed within confidence intervals as the measure was originally specified, tested, and endorsed by the NQF, we note that the THA/TKA Complications measure (NQF #1550) was not endorsed by the National Quality Forum for its use with an interval estimate, since NQF endorses measure specifications and not the use of measures in various programs

or models. We acknowledge that CMS uses outcome measure ratios and rates in different ways that may lead to some confusion for stakeholders. We also want to clarify that during measure development of the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551), these measures were developed and tested to yield risk-standardized ratios, which are multiplied by the national rate and reported as risk-standardized rates in *Hospital Compare*, and that the 95 percent interval estimate is specifically used to display the measure for public reporting on the *Hospital Compare* Web site. We chose to use rates on the *Hospital Compare* Web site because we believe that presentation of a rate on the *Hospital Compare* Web site is better understood by consumers than a measure result expressed as a predicted-to-expected ratio. For purposes of the CJR model, we will also use risk-standardized rates for the THA/TKA Complications measure (NQF #1550) as discussed in section III.D.2.a. of this final rule. We discuss our final decision not to adopt the THA/TKA Readmissions measure (NQF #1551) for this model in section III.D.2.b. of this final rule.

We note that ''worse than national rate'' is the quality performance threshold for reconciliation payment eligibility recommended by many commenters as the statistically certain measure of poor hospital quality performance, yet almost every hospital in the country already exceeds this level on the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551). Nationally, we estimate that only 29 hospitals currently perform at ''worse than national rate'' on one or more of these measures, a number that is similar to the estimate provided by a commenter. Thus, based on current measure performance only a very small number of hospitals would fail to meet the quality performance thresholds for reconciliation payment eligibility recommended by many commenters. We do not believe that adopting ''worse than national rate'' as the threshold for reconciliation payment eligibility, or applying no threshold as recommended by some commenters if a hospital ''worse than national rate'' submits a corrective action plan to CMS, would further encourage quality improvement or maintenance of high performance for participant hospitals in the CJR model, beyond the incentives that already exist in CMS programs.

Either incorporating a ''worse than national rate'' threshold or applying no threshold would essentially eliminate pay-for-performance under the CJR model, which would not be consistent with our final decision discussed in the prior response to public comments to incorporate a pay-for-performance methodology in the CJR model beginning in performance year 1.

Regarding the recommendations to use interval estimates to identify hospitals with performance ''worse than national average'' as the most equitable approach to identifying statistically valid poor hospital performance on quality measures, we have previously explained our position on the use of interval estimates when determining payment outcomes for hospital performance on measures. Specifically for the HRRP where we use point estimates for quality measure performance, we acknowledged outcome measures of risk-standardized condition-specific readmission rates to be statistical measures (77 FR 53394). We also recognized that statistical measures will include some degree of variation and stated that other Medicare programs use similar statistical measures as part of their programs, so any consideration of the use of interval estimates with respect to the HRRP may have implications for other programs (77 FR 53394). Despite this reality, we finalized the HRRP methodology for quality measure performance (76 FR 51673), which results in the use of a point estimate for a hospital's excess readmission ratio (77 FR 53394), and we use point estimates in other CMS programs that rely upon statistically-based outcome measures, such as the HVBP Program. (76 FR 26504). We note that over the past several years the HRRP has shown that use of point estimates in the program has still led to improvement in hospital readmission rates.[42] [43] We, therefore, continue to believe that quality performance can be assessed by measure result point estimates that do not rely on the statistical certainty of interval estimates which may fail to identify real, clinically meaningful differences in hospital measure performance.

However, we agree with the commenters that our proposal to set performance thresholds for reconciliation payment eligibility at the 30th percentile does not reflect the statistical certainty of intervals around hospital measures performance results and may not adequately account for the variation that occurs in risk-standardized rates like the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) proposed for use in the CJR model. We also agree with the commenters that setting required measure performance thresholds for reconciliation eligibility may provide insufficient quality and cost episode improvement incentives for some participant hospitals in the CJR model. We estimate that based on their current quality measure performance one-third of participant hospitals would not be eligible for reconciliation payments under our proposed thresholds for the three required quality measures, even if those hospitals achieved savings beyond the target price. While our estimate is lower than the estimate of more than 50 percent of participant hospitals that was provided by some commenters, we agree with the commenters that the proposed methodology would not provide significant quality and cost episode improvement incentives for a substantial percentage of participant hospitals in the CJR model.

We continue to believe there are real, clinically meaningful differences that are important to Medicare beneficiaries in hospital performance on the THA/TKA Complications measure (NQF #1550) finalized for this model, as well as opportunities for improvement, which are not recognized by the statistical certainty approach that we use for the *Hospital Compare* Web site but can be appropriately recognized by assigning hospitals to measure performance percentiles, such as we proposed for the CJR model. We also believe it is appropriate to make different choices for estimating measure performance for model or program payment policies, depending on the context. For example, in the CJR model where we proposed to use quality performance in the payment methodology of a model specifically focused on quality outcomes directly addressed by the proposed measures, we believe a different approach to estimating performance differences than the statistical certainty approach used on the *Hospital Compare* Web site would allow us to observe and reward real quality performance incentivized by episode payment that otherwise would

[42] Gerhardt G, Yemane A, Hickman P, Oelschlaeger A, Rollins E, Brennan N. Data Shows Reduction in Medicare Hospital Readmission Rates During 2012. Medicare & Medicaid Research Review 2013: 3(2): E1–E12.

[43] Medicare Hospital Quality Chartbook 2014: Performance Report on Outcome Measures. Prepared by Yale New Haven Health Services Corporation Center for Outcomes Research and Evaluation for the Centers for Medicare and Medicaid Services 2014:23. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf.*

be unrecognized. Therefore, we continue to believe that assigning hospital measure results to a performance percentile in comparison with the national distribution is an appropriate strategy to categorize and recognize hospitals achieving different levels of quality performance on the measures. We note that assigning hospitals to performance percentiles based on their measure result point estimates, and then using deciles of performance in a pay-for-performance model payment methodology that does not use hospital performance percentiles as thresholds, would help account for some of the statistical variation that could occur in measure result point estimates and reduce the likelihood that we would consider variation to be a real change in measure performance. Therefore, we are finalizing our proposal discussed in section III.C.5.b.(5)(b) of this final rule to assign each participant hospital's measure point estimate to a performance percentile based on the national distribution of measure results. However, because the statistical uncertainty in measure results increases the challenge of determining the most equitable performance threshold, below which the level of performance is no longer in the best interest of the beneficiary, as well as our interest in providing quality and cost episode improvement incentives for all participant hospitals under the CJR model, we are not finalizing our proposal to set performance percentile thresholds for reconciliation payment eligibility in the CJR model. Because we are not using performance percentile thresholds for reconciliation payment eligibility in the CJR model's final pay-for-performance methodology, we will neither be setting nor changing such thresholds in the context of the model's payment methodology over the model's performance years. We will be adopting the composite score methodology, as discussed in the following response to comments.

Comment: Many commenters offered a variety of other perspectives on CMS' proposal and alternatives considered to link quality and payment in the CJR model. Several commenters recommended that CMS tie a portion of the reconciliation payment to the proposed quality measure threshold performance for each of the 3 measures, specifically: ⅓ of the reconciliation payment would be made if one of the quality measure performance thresholds is achieved, ⅔ of the reconciliation payment would be made if two of the quality measure performance thresholds were achieved, and the full reconciliation payment would be made if all three quality measure performance thresholds were achieved. These commenters urged CMS to accompany this policy with no repayment responsibility in all years for participant hospitals that achieved all three quality measure performance thresholds, even if actual episode spending exceeds the target price. The commenters reasoned that this revised approach would provide the potential for more financial reward for participant hospitals providing high quality episode care, and limit the financial risk for participant hospitals furnishing high quality care.

Some commenters who opposed the use of performance percentiles on quality measures that were included in CMS' threshold proposal also opposed the alternative composite quality score approach for the same reasons, mainly because it would rely on performance percentiles derived from point estimates of quality measure performance to award points toward the composite quality score. However, a number of commenters favored the use of a composite quality score to link quality and payment, rather than thresholds for reconciliation payment eligibility, because the composite quality score would provide an opportunity for more participant hospitals to receive reconciliation payments if episode savings were achieved and would vary a participant hospital's financial reward in direct relationship to its episode quality performance.

Other commenters suggested further refinements to the composite score methodology, including different weighting of the measures. A commenter urged CMS to reconsider the composite score weights discussed in the proposed rule, and establish them as: HCAHPS Survey 25 percent; Complications 50 percent, and Readmissions 25 percent. The commenter reasoned that the Readmissions measure weight should be reduced due to the measure's use in other CMS programs. Finally, the commenter recommended that CMS modify the minimum percentile to receive quality measure score points to the 10th percentile, and add a band for incremental performance between the 10th percentile and the current national average performance, where an increasing proportion of any reconciliation payment from episode savings would be paid. The commenter urged CMS to pay the full reconciliation payment for episode savings beyond the target price to any hospital with quality performance above the national average.

Several commenters, who also recommended additional quality measures, stated that CMS should place greater weight in the composite quality score on ambulation, followed by pain experience and management, and finally followed by the Complications, Readmissions, and HCAHPS Survey measures in descending order of importance when calculating the composite quality score. Another commenter contended that CMS should increase the HCAHPS Survey measure weight and make the submission of THA/TKA voluntary PRO and limited risk variable data mandatory for performance year 2 and subsequent years, to increase the effect of patient experience on the financial opportunity of participant hospitals under the CJR model. A commenter recommended that, rather than participant hospital percentiles of performance compared to the national distribution of hospital measure performance, CMS use hospital-specific metrics that should be able to ''top out'' with high quality performance. The commenter suggested that CMS could measure performance annually on each measure for every participant hospital, and establish a minimum and maximal optimal measure result for the measure that could guide performance scoring. Finally, a commenter urged CMS to reconsider awarding the 50th percentile of performance for individual measure scores that make up the composite quality score without actual measure results, as CMS would not be assured that those hospitals were providing good quality care.

A number of commenters recommended that CMS vary the discount percentage incorporated in the target price at reconciliation based on the participant hospital's level of quality performance. Other commenters stated that high-performing hospitals on quality should have opportunities for greater reconciliation payments if that high-quality performance is sustained, recommending that CMS include no discount in the target price or a smaller discount percentage for these hospitals than would be used for hospitals with lower levels of quality performance. Finally, several commenters contended that hospitals furnishing care of lower quality should incur financial penalties based on their quality performance.

Response: We appreciate the suggestions of the commenters on features of the CJR pay-for-performance methodology that would be valuable in providing the most robust incentives for quality improvement or maintenance of high-quality performance for all CJR participant hospitals. As described

previously in this section, we are finalizing our proposal discussed in section III.C.5.b.(5)(b) of this final rule to assign each participant hospital's quality measure result point estimate to a performance percentile based on the national distribution of measure results, but we are not finalizing our proposal to set performance percentile thresholds for reconciliation payment eligibility under the CJR model.

We agree with many of the commenters that the pay-for-performance methodology under the CJR model should provide the opportunity for financial reward to participant hospitals with an acceptable level of episode quality performance, while also including an incentive for quality improvement if the hospital's current level of quality is low. We also agree with the commenters who stated that the CJR pay-for-performance methodology should provide the potential for increased financial reward for participant hospitals that furnish higher-quality care through payments that would either increase the reconciliation payment to the hospital or reduce the hospital's repayment responsibility depending on the hospital's episode cost performance for the model performance year. However, we do not agree with the commenters who recommended that those hospitals achieving high-quality episode performance should not be expected to improve their episode efficiency because we believe that substantial opportunities to reduce Medicare expenditures in the context of high-quality episode care exist for virtually all participant hospitals. Innovation Center models are generally designed with a focus on both reducing costs and improving the quality of care for model beneficiaries. Therefore, we will continue to incorporate a discount percentage into the target price for every participant hospital as discussed in section III.C.4.b. of this final rule in the methodology for setting target prices for the CJR model.

We also do not agree with the commenters who recommended that hospitals with low-quality performance incur financial penalties under the model, because the model is specifically designed to reward episode quality performance and cost savings. We discussed an alternative under the composite quality score approach in section III.C.5.b.(5)(c)(ii) of the proposed rule that would impose a quality penalty on hospitals with a low composite quality score that would otherwise lead them to be ineligible for reconciliation payments (80 FR 41243 through 41244). Under this alternative, we would reduce the effective discount percentage for these hospitals, thus imposing a 1 percent penalty for their low quality performance, regardless of whether or not episode savings are achieved beyond the target price. We continue to believe that while this approach would provide stronger incentives for quality improvement for participant hospitals with low performance on quality, even if they did not expect to be able to reduce actual episode spending below the target price, it could provide reconciliation payments even to those hospitals that did not achieve acceptable quality performance. Therefore, we believe that the risk to beneficiaries and CMS of these low-quality performing hospitals achieving savings in the context of poor quality care by sharply decreasing utilization to levels that reflect stinting on medically necessary care are so significant that adopting this alternative would not be appropriate. Instead, we will provide the opportunity for quality incentive payments that relate to the participant hospital's overall quality performance and improvement on the model's quality measures as reflected in the hospital's composite quality score that we will calculate for each performance year at the time reconciliation is carried out for that performance year.

As previously discussed, we are not finalizing our proposal to set performance percentile thresholds for reconciliation payment eligibility in the CJR model. Based on public comments that addressed our reconciliation payment eligibility threshold proposal, the alternatives considered, and the objectives of the pay-for-performance methodology under the CJR model, we believe that the composite score methodology that we discussed in the proposed rule that would determine reconciliation payment eligibility and change the effective discount percentage experienced by a participant hospital at reconciliation is the most appropriate pay-for-performance approach to achieve the objectives previously described. While the majority of commenters favored the threshold proposal with modification to adopt much lower quality thresholds of ''worse than national average'' performance that would result in eligibility of almost all participant hospitals for reconciliation payments if savings were achieved beyond the target price, a substantial percentage of commenters supported the composite score methodology or another approach that would provide greater financial reward to participant hospitals for higher quality performance. The composite score methodology omits the proposed 30th percentile performance minimum standard for all required quality measures as a definitive cut-off point for eligibility for reconciliation payments and replaces it with a quality scoring system that provides hospitals with multiple possible combinations of quality performance that can result in a hospital reaching eligibility for the reconciliation payment, thereby providing opportunity for reconciliation payments to hospitals achieving an acceptable or higher level of overall quality performance. This methodology also provides an incentive structure that acknowledges that high-quality episodes should be rewarded with greater financial opportunity under the CJR model, either through increased reconciliation payments or reduced repayment responsibility, depending upon the participant hospital's episode cost performance during a performance year. We appreciate the support of the commenters who share our view on the merits of the composite score approach.

We discussed in the proposed rule, but did not propose, a composite quality score methodology because at the time we believed that such an approach could diminish the importance of each quality measure given the limited number in the model, that the measures represented clinical goals that should be achievable by all hospitals participating in the model, and that a threshold methodology would provide the most achievable and predictable quality targets for the CJR model that requires participation (80 FR 41244). However, we agree with the commenters that the proposed threshold methodology would not sufficiently incentivize and reward quality improvement and acceptable or high quality performance under the CJR model for a substantial proportion of participant hospitals even if savings beyond the target are achieved. In contrast, the composite quality score methodology will allow performance on each required quality measure to be meaningfully valued in the model's pay-for-performance methodology, incentivizing and rewarding cost savings in relation to the quality of episode care provided by the participant hospital. Despite the small number of final CJR model quality measures, the measures represent both clinical outcomes and patient experience, and each carries substantial value in the composite quality score. Participant hospitals could achieve an acceptable or good composite quality score despite performing well on one of the required measures but achieving lower

performance on the other required measure. Thus, while quality performance on each measure would not be required for reconciliation payment eligibility, performance on each measure would be valued in the composite quality score methodology. Based on our review of the public comments, including the technical issues raised about measure result statistical variation in point estimates, we believe that a participant hospital's overall quality performance under the CJR model should be considered in the pay-for-performance approach, rather than performance on each quality measure individually determining the financial opportunity under the model. The composite score methodology also provides a framework for incorporating additional measures of meaningful outcomes for LEJR episodes, as discussed in section III.D.3. of this final rule, in the CJR pay-for-performance methodology in the future. Finally, while we believe that high quality performance on all of the measures represents goals of clinical care that should be achievable by all CJR model participant hospitals that heighten their focus on these measures, we appreciate that many hospitals have room for significant improvement in their current measure performance. The composite score methodology, which does not set performance thresholds for each measure for reconciliation payment eligibility, will provide the potential for financial reward for more participant hospitals that reach overall acceptable or better quality performance, thus incentivizing their continued efforts to improve the quality and efficiency of episodes.

In the proposed rule, we presented weights for the proposed quality measures in the composite quality score and note that we need to revise those weights for the final rule given that we are not adopting the THA/TKA Readmissions measure (NQF #1551) for the CJR model. As some commenters encouraged us to assign more weight than we discussed in the proposed rule to measures of patient experience and functional status, we believe it would be most appropriate to redistribute the 20 percent measure weight from the THA/TKA Readmissions measure (NQF #1551) equally to the two required measures we adopted for the model, specifically assigning an additional 10 percent weight each to the THA/TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0166). We note that the overall distribution of measure weight in the composite quality score would provide 50 percent weight to health-related conditions that arise following LEJR surgery (through the THA/TKA Complications measure (NQF #1550)) and 50 percent weight to patient experience (through the HCAHPS Survey measure (NQF #0166) and THA/TKA voluntary PRO and limited risk variable data submission). We believe this weighting appropriately balances patient experience with meaningful health outcomes for beneficiaries, by providing equal weight in the composite quality score to both dimensions, consistent with the patient-centered priorities for quality measurement that some commenters urged us to adopt.

The final measure weights in the composite quality score for the CJR model are displayed in Table 17.

TABLE 17—FINAL QUALITY MEASURE WEIGHTS IN COMPOSITE QUALITY SCORE

Quality measure	Weight in composite quality score (%)
Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550)	50
HCAHPS Survey (NQF #0166)	40
THA/TKA voluntary PRO and limited risk variable data submission	10

Consistent with the scoring of individual measure percentile performance as assigned to a decile, as we discussed in the proposed rule, and our final decision to use performance percentiles for both required quality measures, as discussed earlier in this section, for each model performance year we will assign individual measure performance scores to each participant hospital based on the values in Table 18. These individual measure performance scores have been set to reflect the final measures weights in Table 17 so they can ultimately be summed without adjustment in calculating the composite quality score. The absolute differences for each performance decile among the two measures reflect the intended weight of the measure performance in the composite quality score.

As we further discussed in the proposed rule, we will assign participant hospitals without a measure value to the 50th performance percentile (80 FR 41242). A participant hospital will not have a value for the THA/TKA Complications measure (NQF #1550) if the hospital does not meet the minimum case count of 25 cases in the 3 year measurement period which is required to ensure reliability of the measure result. In section III.D.4. of this final rule, we discuss the 25 case minimum and note that this quality measure case minimum is the same as the minimum used in the HIQR Program (75 FR 50185 and 76 FR 51609). We further note that as described in section III.D.2.a. of this final rule, the THA/TKA Complications measure (NQF #1550) only includes primary elective THA/TKA procedures which are a subset of the LEJR episodes included in the CJR model. As a result, it is possible for a CJR participant hospital to have LEJR episodes but no cases that meet the criteria to be included in the THA/TKA Complications measure (NQF #1550). Regarding the HCAHPS Survey measure (NQF #0166), a participant hospital will not have a reported value for the HCAHPS Survey measure (NQF #0166) if it did not meet the minimum of 100 completed surveys and did not have 4 consecutive quarters of HCAHPS data, which are required to ensure the reliably of the measure. In section III.D.4. of this final rule, we discuss the 100 case minimum and note that this quality measure case minimum is the same as the minimum used in the HVBP Program (76 FR 26502).

Moreover, we note that in rare cases, if CMS identifies an error in the data used to calculate the measure resulting in suppression of the data for public reporting on *Hospital Compare,* a hospital will not have a value for the THA/TKA Complications measure (NQF #1550) or HCAHPS Survey measure (NQF #0166) measure and would be assigned to the 50th performance percentile of the measure, as applicable.

Lastly, new hospitals that are identified as participants in the CJR model may not have sufficient data within the measure performance periods to calculate a value for the THA/TKA Complications measure (NQF #1550) or HCAHPS Survey measure (NQF #0166) and would be assigned to the 50th performance percentile of the measure, as applicable.

For hospitals that are in the situations previously described, we will assign participant hospitals without a measure value the 50th performance percentile of the measure result distribution. We intend to publicly report the measure results used to calculate the composite quality score for all participant hospitals. While we understand the concerns of the commenter that we have no actual outcome measure results for certain hospitals, we continue to believe it would be unfair to disadvantage a participant hospital in the pay-for-

performance methodology of this model based on insufficient number or no applicable cases alone and, therefore, we will assign these hospitals to the 50th performance percentile, which is the middle of the national measure performance distribution, and assign quality performance points to the participant hospital accordingly based on the performance percentile scale identified in Table 18.

Moreover, as we also discussed in the proposed rule, we will not assign individual measure score performance points to a hospital categorized to a performance percentile below the 30th percentile because we do not believe lower performance percentiles reflect quality performance such that they should be assigned any individual quality measure score performance points for LEJR episodes under the CJR model. Although a commenter suggested providing individual quality measure score points to hospitals beginning at the 10th performance percentile, we continue to disagree that performance below the 30th performance percentile reflects sufficient quality on these two well-established measures in CMS hospital programs to award quality measure points. We note, however, that a participant hospital assigned no performance points for one required quality measure could still be eligible for reconciliation payments if episode savings are achieved beyond the target price as long that hospital has achieved a sufficient performance percentile on the other required quality measure.

Additionally, we will assign a measure quality score of two points for participant hospitals that successfully submit THA/TKA voluntary PRO and limited risk variable data and 0 points for participant hospitals that do not successfully submit these data. The requirements for successful data submission in each performance year are discussed in section III.D.3.a. of this final rule. While we discussed awarding 1 point for successful submission in the proposed rule, this was an error because we also stated that the submission of THA/TKA voluntary PRO and limited risk variable data would constitute 10 percent of the composite quality score, which is based on a maximum score of 20 points. Two points is the correct value that reflects 10 percent of the maximum score.

TABLE 18—FINAL INDIVIDUAL SCORING FOR TWO REQUIRED QUALITY MEASURES

Performance percentile	THA/TKA Complications measure (NQF #1550) quality performance score (points) (1 additional point available for improvement)	HCAHPS Survey measure (NQF #0166) quality performance score (Points) (0.8 additional point available for improvement)
≥90th	10.00	8.00
≥80th and <90th	9.25	7.40
≥70th and <80th	8.50	6.80
≥60th and <70th	7.75	6.20
≥50th and <60th	7.00	5.60
≥40th and <50th	6.25	5.00
≥30th and <40th	5.50	4.40
<30th	0.00	0.00

We will sum the performance and, if applicable, improvement scores (as discussed in the following response to comments) on the two required quality measures with the score on the successful submission of THA/TKA voluntary PRO and limited risk variable data to calculate a composite quality score for each performance year for a participant hospital. This composite quality score will then be incorporated into the pay-for-performance methodology for the CJR model that assigns a participant hospital to a quality category at the time of reconciliation for a performance year. We will first require a minimum composite quality score for reconciliation payment eligibility if the participant hospital's actual episode spending is less than the target price and second, make quality incentive payments that change the effective discount percentage included in the target price experienced by the hospital in the reconciliation process. Thus, hospitals with higher composite quality scores may financially benefit from their episode quality performance compared to hospitals with lower quality performance in a different quality category, regardless of whether episode savings are achieved. For example, in performance year 4, actual episode spending for a hospital with an excellent composite quality score would be reconciled to a target price reflecting a 3.0 percent discount factor, but then the participant hospital would receive a quality incentive payment of 1.5 percent of the hospital's pre-discount target price that would either increase the hospital's reconciliation payment if savings were achieved or reduce the hospital's repayment responsibility if actual episode spending exceeded the target price. In contrast, actual episode spending for a hospital with an acceptable composite quality score would be reconciled to a target price reflecting a 3.0 percent discount factor, but then the participant hospital would not receive any quality incentive payment. Thus, the excellent quality performance by the participant hospital in the excellent quality category would provide a financial benefit to that hospital of 1.5 percent of the pre-discount target price, regardless of whether the hospital achieved savings for episodes.

As discussed in the proposed rule regarding the composite quality score alternative approach to pay-for-for performance under the CJR model, the discount for all participant hospitals included in the target prices will be 3.0 percent. We refer readers to section III.C.4.b.(9) of this final rule for further discussion of the discount factor included in the target prices. Hospitals that provide high-quality episode care will have the opportunity to receive quality incentive payments that will reduce the effective discount percentage as displayed in Tables 19, 20, and 21, based on their composite quality score that places each hospital into one of four quality categories, specifically ''Below Acceptable,'' ''Acceptable,'' ''Good,'' and ''Excellent.'' Three tables are required to display the effective discount percentages for each quality category due to the phase-in of hospital repayment responsibility from no responsibility in performance year 1, to partial responsibility in performance

years 2 and 3, and finally full responsibility in performance years 4 and 5 as discussed in section III.C.4.b.(9) of this final rule. Depending on the participant hospital's actual composite quality score that places the hospital in a quality category, quality incentive payments will be valued at 1.0 percent to 1.5 percent of the hospital's benchmark episode price (that is, of the expected episode spending prior to application of the discount factor to calculate a target price).

While the final policy to place participant hospitals into one of four quality categories to determine reconciliation payment eligibility and, if applicable, the value of quality incentive payments is the same as that presented in the proposed rule, the applicable scoring ranges for each quality category discussed in the proposed rule are different from the ranges we are finalizing in Tables 19, 20, and 21 for several reasons. First, we are not finalizing the THA/TKA Readmissions measure (NQF #1551) as part of the CJR model's pay-for-performance methodology, requiring us to redistribute the 20 percent weight in the composite quality score that we had presented for that measure. That redistribution is discussed earlier in this section. Second, our final policy includes quality improvement points in addition to quality performance points in the composite quality score, as discussed in the following response to comments. We estimate based on current quality measure performance that approximately 4 percent and 7 percent of all participant hospitals would qualify for improvement points on the HCAHPS Survey measure (NQF #0166) and the THA/TKA Complications measure (NQF #1550), respectively.

The most significant reason for a change in the scoring ranges for the quality categories in the final rule is due to our strengthening the financial incentives for participant hospitals under the CJR model through the composite quality score pay-for-performance methodology to improve quality performance or maintain high-quality performance for episodes. We agree with the commenters who urged us to ensure that most participant hospitals that achieve savings beyond the discount included in the target price receive reconciliation payments if their episode quality is acceptable and that we provide the potential for significantly greater financial reward for hospitals that achieve or maintain high quality episode performance. Therefore, we have reassessed our quality performance expectations for each quality category by examining the current quality measure performance of participant hospitals in the context of the national measure performance distribution. We have adjusted the final scoring ranges to balance the quality performance required for each quality category with the financial incentives (reconciliation payment eligibility and quality incentive payments) to achieve the quality performance required for the category. In the context of our final composite quality score ranges for each quality category, we estimate that approximately 10 percent of participant hospitals placed in the ''Below Acceptable'' quality category based on their composite quality score would not be eligible for reconciliation payments based on their current quality measure performance, compared to 14 percent based on the proposed rule composite score measures and ranges. Similarly, we estimate that approximately 12 percent of participant hospitals would be eligible for reconciliation payments through placement in the ''Acceptable'' quality category but would not receive quality incentive payments based on their current quality performance, compared to 30 percent in this quality category based on the proposed rule measures and score ranges. We estimate that the large majority of participant hospitals, specifically 64 percent, would be placed in the ''Good'' quality category based on their current quality performance and would, therefore, be eligible for reconciliation payments and for quality incentive payments valued at 1.0 percent of the hospital's benchmark episode price, compared to 46 percent based on the proposed rule measures and score ranges. Finally, we estimate that 14 percent of participant hospitals through placement in the ''Excellent'' quality category would be eligible for reconciliation payments and for quality incentive payments valued at 1.5 percent of the hospital's benchmark episode price, compared to an estimate of 10 percent based on the proposed rule measures and score ranges. Thus, for each quality performance category, we have slightly lowered our quality performance expectations from our proposed rule discussion of the composite quality score approach, in order to provide participant hospitals with more significant financial incentives to improve their quality and cost performance under the CJR model, as well as their incentives to maintain high-quality performance.

Hospitals will be required to achieve a minimum composite quality of score greater than or equal to 4.0 to be eligible for a reconciliation payment if actual episode spending is less than the target price. Participant hospitals with below acceptable quality performance reflected in a composite quality score less than 4.0 will be assigned to the ''Below Acceptable'' quality category and will not be eligible for a reconciliation payment if actual episode spending is less than the target price. A level of quality performance that is below acceptable will not affect participant hospitals' repayment responsibility if actual spending exceeds the target price. We believe that the requirement that this minimum level of LEJR episode quality be achieved for reconciliation payments to be made is important to protect beneficiaries from excessive reductions in utilization that may result from the financial incentives in an episode payment model to lower actual episode spending. Under the pay-for-performance methodology of the CJR model, this policy should encourage participant hospitals to focus on appropriate reductions or changes in utilization that lead to high quality, more efficient care. Based on current hospital quality measure performance, approximately ninety percent of participant hospitals would have a composite quality score of greater than or equal to 4.0 and be eligible for reconciliation payments based on acceptable or better quality performance.

Participant hospitals with an acceptable composite quality score of greater than or equal to 4.0 and less than 6.0 will be assigned to the ''Acceptable'' quality category and be eligible for a reconciliation payment if actual episode spending is less than the target price because their quality performance is at the acceptable level established for the CJR model. They will not be eligible for a quality incentive payment at reconciliation because their episode quality performance, while acceptable, is not good or excellent. Therefore, these hospitals will be eligible to receive a reconciliation payment if actual episode spending is less than the target price.

Participant hospitals with a good composite quality score of greater than or equal to 6.0 and less than or equal to 13.2 will be assigned to the ''Good'' quality category and be eligible for a quality incentive payment at reconciliation if actual episode spending is less than the target price because their quality performance exceeds the acceptable level required for reconciliation payment eligibility under the CJR model. In addition, they will be eligible for a quality incentive payment at reconciliation for good quality performance that equals 1.0 percent of the participant hospital's benchmark

price, thereby changing the effective discount percentage included in the target price experienced by the hospital at reconciliation. Thus, participant hospitals achieving this level of quality for LEJR episodes under CJR will either have less repayment responsibility (that is, the quality incentive payment will offset a portion of their repayment responsibility) or receive a higher payment (that is, the quality incentive payment would add to the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual episode spending to the target price that reflects a 3.0 percent discount. Therefore, these hospitals will be eligible to receive a reconciliation payment if actual episode spending is less than the target price and will also receive a quality incentive payment.

Finally, hospitals with an excellent composite score quality score of greater than 13.2 will be assigned to the ''Excellent'' quality category and be eligible to receive a reconciliation payment if actual episode spending is less than the target price because their quality performance exceeds the acceptable level required for reconciliation payment eligibility under the CJR model. In addition, they will be eligible for a higher quality incentive payment at reconciliation for excellent quality performance that equals 1.5 percent of the participant hospital's benchmark price, thereby changing the effective discount percentage included in the target price experienced by the hospital at reconciliation. Thus, participant hospitals achieving this level of quality for LEJR episodes under CJR will either have less repayment responsibility (that is, the quality incentive payment will offset a portion of their repayment responsibility) or receive a higher payment (that is, the quality incentive payment would add to the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual episode spending to the target price that reflects a 3.0 percent discount. Therefore, these hospitals will be eligible to receive a reconciliation payment if actual episode spending is less than the target price and would also receive a quality incentive payment.

TABLE 19—PERFORMANCE YEAR 1: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION

Composite quality score	Quality category	Eligible for reconciliation payment	Eligible for quality incentive payment	Effective discount percentage for reconciliation payment (%)	Effective discount percentage for repayment amount
<4.0	Below Acceptable	No	No	3.0	Not applicable.
≥4.0 and <6.0	Acceptable	Yes	No	3.0	Not applicable.
≥6.0 and ≤13.2	Good	Yes	Yes	2.0	Not applicable.
>13.2	Excellent	Yes	Yes	1.5	Not applicable.

TABLE 20—PERFORMANCE YEARS 2 AND 3: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION

Composite quality score	Quality category	Eligible for reconciliation payment	Eligible for quality incentive payment	Effective discount percentage for reconciliation payment (%)	Effective discount percentage for repayment amount
<4.0	Below Acceptable	No	No	3.0	2.0
≥4.0 and <6.0	Acceptable	Yes	No	3.0	2.0
≥6.0 and ≤13.2	Good	Yes	Yes	2.0	1.0
>13.2	Excellent	Yes	Yes	1.5	0.5

TABLE 21—PERFORMANCE YEARS 4 AND 5: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION

Composite quality score	Quality category	Eligible for reconciliation payment	Eligible for quality incentive payment	Effective discount percentage for reconciliation payment (%)	Effective discount percentage for repayment amount
<4.0	Below Acceptable	No	No	3.0	3.0
≥4.0 and <6.0	Acceptable	Yes	No	3.0	3.0
≥6.0 and ≤13.2	Good	Yes	Yes	2.0	2.0
>13.2	Excellent	Yes	Yes	1.5	1.5

Under this methodology, the final stop-loss and stop-gain limits discussed in section III.C.8. of the final rule will not change for participant hospitals in different quality categories. Despite the limited number of quality measures adopted for the CJR model at this point in time compared to other programs, such as the Shared Savings Program and HBVP Program that use more measures in a quality scoring methodology, after considering the public comments we believe this approach to quality incentive payments based on the composite quality score will have the effect of increasing the alignment of the financial and quality performance incentives under the CJR model to the potential benefit of participant hospitals and their collaborators as well as CMS, although it substantially increases the

complexity of the pay-for-performance methodology to link quality and payment. The final methodology also provides a framework for incorporating quality performance and quality improvement in the pay-for-performance methodology of the CJR model as additional measures become available for consideration for the CJR model. We refer readers to section III.D.3. of this final rule for discussion of future measures for the model.

Comment: Many commenters urged CMS to provide incentives for hospitals to continuously improve the quality of care under the model. The commenters asserted that scoring approaches incorporating improvement have been successfully used in other CMS programs, such as the Shared Savings Program and HVBP Program, as well as other Innovation Center payment models. The commenters recommended that the proposed thresholds for reconciliation payment eligibility were inadequate as they would provide no incentive for further quality improvement for the approximately 50 percent of participant hospitals currently performing better than the proposed thresholds on all three proposed quality measures. Some of these commenters favored the composite quality score methodology and further recommended that in addition to incorporating quality performance on the quality measures in the CJR model payment methodology through the composite quality score, CMS should reward year-over-year quality improvement, like the Shared Savings Program.

A few commenters recommended that CMS reward quality improvement under the CJR model as long as there is no increase in episode spending, observing that under the statutory authority for the CJR model, one of the three expectations for a model is that it would increase the quality of care without increasing spending. The commenters claimed that setting a target price that always includes a discount over expected episode spending should not be necessary for participant hospitals that demonstrate improvements in quality performance.

Response: We appreciate the perspectives of the commenters who recommended that we directly reward hospitals for quality improvement, consistent with pay-for-performance policies under other CMS programs such as the HVBP Program and the Shared Savings Program. We note that the proposed pay-for-performance quality threshold methodology would have provided no additional potential for financial reward for quality improvement once participant hospitals met the 30th performance percentile threshold for reconciliation payment eligibility in the first three performance years and the 40th performance percentile threshold in the fourth and fifth performance years on the three proposed quality measures. As some commenters pointed out, the proposal was unlikely to advance a major goal of the CJR model to continue to improve the quality or maintain current high quality of care for beneficiaries in LEJR episodes at all participant hospitals. In contrast, the composite quality score methodology that incorporates quality measure performance and that we finalized in the preceding response to public comments may indirectly reward quality improvement. Quality measure performance for a performance year within a higher performance decile than the prior performance year may result in a higher number of quality performance points for that measure and, ultimately, a higher composite quality score that may result in participant hospital assignment to a quality category that provides quality incentive payments or a higher amount of quality incentive payments than the prior performance year's lower composite quality score. However, without further refinement of the composite quality score methodology finalized previously, unlike the pay-for-performance methodology in other CMS programs such as the Shared Savings Program, the CJR model would not directly reward quality improvement in the scoring methodology, thereby providing a lesser incentive for quality improvement than directly including points for improvement in the composite quality score as recommended by some commenters.

As we stated earlier in this section, we are not yet certain in this model test what performance outcomes can be achieved under best practices. Therefore, we believe a refinement to the composite score methodology in order to drive quality improvement for participant hospitals that have historically lagged in quality performance on the CJR model quality measures is appropriate, to supplement the composite score's valuing of quality performance in the pay-for-performance methodology of the model. We agree with the commenters that we should directly reward quality improvement under the CJR model pay-for-performance methodology to encourage participant hospitals currently at all levels of quality performance to improve their performance as they strive to achieve high quality performance outcomes under best practices. Like the commenters, we recognize that the heightened focus on episode cost and quality performance by participant hospitals may lead to substantial year-over-year quality measure improvement over the model performance years, and we agree that improvement should be valued in the pay-for-performance methodology, in addition to the quality measure performance percentile actually achieved by the hospital. However, we disagree with the commenters who suggested that participant hospitals demonstrating quality improvement should not be expected to demonstrate episode cost efficiency in order for quality improvement to be rewarded. Improved quality performance and cost savings are closely linked in the CJR pay-for-performance methodology, as both are major goals of the CJR model.

Therefore, we will refine the composite score methodology discussed in the proposed rule that assigns quality performance points based on performance percentiles for each measure to add the potential for incremental quality improvement points to be awarded for substantial improvement in performance on a required quality measure. We believe that the actual level of quality performance achieved should be most highly valued in the composite quality score to reward those hospitals furnishing high-quality care to CJR model beneficiaries, with a smaller contribution to the composite quality score made by improvement points if measure result improvement is achieved. We acknowledge that just because a hospital shows substantial improvement on a measure result, this does not necessarily mean the episode care is high-quality, yet the improvement spurred by the hospital's participation in the CJR model deserves to be valued as the hospital's performance is moving in a direction that is good for the health of beneficiaries. Valuing improvement is especially important because the CJR model involves such a wide range of hospitals that must participate if they are located in the selected MSAs, and the hospitals will be starting from many different current levels of quality performance. This refinement to the composite quality score methodology will help to provide all participant hospitals with a strong incentive to improve LEJR episode outcomes, including those hospitals with historically lagging quality performance.

Specifically, we will add into the composite quality score 10 percent of the maximum value for one or both of

the required measures, as applicable, which would equal 1 point for the THA/TKA Complications measure (NQF #1550) or 0.8 point for the HCAHPS Survey measure (NQF #0166), for those participant hospitals that demonstrate substantial improvement from the prior year's measure performance percentile on that measure. This modest increment of 10 percent will allow us to continue to value most significantly quality performance in the composite quality score, while incorporating a significant but lesser value on quality improvement. We believe that rewarding improvement by allocating 10 percent of the maximum quality performance points to improvement on a measure provides a significant incentive for participant hospitals to achieve national high performance benchmarks on the quality measures, as well as provides an incentive for historically lagging hospitals to make significant quality improvements.

Because of the uncertainty of statistical measures, as discussed previously in this section, and our annual comparison of a participant hospital's measure result to the national distribution to determine the hospital's performance percentile, we will only award measure quality improvement points where improvement is substantial and reflective of true improvement in quality performance on the individual measure. Thus, in order to be considered for improvement points on one of the measures, a participant hospital must have had a reportable measure performance result for that measure in the prior year. We note that in considering quality improvement points for award in the first model performance year, we will use measure results from the prior year quality measure performance period in determining each participant hospital's measure performance percentile against which we will compare its measure performance percentile for CJR model performance year 1 to determine if quality improvement points should be awarded. For the HCAHPS Survey measure (NQF #0166), the prior year quality measure performance period used will be July 1, 2014 through June 30, 2015. For the THA/TKA Complications measure (NQF #1550), the prior year quality measure performance period used will be April 1, 2012 through March 31, 2015. The measure performance percentiles for performance year 1 will be determined from measure results from the performance year 1 quality measure performance periods as displayed in Table C5 of this final rule.

We are defining substantial as improving 3 deciles or more in comparison to the national distribution of measure results. Improvement of three deciles represents a quality measure result change of over one-third of the range between the 10th percentile and the 90th percentile measure results. The 3 decile threshold to define substantial improvement is based on historical *Hospital Compare* information demonstrating that improving three deciles in measure performance on an annual basis is a challenging but attainable threshold for hospitals and reflects true improvement in quality performance on the individual measure. We estimate based on current quality measure performance over the most recent two years of available quality measure result data that 30 and 55 participant hospitals would qualify for improvement points on the HCAHPS Survey measure (NQF #0166) and the THA/TKA Complications measure (NQF #1550), respectively.

We note that when a participant hospital is awarded improvement points in addition to performance points on a specific required measure, the sum of these points for the measure will be slightly greater than the measure performance points that would be awarded to a hospital in the performance decile that is one level higher than the participant hospital's actual performance decile. By recognizing quality performance in the CJR model pay-for-performance methodology, supplemented by valuing quality improvement, we believe participant hospitals at all current levels of quality performance, including those historically lagging, will have the greatest incentives to achieve high and/or improved quality of care under the CJR model through strong financial incentives that are linked to quality.

Comment: A number of commenters urged CMS to further reduce the CJR model discount percentage in the target price for those participant hospitals who successfully reported THA/TKA voluntary PRO and limited risk variable data. They recommended that CMS apply a discount of 1.5 percent, rather than the proposed 1.7 percent, to the target price in order to support a participant hospital's development of an effective and efficient process for reporting. A commenter requested that CMS provide a stronger financial incentive for THA/TKA PRO voluntary and limited risk variable data submission as well as compensation for the additional hospital costs of data collection, reasoning that because the proposal for the reduced discount percentage only covers the expected additional costs of data collection, no financial incentive is present for hospitals to report these data. Several commenters stated that CMS should go further and require the submission of THA/TKA voluntary PRO and limited risk variable data by participant hospitals in order for reconciliation payments to be paid because, while limiting structure and process measures to value more highly outcome measures is laudable, the most important consideration in quality outcomes for CJR model beneficiaries should be beneficiary functional status. The commenters expressed disappointment in CMS' proposal that reporting would be voluntary and urged CMS to institute pay-for-reporting for these data are a requirement for hospitals to be paid any savings achieved for their episodes beyond the target price. Many commenters encouraged CMS to incorporate patient-reported outcomes measure performance in the CJR model as soon as possible, and some commenters further recommended that CMS delay implementation of the model until the PRO measure is available for use.

Response: We appreciate the emphasis the commenters placed upon measure development and implementation to capture the functional status of beneficiaries following LEJR procedures. Patient-reported outcomes following elective THA and TKA, which are the focus of the measure under development, are critically important for these costly procedures that beneficiaries choose to improve their quality of life, despite the lengthy recovery period involved. Pay-for-performance in the CJR model, an episode payment model that is designed to incentivize efficient, high-quality episode care, will benefit greatly from the incorporation of participant hospital performance on a measure of functional status when it is fully developed. We refer readers to section III.D.3.a.(9) of this final rule for further discussion of our plans and timeline to incorporate the THA/TKA Patient-Reported Outcome Performance Measure (PRO–PM) result in the CJR model when its development is complete after the period of THA/TKA voluntary PRO and limited risk variable data submission under the CJR model. We do not believe it would be appropriate to delay implementation of the CJR model until the measure has completed development, because the other final measures adopted for the model, as described in section III.D.2.a. through c. of this final rule, are meaningful measures of LEJR episode quality and

the CJR model provides an unprecedented opportunity to complete development of the THA/TKA PRO–PM because of the broad scope of the model test.

Because the measure is currently under development, we believe our final model payment policies and future plans for use of the measure result in the CJR model provide sufficient incentive and increased financial opportunity to encourage robust reporting by participant hospitals of THA/TKA voluntary PRO and limited risk variable data. For the reasons discussed earlier in this section, we are not finalizing our proposed pay-for-performance threshold methodology to determine a participant hospital's reconciliation payment eligibility if episode savings are achieved beyond the target price. Therefore, we are not finalizing our proposal to reduce the discount percentage to 1.7 percent from 2.0 percent for successful submission of THA/TKA voluntary PRO and limited risk variable data. Instead, under our final policy we are incorporating the successful criterion for submission of THA/TKA voluntary PRO and limited risk variable data into our composite quality score methodology for the CJR model, awarding points to participant hospitals who successfully submit these data that will be added into the calculation of the hospital's composite quality score, consistent with our discussion of the alternative approach to linking quality and payment in the proposed rule as described in detail earlier in this section. We refer readers to section III.D.3.a.(9) of this final rule for our final definition of successful reporting of THA/TKA voluntary PRO and limited risk variable data for each performance year of the CJR model. Furthermore, as the PRO–PM remains under development, we will not require the reporting of THA/TKA voluntary PRO and limited risk variable data for reconciliation payment eligibility. However, the successful reporting of the voluntary data may increase a participant hospital's financial opportunity under the model, which may be greater than the hospital's increased administrative cost to report the data. While the final policy to incorporate successful reporting of THA/TKA voluntary PRO and limited risk variable data into the composite quality score methodology is not directly keyed to addressing the hospital resources required for reporting as would have been true for the voluntary reporting payment adjustment that we proposed, we note that voluntary reporting can only help a hospital qualify for quality incentive payments and unsuccessful reporting will not hurt a participant hospital's eligibility for reconciliation payments.

Summary of Final Decisions: After consideration of the public comments we received, we are finalizing our proposal discussed in section III.C.5.b.(5)(b) of this final rule to assign participant hospital required outcome measure point estimates to performance percentiles based on the national distribution. We summarize the public comments we received on the proposed criteria for successfully reporting the voluntary THA/TKA data, as discussed in section III.C.5.b.(5)(b) of this final rule, and provide our responses in section III.D.3.a. of this final rule. However, we are not finalizing our proposal discussed in section III.C.5.b.(5)(c)(iii) of this final rule of a pay-for-performance methodology that identifies specific performance thresholds for the required quality measures that must be met for reconciliation payment eligibility. We are also not finalizing our proposal discussed in section III.C.5.b.(2) of this final rule to reduce the discount factor included in the target price for successful submission of THA/TKA voluntary PRO and limited risk variable data. Instead, based on our review of the public comments, we are finalizing the use of a composite quality score, as discussed in section III.C.5.b.(5)(c)(ii) of this final rule, that is based on quality performance and improvement on the THA/TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0116), as well as submission of THA/TKA voluntary PRO and limited risk variable data, and places participant hospitals in one of four quality categories for each performance year, ''Below Acceptable,'' ''Acceptable,'' ''Good,'' and ''Excellent.'' The final payment policies for the quality categories for the CJR model performance years are discussed earlier in this section and displayed in Tables 19, 20, and 21. We summarize the public comments we received on the proposed applicable time period, as discussed in section III.C.5.b.(4) of this final rule, and provide our responses in section III.D.3.d. of this final rule. We also summarize the public comments we received on the reporting time period for the THA/TKA patient reported outcome and limited risk variable data discussed in section III.C.5.b.(4) of this final rule and provide our responses in section III.D.3.a.(8) of this final rule.

We have added new definitions to § 510.2, specifically: ''Composite quality score'' means a score computed for each participant hospital to summarize the hospital's level of quality performance and improvement on specified quality measures, as described in § 510.315; ''Quality performance points'' are points that CMS adds to a participant hospital's composite quality score for a measure based on the performance percentile scale and for successful data submission of patient reported outcomes; and ''Quality improvement points'' are points that CMS adds to a participant hospital's composite quality score for a measure if the hospital's performance percentile on an individual quality measure increases from the previous performance year by at least three deciles on the performance percentile scale. We have revised § 510.305(f)(2) and (g)(2) and (3) to reflect the role of the composite quality score in determining reconciliation payment eligibility. The final pay-for-performance methodology is set forth in § 510.315, which has been retitled, ''Composite quality scores for determining reconciliation payment eligibility and quality incentive payments,'' and revised to set forth the final pay-for-performance methodology of the CJR model as described in this final rule.

6. Process for Reconciliation

We outlined in the proposed rule our proposals for how we intend to reconcile aggregate related Medicare payments for a hospital's beneficiaries in CJR episodes during a performance year against the applicable target price in order to determine if reconciliation payment (or repayment, beginning in performance year 2) is applicable under this model. We refer readers to section III.B. of this final rule for our definition of related services for LEJR episodes under CJR, to section III.C.2.a. of this final rule for our definition of performance years, and to section III.C.4. of this final rule for discussion of our approach to establish target prices.

a. Net Payment Reconciliation Amount (NPRA)

The proposed rule detailed our proposal to conduct reconciliation by calculating a NPRA for each hospital participant in the model. After the completion of a performance year, we proposed to retrospectively calculate a participant hospital's actual episode performance based on the episode definition. We noted that episode payments for purposes of the CJR model would exclude the effects of special payment provisions under existing Medicare payment systems (section III.C.3.a. of this final rule), be subject to

proration for services that extend beyond the episode (section III.C.3.b. of this final rule), and exclude certain PBPM payments for programs and models specified in section III.C.7.d. of this final rule. We proposed that some episodes may be excluded entirely from the CJR model due to overlap with BPCI episodes, as discussed in section III.C.7.b. of this final rule. Finally, we proposed that actual episode payments calculated for purposes of CJR would be capped at anchor MS–DRG and region-specific high episode payment ceilings (section III.C.3.c. of this final rule). We proposed to apply the high episode payment ceiling policy to episodes in the performance year similarly to how we apply it to historical episodes (section III.C.4.c. of this final rule). Episode payments for episodes attributed to CJR eligible hospitals would be determined and the high episode payment ceiling would be calculated as two standard deviations above the mean. Any actual episode payment amount above the high payment ceiling would be capped at the applicable ceiling.

We proposed to compare each participant hospital's actual episode payment performance to its target prices. We proposed that, as discussed in section III.C.4. of this final rule, a participant hospital would have multiple target prices for episodes ending in a given performance year, based on the MS–DRG anchor (MS–DRG 469 versus MS–DRG 470), the performance year when the episode was initiated, when the episode was initiated within a given performance year (January 1 through September 30 of the performance year, October 1 through December 31 of the performance year, October 1 through December 31 of the prior performance year), and whether the participant hospital successfully submitted THA/TKA voluntary PRO and limited risk variable data. The applicable target price for each episode would be determined using the previously stated criteria, and the difference between each CJR episode's actual payment and the relevant target price (calculated as target price subtracted by CJR actual episode payment) would be aggregated for all episodes for a participant hospital within the performance year, representing the raw NPRA. This amount would be adjusted per the steps discussed later in this section, creating the NPRA.

We proposed to adjust the raw NPRA to account for post-episode payment increases (section III.C.8.e. of this final rule) and stop-loss and stop-gain limits (section III.C.8.b. of this final rule). Any NPRA amount greater than the proposed stop-gain limit would be capped at the stop-gain limit, and any NPRA amount less than the proposed stop-loss limit would be capped at the stop-loss limit.

We did not propose to include any CJR reconciliation payments or repayments to Medicare under this model for a given performance year in the NPRA for a subsequent performance year. We want to incentivize providers to provide high quality and efficient care in all years of the model. If reconciliation payments for a performance year are counted as Medicare expenditures in a subsequent performance year, a hospital would experience higher Medicare expenditures in the subsequent performance year as a consequence of providing high quality and efficient care in the prior performance year, negating some of the incentive to perform well in the prior year. Therefore, we proposed to not have the NPRA for a given performance year be impacted by CJR repayments or reconciliation payments made in a prior performance year. For example, if a CJR hospital receives a $10,000 reconciliation payment in the second quarter of 2017 for achieving episode spending below the target price for performance year 1, that $10,000 reconciliation payment amount would not be included in the performance year 2 calculations of actual episode spending. However, as discussed in section III.C.6.b. of this final rule, during the following performance year's reconciliation process, we proposed to account for additional claims run-out and overlap from the prior performance year, and net that amount with the subsequent performance year's NPRA to determine the reconciliation or repayment amount for the current reconciliation. The following is a summary of comments received and our response.

Comment: Commenters emphasized the need to accurately account for wage index differences when calculating target prices and conducting reconciliation activities.

Response: We refer readers to comments and responses to comments in section III.C.4.b.(7) of this final rule for further discussion on the finalized target price calculation policy to normalize for wage index differences at the claim level and to reintroduce wage index differences based on the participant hospital's wage index and labor cost share. In order to maintain consistency with the target price calculations, and to more accurately normalize for the effects of wage index differences, we will apply the same claim-level wage index normalization to claim payments included in actual episode expenditures for each performance year when calculating a hospital's NPRA.

We also refer readers to response to comments in section III.C.4.b.(7) of this final rule on the importance of reintroducing wage index differences when calculating target prices and reconciliation and repayment amounts. In order to maintain consistency with the target price calculations, we will reintroduce wage index differences when calculating NPRA by applying the participant hospital's wage index and 0.7 as the labor cost share. By mirroring the target price calculation approach for accounting for wage index differences, we can better ensure that any reconciliation amounts or repayments to Medicare are due to differences in practice patterns, not Medicare FFS wage index policy variations.

Comment: A commenter suggested that CMS perform reconciliation calculations differently when a beneficiary in a CJR episode receives PAC from a SNF or HHA not recommended by the CJR hospital discharge planners. Another commenter noted that the reconciliation calculation CMS proposed needed refinement as it pertains to the proposed methodology for setting episode prices and paying model participants; the commenter's suggestions pertaining to the payment methodology are addressed in section III.C.4. of this final rule.

Response: We thank commenters for their suggestions. However, we do not believe it is appropriate to make adjustments to a given hospital's NPRA based on the choice of PAC facility for beneficiaries discharged from that facility. Such a change would be inconsistent with our goal of maintaining beneficiary choice and access to care, discussed in section III.F. of this final rule. We also note that the process for calculating the NPRA is consistent with our methodology for calculating target prices and actual episode spending during the performance period (section III.C.4.b. of this final rule), along with the adjustments to NPRA that would account for post-episode spending (III.C.8.d. of this final rule) and the stop-loss and stop-gain limits discussed in section III.C.8.b. of this final rule.

Final Decision: We refer readers to section III.C.4. of this final rule for discussion of modifications to how the target prices and performance period episode spending are calculated, including risk stratification for fracture patients. In addition, section III.C.5. of this final rule addresses our final policy on how quality performance will be

used to determine a CJR hospital's effective discount percentage. However, after consideration of the public comments we received, we are modifying our proposal to calculate the NPRA utilizing the methodology described in this subsection to account for wage index normalization and reintroduction when calculating actual episode expenditures in a performance year and including the modifications to calculation of target prices and actual episode spending as described elsewhere in this section. After the completion of a performance year, we will retrospectively calculate a participant hospital's actual episode spending based on the episode definition. Each participant hospital's actual episode payment performance will be compared to its target prices, creating the raw NPRA, and then adjusted for the stop-loss and stop-gain limits, as well as post-episode spending, creating the NPRA.

b. Payment Reconciliation

We proposed to reconcile payments retrospectively through the following reconciliation process. We proposed to reconcile a participant hospital's CJR actual episode payments against the target price 2 months after the end of the performance year. More specifically, we would capture claims submitted by March 1st following the end of the performance year and carry out the NPRA calculation as described previously to make a reconciliation payment or hold hospitals responsible for repayment, as applicable, in quarter 2 of that calendar year.

Comment: Some commenters explicitly supported CMS's proposal to implement a retrospective reconciliation process. However, a few commenters suggested CMS implement a prospective reconciliation process (see section III.C.2.b. of this final rule for discussion of comments on the retrospective payment methodology). Commenters suggested CMS make a prospective bundled payment to hospitals for all services provided during a CJR episode; hospitals would then distribute payments to other providers and suppliers. A commenter suggested that CMS hold a specified percentage of total episode payments for downstream (non-hospital) providers and suppliers furnishing services during CJR episodes and hospitals would later distribute the amount of the withheld payment to providers and suppliers based on quality and efficiency.

Response: We refer readers to section III.C.4.b. of this final rule for discussion of comments received on our proposed methodology to establish target prices and retrospectively calculate performance period episode spending.

We considered the suggestion to implement a blended reconciliation approach by withholding a specified percentage of FFS payments and later distributing the remainder of payments to hospitals for disbursement to downstream providers and suppliers. We believe that the operational challenges associated with such an approach would introduce significant administrative burden for hospitals. We also note that, as discussed in section III.C.10. of this final rule, we are finalizing policies that will allow participant hospitals to engage in financial arrangements and relationships with downstream providers and suppliers. We believe these relationships will allow participant hospitals the opportunity to share financial risk with downstream providers and suppliers and engage such entities in efforts to improve quality and efficiency throughout the episode.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal, without modification, to conduct a retrospective reconciliation process for the CJR model.

To address issues of overlap with other CMS programs and models that are discussed in section III.C.7. of the proposed rule, we also proposed that during the following performance year's reconciliation process, we would calculate the prior performance year's episode spending a second time to account for final claims run-out, as well as overlap with other models as discussed in section III.C.7. of this final rule. This would occur approximately 14 months after the end of the prior performance year. As discussed later in this section, the amount from this calculation, if different from zero, would be applied to the NPRA for the subsequent performance year in order to determine the amount of the payment Medicare would make to the hospital or the hospital's repayment amount. We note that the subsequent reconciliation calculation would be applied to the previous calculation of NPRA for a performance year to ensure the stop loss and stop gain limits discussed in section III.C.8. of this final rule are not exceeded for a given performance year.

For the performance year 1 reconciliation process, we would calculate a participant's, as previously described, and if positive, the hospital would receive the amount as a reconciliation payment from Medicare. If negative, the hospital would not be responsible for repayment to Medicare, consistent with our proposal to phase in financial responsibility beginning in performance year 2. Starting with the CJR reconciliation process for performance year 2, in order to determine the reconciliation or repayment amount, the amount from the subsequent reconciliation calculation would be applied to the NPRA. We proposed that if the amount is positive, and if the hospital meets the minimum quality score required to be eligible for reconciliation, (discussed further in section III.C.5. of this final rule), the hospital would receive the amount as a reconciliation payment from Medicare. If the amount is negative, Medicare would hold the participant hospital responsible for repaying the absolute value of the repayment amount following the rules and processes for all other Medicare debts. Note that given our proposal to not hold participant hospitals financially responsible for repayment for the first performance year, during the reconciliation process for performance year 2 only, the subsequent calculation amount (for performance year 1) would be compared against the performance year 1 NPRA to ensure that the sum of the NPRA calculated for performance year 1 and the subsequent reconciliation calculation for year 1 is not less than zero. For performance years 2 through 5, though, we proposed that Medicare would hold the participant hospital responsible for repaying the absolute value of the repayment amount following the rules and processes for all other Medicare debts. The following table illustrates a simplified example of how the subsequent reconciliation calculation may affect the following year's reconciliation payment. The second column represents the raw NPRA calculated for Performance Year 1, meaning that Hospital A's aggregated episode spending was $50,000 below the target price multiplied by the number of episodes. The third column represents the subsequent reconciliation calculation, indicating that when calculating episode spending during Performance Year 1 a second time, we determined that Hospital A's aggregated episode spending was $40,000 below the target price multiplied by the number of episodes, due to claims runout, accounting for model overlap, or other reasons. The fourth column represents the difference between the subsequent reconciliation calculation and the raw NPRA calculated for Performance Year 1. This difference is then combined with the amount in the fifth column to create the reconciliation

payment amount for PY2, which is reflected in the sixth column.

TABLE 22—SAMPLE RECONCILIATION RESULTS

	Performance Year 1 (2016) raw NPRA	Performance Year 1 subsequent reconciliation calculation	Difference between PY1 subsequent reconciliation calculation and raw NPRA	Performance Year 2 (2017) raw NPRA	Reconciliation payment made to hospital in quarter 2 2018
Hospital A	$50,000	$40,000	($10,000)	$25,000	$15,000

This reconciliation process would account for overlaps between the CJR model and other CMS models and programs as discussed in section III.C.7. of this final rule, and would also involve updating performance year episode claims data. We also note that in cases where a hospital has appealed its quality performance results on the complications and HCAHPS quality measures through the IQR program appeal process, discussed in section III.D. of this final rule, and where such appeal results would result in a different effective discount percentage or quality incentive payment under the CJR model, the subsequent reconciliation calculation will account for these updates as well.

For example, for performance year 1 for the CJR model in 2016, we would capture claims submitted by March 1st, 2017, and reconcile payments for participant hospitals approximately 6 months after the end of the performance year in quarter 2 of calendar year 2017. We would carry out the subsequent calculation in the following year in quarter 2 of calendar 2018, simultaneously with the reconciliation process for the second performance year, 2017. Table 23 provides the reconciliation timeframes for the model. Lastly, we proposed that the reconciliation payments to or repayments from the participant hospital would be made by the MAC that makes payment to the hospital under the IPPS. This approach is consistent with BPCI Model 2 operations.

We proposed this approach in order to balance our goals of providing reconciliation payments in a reasonable timeframe, while being able to account for overlap and all Medicare claims attributable to episodes. We stated that pulling claims 2 months after the end of the performance year would provide sufficient claims run-out to conduct the reconciliation in a timely manner, given that our performance year includes episodes ending, not beginning, by December 31st. We note that in accordance with the regulations at § 424.44 and the Medicare Claims Processing Manual (Pub. L. 100–04), Chapter 1, Section 70, Medicare claims can be submitted no later than 1 calendar year from the date of service. We recognized that by pulling claims 2 months after the end of the performance year to conduct reconciliation, we would not have complete claims run-out. However, we believed that the 2 months of claims run-out would be an accurate reflection of episode spending and consistent with the claims run-out timeframes used for reconciliation in other payment models, such as BPCI Models 2 and 3. The alternative would be to wait to reconcile until we have full claims run out 12 months after the end of the performance year, but we were concerned that this approach would significantly delay earned reconciliation payments under this model. Because we proposed to conduct a second calculation to account for overlap with other CMS models and programs, we proposed to incorporate updated claims data with 14 months run out at that time. However, we did not expect that the updated data should substantially, in and of itself, affect the reconciliation results assuming hospitals and other providers and suppliers furnishing services to Medicare beneficiaries in CJR episodes follow usual patterns of claims submission and do not alter their billing practices due to this model.

TABLE 23—PROPOSED TIMEFRAME FOR RECONCILIATION IN CJR

Model performance year	Model performance period	Reconciliation claims submitted by	Reconciliation payment or repayment	Second calculation to address overlaps and claims run-out	Second calculation adjustment to reconciliation amount
Year 1 *	Episodes ending April 30, 2016 to December 31, 2016.	March 1, 2017	Q2 2017	March 1, 2018	Q2 2018.
Year 2	Episodes ending January 1, 2017 through December 31, 2017.	March 1, 2018	Q2 2018	March 1, 2019	Q2 2019.
Year 3	Episodes ending January 1, 2018 through December 31, 2018.	March 1, 2019	Q2 2019	March 2, 2020	Q2 2020.
Year 4	Episodes ending January 1, 2019 through December 31, 2019.	March 2, 2020	Q2 2020	March 1, 2021	Q2 2021.
Year 5	Episodes ending January 1, 2020 through December 31, 2020.	March 1, 2021	Q2 2021	March 1, 2022	Q2 2022.

* Note that the reconciliation for Year 1 would not include repayment responsibility from CJR hospitals.

Comment: Several commenters supported the proposed reconciliation process. However, many commenters requested that CMS conduct reconciliation activities on a quarterly or semi-annual, instead of annual, basis. Some commenters suggested that CMS offer participant hospitals the option of electing annual or a more frequent reconciliation timeline. Commenters stated numerous reasons for their request, including: Providing revenue and cash flow to hospitals throughout the year to aid in care coordination and redesign efforts; giving hospitals interim data on financial performance; the time lag between the end of a performance year and the subsequent reconciliation calculation; utilizing data for improving care processes; giving hospitals the opportunity to gainshare with other providers and suppliers with greater frequency; and consistency with the frequency of reconciliation in the BPCI initiative, among other reasons. Some commenters supported the proposal to make reconciliation payments or require repayment on an annual basis, but requested that CMS also conduct interim quarterly reconciliation projections to provide hospitals with information on financial performance throughout the performance year. Several commenters claimed that the proposed reconciliation process would result in reduced revenue for hospitals throughout the performance period. However, a commenter stated that receiving annual reconciliation results in the second quarter of the calendar year following the completion of a performance year would provide hospitals with timely feedback and opportunity to adjust strategies in subsequent years to improve or maintain financial performance. Another commenter noted that annual reconciliation at the end of each performance year would give participants an early indication of progress under the model.

Response: We appreciate the perspectives of the commenters on our proposal. In response to commenters' concerns that an annual reconciliation process would result in reduced revenue for hospitals, we are clarifying that model participants, and all providers and suppliers, would continue to bill and be paid through normal Medicare FFS processes throughout the model for Part A and Part B services furnished to beneficiaries during a CJR episode, with a retrospective reconciliation process after the conclusion of a performance year. We disagree that an annual reconciliation process would result in reduced revenue for hospitals. In addition, we note that beginning in the second quarter of 2017 when the first reconciliation is performed, CJR hospitals will be able to utilize any reconciliation payments they earn to invest in care redesign and coordination efforts on an ongoing basis. We emphasize that the delay of financial repayment responsibility until performance year 2 means no hospital will be required to make a repayment to Medicare until the second quarter of 2018 for actual episode spending exceeding the target price. In addition, the delay of the model start date until April 1, 2016 and truncated first performance year will reduce the amount of time between beginning participation in the CJR model and the first reconciliation.

We appreciate commenters' concerns and request for more frequent feedback on performance throughout the performance period. However, we continue to believe that an annual reconciliation process is most appropriate for the following reasons. As previously stated in this section, providers and suppliers have a calendar year to submit FFS claims for payment. Implementing a quarterly reconciliation process, as we do for the BPCI models, would mean that many claims may be incomplete at the time of the reconciliation. The BPCI reconciliation process incorporates 3 subsequent reconciliation calculations, and BPCI participants have experienced significant fluctuation in financial results between the initial reconciliation and the subsequent calculations. We believe our proposed annual reconciliation approach will lead to more stable financial results for providers. We also note based on our experience with the BPCI models that a quarterly reconciliation process results in model participants' near constant engagement in the reconciliation and appeals processes. This can potentially take time away from efforts focused on care redesign and coordination with providers and suppliers engaged in furnishing care for beneficiaries under the model. In addition, given our plan to assess hospital performance on quality measures (discussed in section III.C.5. of this final rule), we note that annual reconciliation processes will be necessary in order to calculate an accurate composite quality score for hospital participants, since quality measures are calculated on an annual basis. We also proposed to perform annual reconciliation for consistency with other models and programs such as the Shared Savings Program. As discussed in section III.C.7.e.of this final rule, we will allow for beneficiaries to be assigned to an ACO and have a concurrent CJR episode. We will perform our reconciliation calculations and then make the reconciliation and repayment amounts available to other models and programs in order to account for overlapping beneficiaries. We have aligned our annual reconciliation timeline with the ACO models and program in order to make this information available before the ACO models and program begin their annual financial reconciliation calculations; such a timeline is necessary to be able to account for program and model overlap.

We understand commenters' assertions that annual reconciliation does not allow for frequent feedback on financial performance under the model. We would like to reiterate that we will be providing both line-level and summary claims data to model participants on a quarterly basis, as discussed in section III.E. of this final rule. Such data are intended to provide hospitals with information about their care patterns and to identify opportunities for care redesign and savings. This data will also provide ongoing feedback to hospitals about their performance under the model, by including both raw claims as well as summary data with information about their episode spending and care patterns. Moreover, unlike in BPCI Models 2 and 3, we will be providing model participants with performance year target prices on a prospective basis, as discussed in section III.C.4 of this final rule. Prospective target pricing will provide hospitals with increased certainty about financial targets under the model. Finally, we also considered commenters' requests to conduct interim financial reconciliation calculations on a quarterly basis and provide the results of such calculations to hospitals. Because of the potential for volatility between the interim results and the final reconciliation results, and our concern that such results would not provide additional meaningful information to hospitals not present in the claims data and prospective target prices, we are not pursuing an interim reconciliation process at this time. However, we will continue to consider commenters' suggestions and will consider the feasibility of providing interim results in the future if we believe it could aid hospitals in succeeding under this model and would provide additional information not already present in the previously stated claims data and target prices.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal, without modification, to conduct financial reconciliation on an annual basis. We will engage with CJR hospitals throughout the model to ensure the prospective target prices and quarterly data provided to hospitals provide sufficient ongoing feedback and data to hospitals between reconciliations. As previously noted, we will continue to consider commenters' suggestions and consider the feasibility of further interim financial results in the future if warranted.

Comment: Several commenters expressed concerns about post-payment denials and Recovery Audit Contractor (RAC) or MAC reviews that may occur after the CJR model reconciliation processes are complete. A commenter asserted that providers could be doubly penalized for such claims if review and denial occurs after the subsequent reconciliation calculation, in particular if a claim is denied for more than 100 percent of the payment amount. The commenter noted further concern due to the aggregated reconciliation calculation; that is if a given claim is later denied for an amount greater than 100 percent of the payment amount, the denied amount could affect more than just the claim in question. The commenter urged CMS to exempt all claims attributed to the CJR model from post-payment review and denial.

Another commenter requested that CMS further outline the reconciliation and repayment processes, including how reconciliation would be conducted for Periodic Interim Payment (PIP) hospitals. Finally, a commenter requested a more flexible repayment process for hospitals meeting certain eligibility criteria, but did not suggest specific criteria.

Response: We appreciate the commenters' views. We believe the proposed process to perform a reconciliation calculation 2 months after the conclusion of a performance year, with a subsequent reconciliation calculation 12 months later, will allow sufficient time for routine monitoring, review, and adjustment. We acknowledge that audits and reviews may occur after our reconciliation processes are complete, agreeing that post-payment reviews may occur up to 3 years after the submission of a claim, or longer in some instances. However, we believe that concluding reconciliation processes 14 months after the completion of a performance year provides a reasonable timeframe for claims run-out and subsequent actions on a claim and is consistent with other payment reconciliation processes, such as the reconciliation of hospital cost reports, which can have impacts that are mostly but not entirely reconciled across multiple payment systems. With respect to commenters' specific suggestions, we note that prohibiting review of all claims submitted for a beneficiary during a CJR episode would not be consistent with our stated goals of the model to monitor for quality and appropriateness of care. While we appreciate the concern that the price setting methodology under this model already provides a limit on spending during the episode, we point out that provider payments are not absolutely capped and hospitals are therefore not completely at risk. During the initial model period in which hospitals will not be financially responsible for repayment to Medicare for spending exceeding the target price, all risk will be borne by Medicare. In addition, in later years of the model all CJR hospital gains and losses are capped, as discussed in section III.C.8. of this final rule, meaning that Medicare will continue to bear risk for unusually costly cases. We do not believe that CMS should be denied the full flexibility to utilize all current processes for pre- and post-payment review based on existing rules and regulations for claims associated with care furnished under this model. Such a policy could potentially encourage inefficient or inaccurate billing practices, or hinder CMS' ability to appropriately monitor provider and supplier practices under the model. We also note that such situations would only happen if a claim were later denied and as such, encourage providers and suppliers submitting claims to ensure accuracy and that policies as laid out in this final rule are followed by all providers and suppliers submitting Medicare FFS claims for services furnished to beneficiaries under the model.

In response to these comments we have considered whether it would be appropriate to allow subsequent reconciliations if claims are denied and reprocessed after the second reconciliation. We do not believe this is appropriate for several reasons. First, we note that in the event that the hospital's total episode spending exceeded the target price, we are finalizing policies that limit hospitals' financial responsibility for such spending, as discussed in section III.C.8. of this final rule. Second, the entire purpose of MAC and RAC audits is to ensure that Medicare payments are correctly administered and made only for services delivered in accordance with statute and regulation. If the hospital enters into appropriate collaboration agreements with high quality, responsible, and compliant PAC providers, the 14-month period prior to the second reconciliation provides ample opportunity for the hospital and its collaborators to work together to conduct internal audits and ensure that PAC claims are properly submitted or corrected. We believe it is appropriate for hospitals to continue to share some risk with Medicare even after the final reconciliation, and believe this provides additional incentives for them to work closely with their collaborators to ensure that all services are delivered appropriately. Third, we believe it is important to conclude the reconciliation process in the timeframe we have previously outlined in this section, in order to provide hospitals with financial results and certainty over their performance under the model. Additional subsequent reconciliations could introduce uncertainty for model participants. Finally, we do agree that we have a responsibility to ensure that MACs, RACs, and other auditing entities audit services delivered under the CJR using the rules and regulations governing the CJR model in addition to all other relevant statute, regulation, and guidance. We believe that appropriate contractor training and oversight will protect hospitals from inappropriate denials while protecting beneficiaries from the use of inappropriate services and protecting Medicare from making payments on inappropriate claims. We reiterate the information provided in the proposed rule that when a hospital is eligible for a reconciliation payment, such payment would be made to participant hospitals in a form and manner specified by CMS. In cases where repayment is required, as stated in the proposed rule, CMS will follow the normal Medicare debt processes, such as issuing a demand letter. CMS intends to build on existing processes for making reconciliation payments to hospitals or requiring repayment which are familiar to hospitals. Such processes will rely on electronic and other established processes to the extent possible. We also reiterate that as discussed in section III.C.8. of this final rule, certain hospitals would be afforded additional financial protections. We believe are protections are sufficient and an extended repayment process for such hospitals is not necessary.

With regard to PIP hospitals, we appreciate that commenters point out the different payment processes that apply to such hospitals. PIP hospitals receive biweekly payments based on

hospitals' estimates of applicable Medicare reimbursement for a given cost period. Such hospitals also submit FFS claims to Medicare, which are reconciled against the payments made through the PIP processes. Given that such hospitals continue to submit FFS claims and the reconciliation and repayment amounts from the CJR model would not be included in the PIP hospital cost reports at settlement, we do not believe it is necessary to institute a separate reconciliation process for PIP hospitals.

Summary of Final Decisions: After consideration of the public comments we received, we are finalizing our proposal to calculate the NPRA as previously outlined. We are also finalizing, without modification, our proposal to conduct an annual retrospective reconciliation with one subsequent reconciliation calculation in the following year.

The following table illustrates the final timeframe for reconciliation.

TABLE 24—FINAL TIMEFRAME FOR RECONCILIATION IN CJR

Model performance year	Model performance period	Reconciliation claims submitted by	Reconciliation payment or repayment	Second calculation to address overlaps and claims run-out	Second calculation adjustment to reconciliation amount
Year 1*	Episodes ending June 30, 2016 to December 31, 2016.	March 1, 2017	Q2 2017	March 1, 2018	Q2 2018.
Year 2	Episodes ending January 1, 2017 through December 31, 2017.	March 1, 2018	Q2 2018	March 1, 2019	Q2 2019.
Year 3	Episodes ending January 1, 2018 through December 31, 2018.	March 1, 2019	Q2 2019	March 2, 2020	Q2 2020.
Year 4	Episodes ending January 1, 2019 through December 31, 2019.	March 2, 2020	Q2 2020	March 1, 2021	Q2 2021.
Year 5	Episodes ending January 1, 2020 through December 31, 2020.	March 1, 2021	Q2 2021	March 1, 2022	Q2 2022.

*Note that the reconciliation for Year 1 would not include repayment responsibility from CJR hospitals.

This final policy is set forth at § 510.305.

7. Adjustments for Overlaps With Other Innovation Center Models and CMS Programs

a. Overview

In the proposed rule, we acknowledged that there may be circumstances where a Medicare beneficiary in a CJR episode may also be assigned to an ACO participating in the Shared Savings Program or otherwise accounted for in a payment model being tested by the Innovation Center. Current or forthcoming programs and models with potential overlap with CJR are displayed in Table 24. For purposes of this final rule, ''total cost of care'' models refers to models in which episodes or performance periods include participant financial responsibility for all Part A and Part B spending, as well as some Part D spending in select cases. We use the term ''shared savings'' to refer to models in which the payment structure includes a calculation of total savings and CMS and the model participants each retain a particular percentage of that savings. We note that there exists the possibility for overlap between CJR episodes and shared savings programs and models such as the Pioneer ACO Model, other total cost of care models such as the OCM, other Innovation Center payment models such as BPCI, and other models or programs that incorporate per-beneficiary-per-month fees or other payment structures.

TABLE 25—CURRENT PROGRAMS AND MODELS WITH POTENTIAL OVERLAP WITH CJR MODEL

Program/model	Brief description	Shared savings?	Per-beneficiary-per-month (PBPM) payments?
Pioneer ACO Model	ACO shared savings model	Yes	No.
Medicare Shared Savings Program (Shared Savings Program).	ACO shared savings program	Yes	No.
Next Generation ACO Model*	ACO shared savings model	Yes	No.
Comprehensive Primary Care initiative (CPCi)	Pays primary care providers for improved and comprehensive care management.	Yes	Yes.
Multi-payer Advanced Primary Care Practice (MAPCP).	Multi-payer model for advanced primary care practices, or ''medical homes''.	Yes	Yes.
Bundled Payments for Care Improvement (BPCI)	Bundled payment program for acute or PAC services or both.	No	No.
Oncology Care Model (OCM)*	Multi-payer model for oncology physician group practices (PGPs).	No	Yes.
Comprehensive ESRD Care Initiative (CEC)*	ACO for ESRD Medicare beneficiaries	Yes	No.
Million Hearts*	Model targeting prevention of heart attack and stroke.	No	Yes.

TABLE 25—CURRENT PROGRAMS AND MODELS WITH POTENTIAL OVERLAP WITH CJR MODEL—Continued

Program/model	Brief description	Shared savings?	Per-beneficiary-per-month (PBPM) payments?
Medicare Care Choices Model (MCCM)*	Hospice concurrent care model	No	Yes.

*Denotes model in pre-implementation phase.

In the proposed rule, we outlined the following issues that may arise in such overlap situations that must be addressed under CJR. First, beneficiaries in CJR episodes could also be part of BPCI Model 2 or 3 LEJR episodes or BPCI non-LEJR episodes, and the clinical services provided as part of each episode may overlap entirely or in part. Second, CJR reconciliation payments and repayments that are made under Part A and B and attributable to a specific beneficiary's episode may be at risk of not being accounted for by other models and programs when determining the cost of care under Medicare for that beneficiary. Third, some Innovation Center models make PBPM payments to entities for care coordination and other activities, either from the Part A or B Trust Fund or both, or from the Innovation Center's own appropriation (see section 1115A(f) of the Act). These payments may occur during a CJR episode. Finally, there could be instances when the expected Medicare savings for a CJR beneficiary's episode (represented by the discount percentage) is not achieved by Medicare because part of that savings is paid back to the hospital or another entity under the Shared Savings Program or a total cost of care model in which the beneficiary is also included. We sought comment on our proposals to account for overlap with the Shared Savings Program and other models, including those listed in Table 24 as well as other CMS models or programs.

The following is a summary of the comments received and our responses.

Comment: A commenter requested that CMS not limit providers from developing and implementing other episode-based payment models while participating in the CJR model.

Response: We clarify that we have not included any limitations on participation in future or current models through this final rule. In addition, we have included the policies in this section in order to allow for CJR hospitals to participate in other models and initiatives concurrently with the CJR model.

b. CJR Beneficiary Overlap With BPCI Episodes

BPCI is an episode payment model testing LEJR episodes, as well as 47 other episodes, in acute or PAC or both settings (Models 1, 2, 3 or 4). As discussed in section III.A. of the proposed rule, we proposed to exclude from selection for participation in the CJR payment model those geographic areas where 50 percent or more of LEJR episodes are initiated at acute care hospitals testing the LEJR episode in BPCI in Models 1, 2 or 4 as of July 1, 2015. In that same section, we proposed that acute care hospitals in selected geographic areas participating in BPCI under Model 1 (acute care only) and those participating as episode initiators for the LEJR episode in Model 2 (acute and PAC from 30 to 90 days post-discharge) or Model 4 (prospective episode payment for the LEJR anchor hospitalization and related readmissions for 30 days post-discharge) be excluded from CJR. We discuss the comments received on this proposal and our responses in section III.A.4. of this final rule.

While we believed these proposals will mitigate the overlap of CJR beneficiaries with BPCI episodes, there may still be instances of model overlap that we need to account for under CJR. These include circumstances when a beneficiary is admitted to a CJR participant hospital for an LEJR procedure where the beneficiary would also be in a BPCI Model 2 episode under a PGP that would initiate the episode under BPCI. In another example, a beneficiary discharged from an anchor hospitalization under CJR could enter a BPCI Model 2 LEJR episode at another hospital for a phased second joint replacement procedure or enter a BPCI Model 3 LEJR episode upon initiation of PAC services at a BPCI PAC provider episode initiator for the LEJR episode. Similarly, a beneficiary in a BPCI Model 2 or Model 3 LEJR episode could be admitted to a CJR participant hospital for a phased second joint replacement. In all such scenarios in which there is overlap of CJR beneficiaries with any BPCI LEJR episodes, we proposed that the BPCI LEJR episode under Models 1, 2, 3, or 4 take precedence and we would cancel (or never initiate) the CJR episode. Because the cancelation (or lack of initiation) would only occur for overlap with BPCI LEJR episodes, we expect that the participant hospital and treating physician would generally be aware of the beneficiary's care pathway that would cancel or not initiate the CJR episode. Therefore, we would exclude the CJR episode from the CJR participant hospital's reconciliation calculations where we compare actual episode payments to the target price under the CJR model. If we were to allow both CJR and BPCI LEJR episodes to overlap, we would have no meaningful way to apply the payment policies in two models with overlapping care redesign interventions and episodes. Participants in BPCI have an expectation that eligible episodes will be part of the BPCI model test, whereas CJR participants would be aware that episodes may be canceled when there is overlap with BPCI episodes as previously discussed in this final rule. We aim to preserve the integrity of ongoing model tests without introducing major modifications (that is, CJR episode precedence) that could make evaluation of existing models more challenging. We considered that there may also be instances of overlap between CJR and BPCI Model 3 LEJR episodes where our proposal to give precedence to all BPCI episodes could lead to undesirable patient steering because the BPCI Model 3 episode does not begin until care is initiated at an episode-initiating PAC provider. It could be possible for a participating CJR hospital to purposefully guide a beneficiary to a BPCI Model 3 LEJR episode initiating PAC provider to exclude that beneficiary's episode from CJR. We considered giving precedence to the CJR episode in overlap with Model 3 beneficiaries because the CJR episode begins with admission for the anchor hospitalization and thus includes more of the episode services. However, we believed the steering opportunities would be limited due to the preservation of beneficiary choice of provider in this model (as discussed in section III.E. of the proposed rule). As outlined in section III.F. of this final rule, CJR hospitals must provide patients with a complete list of all

available PAC options. Moreover, BPCI Model 3 PAC providers are actively involved in the decision to admit patients to their facilities. As episode initiators in BPCI, such providers are subject to monitoring and evaluation under that model and would be vigilant about not engaging in steering themselves or spurred by other providers. Nevertheless, we will monitor CJR hospitals to ensure steering or other efforts to limit beneficiary access or move beneficiaries out of the model are not occurring (see section III.F.).

We sought comment on the proposed approach to address overlap between CJR and BPCI episodes. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to apply precedence rules that attribute episodes to BPCI PGPs and PAC providers in cases of overlap with CJR. Commenters noted the significant investment PGPs and PAC providers have made in BPCI and a desire for these entities to continue engagement in care redesign under BPCI. A commenter noted that for many providers, 3-year participation in BPCI will expire near the time when CJR begins requiring participant hospitals to accept full financial responsibility for episode spending. The commenter believes it would not be appropriate to change the episode precedence rules for BPCI providers prior to the conclusion of providers' 3-year BPCI participation, as attributing Model 2 and Model 3 PGP and PAC LEJR episodes to CJR in lieu of BPCI could create confusion. Commenters also requested that CMS provide additional clarification of a number of potential scenarios beyond those addressed in the proposed rule.

Some commenters disagreed with our proposed policy to apply precedence to BPCI Model 2 and Model 3 PGPs and PAC providers. Commenters contended that the proposed policy was unfair, given that BPCI participants entered models voluntarily, but hospitals in CJR were not given the opportunity to opt out and would be at risk for episodes where others did not perceive enough opportunity to voluntarily enter into risk agreements under BPCI. Commenters expressed concern that, given the precedence rules, CJR hospitals could potentially lose many episodes to BPCI and may be financially responsible for a low volume of episodes. Some commenters also suggested we apply a minimum threshold to remove hospitals from the CJR model based on BPCI PGP participation.

A commenter disagreed with the proposal for BPCI PAC entities at risk for a shorter episode duration than the CJR proposed episode to be given precedence. Another commenter cited the potential for patient steering issues that could arise due to our proposed policy to give BPCI PGPs precedence over CJR hospitals for LEJR episodes. In particular, the commenter was concerned that the precedence rules would lead to BPCI PGPs capturing lower-risk episodes, leaving CJR hospitals at risk for more high-risk episodes. The commenter suggested we give precedence to CJR episodes over BPCI PGP and PAC episodes to mitigate steering concerns.

Another commenter was concerned about potential confusion when episodes initiated at the same acute care hospital could be in both models; for example, when episodes initiated by a BPCI PGP at a hospital or discharged to a Model 3 PAC are attributed to BPCI while the remaining episodes are a part of CJR. The commenter believed that following both sets of rules (for the BPCI and CJR models) within the same hospital could be confusing for hospitals and partner providers and suppliers, limiting providers' ability to target care redesign efforts toward patients for whom a CJR hospital is financially responsible. Another commenter requested CMS publish a public list of BPCI episode initiators whose episodes would take precedence over CJR episodes.

Response: We agree with commenters' assertion that maintaining participation in the voluntary BPCI models and recognizing the significant investments in care redesign and care coordination already made by BPCI participants is important. BPCI participants have an agreement with CMS and in some cases have already been participating in the voluntary BPCI initiative for several years.

In response to commenters' requests for additional examples of overlap scenarios, we clarify that LEJR overlap could occur in, but is not limited to, the following situations:

- A beneficiary is admitted to a CJR hospital for an LEJR procedure and discharged to a PAC provider participating in BPCI Model 3 for the LEJR episode; the episode is attributed to the BPCI Model 3 PAC provider.
- A beneficiary is admitted to a CJR hospital for an LEJR procedure by a PGP participating in BPCI Model 2; the episode is attributed to the BPCI Model 2 PGP.
- A beneficiary is admitted to a CJR hospital for an LEJR procedure by a PGP participating in BPCI Model 3; the episode is attributed to the BPCI Model 3 PGP.
- A beneficiary is admitted to a CJR hospital for an LEJR procedure, followed by a second phased LEJR procedure within 90 days of the first procedure. The second LEJR procedure is attributed to a PGP participating in BPCI Model 2 or 3 or is followed by admission to a PAC provider participating in BPCI Model 3 for the LEJR episode. The first LEJR episode would be canceled and the second episode would be attributed to the BPCI provider.

We acknowledge that some CJR hospitals could be financially at risk for a small proportion of LEJR episodes initiated at the hospital if there are high-volume PGPs or PAC providers in their community initiating LEJR episodes under BPCI, yet we continue to believe those hospitals have opportunity under the CJR model. Physicians and PAC providers may already have worked on care redesign for LEJR beneficiaries, and the hospitals have an opportunity to learn from that experience. Having a smaller number of beneficiaries in the CJR model to begin with also places hospitals at less financial risk, which may allow them to more rapidly and nimbly design care pathways, test them, and refine them on a smaller number of beneficiaries and with less resources than if all of the hospital's LEJR beneficiaries were in the CJR model from the start. We also note that, given that many providers' 3-year participation in BPCI would end in 2017 or 2018, in many cases full financial responsibility for all of a participant hospital's LEJR procedures under the CJR model would not be in effect until the conclusion of the BPCI participation period when the CJR participant hospitals could have responsibility for a larger number of episodes. By that point in time, CJR participant hospitals should have several years of experience with LEJR episodes focusing on quality and efficiency, and the larger number of beneficiaries can then be integrated into existing pathways.

While we understand the concerns of some commenters that physician and PAC providers participating in BPCI will focus on low-risk beneficiaries, leaving higher-risk beneficiaries to be the participant hospital's responsibility under the CJR model so that the CJR model beneficiaries in a performance year will not resemble those in the baseline period used to set target prices, there are a number of model design features that make this unlikely. First, as discussed in section III.C.4.b.(1) of this final rule, we are stratifying episodes on the basis of a beneficiary's hip fracture

status, a major factor related to higher-cost episodes, so that CJR model participant hospitals will be appropriately paid for higher-risk beneficiaries with hip fractures. Second, we will be monitoring for access to care and delayed care as discussed in section III.F. of this final rule as well as under BPCI, and examining the CJR model for unintended consequences such as adverse selection of patients and inappropriate referral practices in the evaluation as discussed in section IV. of this final rule. Section III.C.12. of this final rule also details our enforcement mechanisms for the CJR model.

We appreciate commenters' contention that allowing for both models to coexist for LEJR episodes within the same acute care hospital may be confusing for providers. However, we believe the importance of continuing PGP and PAC participation in BPCI Models 2 and 3 outweighs this risk, and believe that local providers, in the best interest of Medicare beneficiaries and cost and quality success under the two models, will coordinate and collaborate to respond to their circumstances. We also note that while the BPCI and CJR models differ in various ways, the broad goals of the models are the same: Improving quality of care while reducing spending during the episode. We believe it is reasonable for hospitals, PGPs, and PAC providers to engage in care redesign strategies targeted at LEJR episodes in general, regardless of attribution of an LEJR episode to a particular model. Such overlap within the same hospital may incentivize additional coordination between the entities already engaged in care redesign under BPCI and acute care hospitals that will begin such activities as participants in CJR.

In response to the commenter who requested a list of BPCI episode initiators, we refer readers to the publicly available list of current episode initiators in BPCI on the model Web site at *http://innovation.cms.gov/initiatives/Bundled-Payments/Participating-Health-Care-Facilities/index.html.*

Final Decision: After consideration of the public comments received, we are finalizing our proposal, without modification, to apply precedence to BPCI Model 2 and Model 3 PGP and PAC provider LEJR episodes. Specifically, if at any time during a beneficiary's CJR LEJR episode, that beneficiary would also be in a BPCI Model 2 or Model 3 LEJR episode, the beneficiary's CJR episode would either not be initiated or would be canceled such that it would not be included in the participant hospital's CJR reconciliation where actual episode spending is compared to the target price.

Comment: Many commenters requested that CMS apply precedence rules in cases of CJR and BPCI non-LEJR overlap. Some commenters requested that BPCI non-LEJR episodes would have precedence in the case of overlap between a BPCI non-LEJR episode and a CJR LEJR episode, while others requested that CJR have precedence. Commenters stated that there was no way to fairly attribute savings between the two models in such scenarios, if CMS allows for overlap between CJR and BPCI non-LEJR episodes as proposed. A commenter stated that it would not be possible to comment on which model should have precedence (CJR or BPCI) due to ambiguity about which model would be more prevalent or expanded in the future; another commenter shared this view, but stated that its opinion on which model should have precedence was dependent upon the specific financial arrangements and waivers finalized for the CJR model.

Response: We appreciate the feedback and request for clarification on whether BPCI or CJR episode would have precedence when the same beneficiary could be in a CJR model episode and a BPCI non-LEJR episode for an overlapping period of time. We clarify that we did not propose a calculation to attribute savings between the two models when concurrent episodes occur. We proposed that each model would continue to perform financial reconciliation activities as usual. We also believe such overlap situations will be relatively rare, given that many LEJR procedures are elective and would only be furnished when a physician determines it is clinically appropriate for a beneficiary to undergo a major surgery. We believe a beneficiary undergoing an LEJR procedure in close proximity to an inpatient hospitalization for another condition will be an infrequent occurrence. Applying precedence rules could introduce confusion for providers participating in BPCI for non-LEJR episodes and in the CJR model. For example, if a CJR hospital could retrospectively have an LEJR episode canceled if the beneficiary is readmitted to another hospital and initiates a BPCI episode for a non-LEJR episode such as congestive heart failure, the CJR hospital could be generally unaware of the beneficiary's care pathway.

As we noted in the proposed rule, we believe that where there is overlap between BPCI and CJR LEJR episodes, providers would generally be aware of such situations. For example, BPCI PGPs and PAC providers would be aware that a PGP initiating an LEJR episode at a CJR hospital, or an admission to a PAC facility in BPCI Model 3 would cancel the CJR episode. CJR hospitals could maintain a list of BPCI participants in their area. In contrast, if we allow any BPCI non-LEJR episode to cancel all CJR episodes, CJR hospitals may not be aware of the beneficiary's eventual care pathway. For example, CJR hospitals may be unaware of cases in which the CJR LEJR episode is canceled and the non-LEJR BPCI episode takes precedence because a wide range of BPCI clinical episodes and provider types could cancel the CJR episode during the 90 day post-discharge period.

We expect such cases of overlap to be rare given current BPCI participation and the participant CJR model hospitals. We also reiterate that when such overlap occurs, each model (BPCI and CJR) would continue its normal financial reconciliation processes. When overlap occurs, it is possible that savings achieved during one model could also be counted as savings under the other model. In such cases it could be difficult to determine whether savings achieved during an episode were attributable to care redesign activities under BPCI or CJR. However, allowing for overlap between BPCI non-LEJR and CJR episodes will maximize the testing of episodes under both models and encourage providers under BPCI and CJR to engage in care redesign and coordination activities for all beneficiaries attributed to either model. The following examples illustrate potential situations of overlap:

- A beneficiary is admitted to a CJR hospital for an LEJR procedure and later readmitted to the same or a different CJR hospital for a congestive heart failure episode under BPCI.
- A beneficiary is in a BPCI PGP Model 2 episode for chronic obstructive pulmonary disease at a CJR hospital and has an LEJR procedure at the same or a different CJR hospital during the post-anchor hospital discharge period of the BPCI episode.

In both situations, each model would calculate episode spending and perform financial reconciliation as normal.

Summary of Final Decisions: After consideration of the public comments received, we are finalizing our proposal, without modification, to apply precedence to BPCI Model 2 and Model 3 PGP and PAC LEJR episodes. By precedence, we mean that if for any portion of CJR model episode, a beneficiary would also be in a BPCI LEJR episode under Model 2 or Model 3, we will cancel (or never initiate) the CJR episode. We refer readers to III.B.3.

for further discussion of the circumstances under which CJR episodes will be canceled. We are also finalizing the proposal, without modification, to allow for overlap between the period of time in which a beneficiary is in a CJR episode and a BPCI non-LEJR episode.

c. Accounting for CJR Reconciliation Payments and Repayments in Other Models and Programs

Under CJR, we proposed to annually, as applicable, make reconciliation payments to or receive repayments from participating CJR hospitals based on their quality performance and Medicare expenditures, as described in section III.C.6. of the proposed rule. While we proposed that these reconciliation payments or repayments would be handled by MACs, the calculation of these amounts would be done separately before being sent through the usual Medicare claims processing systems. Nevertheless, it is important that other models and programs in which providers are accountable for the total cost of care be able to account for the full Medicare payment, including CJR-related reconciliation payments and repayments as described in section III.C.6. of the proposed rule, for beneficiaries who are also in CJR episodes. Accordingly, it is necessary to have beneficiary-specific information on CJR-related reconciliation payments and repayments available when those models and programs make their financial calculations. Thus, in addition to determining reconciliation payments and repayments for the participant hospitals in the CJR model, we proposed to also calculate beneficiary-specific reconciliation payment or repayment amounts for CJR episodes to allow for those other programs and models, as their reconciliation calculation timeframes permit, to determine the total cost of care for overlapping beneficiaries. We would perform the reconciliation calculations for CJR hospitals and make information about the CJR reconciliation or repayment amounts available to other programs and models, such as the Shared Savings Program and Pioneer ACO as well as non-ACO total cost of care models such as CPCi and OCM that begin reconciliation calculations after CJR. For example, this strategy is currently in place to account for overlaps between beneficiaries assigned or aligned to Pioneer and Shared Savings Program ACOs and BPCI model beneficiaries. Beneficiary-specific reconciliation payment or repayment amounts are loaded into a shared repository for use during each program or model's respective reconciliations. However, we note that we proposed not to make separate payments to, or collect repayments from, participating CJR hospitals for each individual episode, but, instead, to make a single aggregate reconciliation payment or repayment determination for all episodes for a single performance year, as discussed in section III.C.6. of the proposed rule. As described in section III.C.6 of the proposed rule, we proposed to conduct reconciliation based on claims data available 2 months after the end of the performance year and a second calculation based on claims data available 14 months after the end of a performance year to account for claims run-out and potential overlap with other models. The rationale for this proposed reconciliation process was to be able to make payments to, and require repayment from, CJR participant hospitals in a timely manner and to be able to account for overlaps in other models and programs. In addition, the timing of the reconciliation was determined giving consideration to when the other total cost of care programs and models conduct their reconciliations so that when they perform their financial calculations, they will have the information necessary to account for beneficiary-specific payments/repayments made under the CJR model as it is consistent with their policies. We intend to report beneficiary-specific payments and repayment amounts made for the CJR model in the CMS Master Database Management (MDM) System that generally holds payments/repayment amounts made for CMS models and programs. Other total cost of care models and programs can use the information on CJR payment/repayment amounts reported in the Master Database Management System in their financial calculations such as in their baseline or benchmark calculations or reconciliations, to the extent that is consistent with their policies.

We sought comment on our proposed approach to ensuring that the full CJR episode payment for a beneficiary is accounted for when performing financial calculations for other total cost of care and episode-based payment models and programs. The following comments and responses refer to the implications of our proposal to ensure other models are able to account for the full CJR episode payment, including any reconciliation payment or repayment amount. As discussed later in this section, many commenters expressed concern about how this policy would affect ACO financial calculations. Because total cost of care models and programs, including the Shared Savings Program and other ACO models, would include the full CJR episode payment (that is, including any reconciliation or repayment amounts) in their annual financial calculations determining the total spending for a beneficiary, most of the savings achieved during a CJR episode would be attributed to the CJR model. As discussed in section III.C.7.e. of this final rule, in some select cases the savings amount represented by the discount percentage could be attributed to a Shared Savings Program or other ACO model entity.

The following is a summary of comments received and our response.

Comment: Commenters did not offer feedback on the implications of the proposed policy on overlap with non-ACO total cost of care models. Commenters generally supported the proposal to attribute episode savings to the CJR model when the CJR hospital is aligned to an ACO as a participant or provider/supplier. However, several commenters expressed concern about the proposed policy, requesting that savings earned during an episode (that is, any reconciliation payments) be fully attributed to the ACO—by not accounting for reconciliation payments in determining Medicare spending for an ACO's assigned beneficiaries—when the ACO and CJR participant hospital are unrelated. These commenters claimed that attributing savings to the ACO in such cases is important for the following reasons: Ensuring ACOs are able to earn savings during a CJR episode in some situations, supporting population-based health models, not penalizing providers already taking on risk, and testing a different method of overlap from the BPCI initiative. Several commenters stated that attributing savings to the CJR episode, regardless of whether the ACO and CJR hospital are related, would make ACOs unable to earn savings during any CJR episode and could erode the Shared Savings Program over the long-term as episode-based payment models grow. A commenter also asserted that the proposed policy could result in increased utilization of LEJR procedures in lieu of less costly clinical interventions.

Response: We thank commenters for their feedback and engagement on the issue of how to attribute savings among various models and programs when overlap occurs. We also appreciate commenters' support for the proposal to attribute savings to the CJR episode when the CJR hospital is aligned to the ACO as a participant or provider/supplier.

In response to commenters who requested that we fully attribute savings achieved (represented by reconciliation payments) during CJR episodes to the ACO in cases where a beneficiary is assigned to an ACO and initiates a CJR episode at a hospital that is not aligned to the ACO as a participant or provider/supplier, we decline to diverge from the approach we have taken in other episode payment models because we wish to maintain consistency and because such a change would be unworkable, as we discuss later in this section. There are several ways in which CMS potentially could attribute savings achieved during a CJR episode to the ACO in lieu of the CJR hospital, but after considering them, we have concluded that each option has far-reaching and undesirable implications for the policies and operations of both the CJR model and ACOs. The first option would involve making the ACO to which a beneficiary is assigned the financially responsible entity for the CJR episode so that reconciliation payments or repayments would ultimately be the responsibility of the ACO. To accomplish this, we would need to determine a way to make the reconciliation payment to or request the repayment amount from the unrelated CJR hospital on behalf of the ACO. This would mean that the CJR hospital would need to have a financial arrangement with the unrelated ACO to pay the ACO the reconciliation payment or the ACO would need to pay the CJR hospital if payment is due to Medicare. Under this approach, it would be necessary to conduct a separate reconciliation process for beneficiaries attributed to the unrelated ACO and another reconciliation for all other beneficiaries with CJR episodes. This would disrupt our approach to the financial protections discussed in section III.C.8. of this final rule—that is, stop-loss and stop-gain, which are intended to apply to all of a CJR hospital's episodes, because we would need to apply those thresholds separately to the episodes attributed to the unrelated ACO. We believe this, in turn, would be confusing for participant hospitals. We note that this is distinct from our policy to report beneficiary-specific reconciliation amounts in the MDM, as previously discussed in this section, which would occur after performing the reconciliation calculations and applying the stop-loss and stop-gain thresholds for a given hospital across all of its aggregated episodes.

A second approach would be for all models or programs (CJR and the Shared Savings Program or other ACO) to conduct reconciliation activities for all beneficiaries as normal. The attribution of savings for those CJR beneficiaries assigned to an unrelated ACO could be accounted for through the subsequent reconciliation through the following process. Reconciliation payments could be recouped from CJR participant hospitals and paid to the ACOs in cases where a beneficiary was assigned to an ACO and had a CJR episode at an unrelated CJR hospital. However, we decline to adopt this approach because it would introduce significant uncertainty for CJR participant hospitals and could cause large fluctuations in reconciliation and repayment amounts between the initial reconciliation and subsequent calculation. Additional policies would also need to be adopted in order to ensure the financial reconciliation activities for the CJR model and the Shared Savings Program or shared savings models are able to account for such transactions, including further coordination of reconciliation timelines and policies to account for the subsequent reconciliation calculations. At present, we have not made any proposals for such types of financial arrangements between the initiatives that would allow for such transactions.

A final option would be to cancel (or never initiate) a CJR episode for any beneficiary assigned to an unrelated ACO. Beneficiaries assigned to such ACOs would need to be excluded from CJR financial reconciliation calculations. Implementing such a policy would be challenging, given our plan to conduct CJR reconciliation activities prior to ACO financial reconciliations, in which ACOs finalize their list of assigned beneficiaries. It would not be possible to finalize a list of CJR episodes or beneficiaries until after the ACO models or the Shared Savings Program, as applicable, had completed their financial reconciliations. Additionally, CJR participant hospitals would not know until well after episodes were completed whether the hospital was actually responsible for a particular beneficiary's episode under the CJR model. While we note that in some cases a CJR episode could be canceled for other reasons, such as precedence for a BPCI PGP episode as discussed in III.C.7.b, in such cases we believe that CJR hospitals will generally be aware of the possibility of episode cancelation due to BPCI precedence. For example, a CJR hospital may be aware that any time a given PGP furnishes an LEJR procedure to a Medicare beneficiary in the CJR hospital, that beneficiary will most likely be in a BPCI, not CJR, episode. In contrast, the uncertainty of final ACO assignment lists prior to the CJR reconciliation activities could lead to significant unanticipated changes in episode attribution. In addition, the high volume of potential CJR episodes that would be canceled under this approach could potentially limit the scope of the CJR model test. As discussed in section I.A. of this final rule, CJR is intended to be a robust test of episode payment across many types of hospitals.

Because this approach is generally inconsistent with our proposals for the CJR model, we decline to adopt it. In addition, if CMS were to pursue a policy for attributing CJR model episode savings to an ACO in lieu of to the CJR hospital, the ACO—not the hospital—would become the risk-bearing entity for some beneficiaries (those assigned to the ACO), which is inconsistent with our stated policy in section III.A.2. of this final rule to designate hospitals as financially responsible for all CJR episodes. As discussed in detail in section III.A.2. of this final rule, we believe hospitals are the most appropriate entities to manage the care and financial responsibility for CJR episodes. CJR hospitals could be unaware that beneficiaries are assigned to an ACO, given that their episodes would be canceled or attributed to the ACO only in cases where the CJR hospital is not participating in the ACO.

Given the significant complexity such a change would introduce, and the changes in other CJR model and ACO policies and operations that would be required to implement such a change (such as CJR model reconciliation processes, application of financial protections for hospitals, and financial arrangements), we continue to believe it is most appropriate, consistent with the policies of both the CJR model and the Shared Savings Program and other ACO models, and operationally feasible to attribute savings achieved during a CJR episode (that is, reconciliation payments) to the CJR model in all cases. Doing so also attributes these savings to the episode that is most proximate to the beneficiary's care during an LEJR episode. We refer readers to section III.C.7.e. of this final rule for discussion of the CJR discount percentage and attribution of the savings represented by the discount percentage.

We do not agree that our proposal to attribute savings achieved during CJR episodes via reconciliation payments to the CJR participant instead of the ACO incentivizes overutilization of LEJR procedures, penalizes providers taking on risk, or harms population-based health models. First, as discussed in

section III.F.2. of this final rule, we believe that the usual tools employed by CMS including data analysis, the process of tracking patterns of utilization and trends in the delivery of care, and medical review, a clinical audit process by which we verify that services paid by Medicare were reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act, will help to ensure that LEJR procedures under the CJR model are reasonable and necessary. Second, ACOs will be assured of predictable spending (at the amount of the target price, which would in all cases reflect a discount off total spending that would have occurred absent the CJR model) for care provided during CJR episodes, as opposed to the uncertainty of spending for beneficiaries not included in CJR episodes. Although ACOs may estimate they can achieve more savings for these beneficiaries' episodes than the discount factor reflected in the CJR model target price, higher savings are not certain. ACOs will continue to have savings opportunities for CJR model beneficiaries during the other 9 or so months of the ACO's performance year, as well as for unrelated services throughout the CJR model episode. This also holds true for the BPCI episodes currently in testing, which include 48 surgical and medical episodes, many of them far less frequent and with less predictable costs than the LEJR episodes in the CJR model. Finally, the population health focus of ACOs will continue to be valuable as it is much broader than the CJR model, with great potential for improving the overall health of Medicare beneficiaries and reducing costs. For example, the CJR model begins with admission to the inpatient hospital for the LEJR procedure, yet the underlying clinical condition for beneficiaries undergoing elective THA or TKA is most likely to be long-standing osteoarthritis. Evidence-based conservative management of this condition may delay the THA or TKA or eliminate the need for it altogether, in which case a CJR model episode would never occur. The same concept holds true for all of the episode payment models currently in testing that are focused around an inpatient hospitalization. An ACO's expertise and skill in population health care management may sharply reduce the need for inpatient hospitalization, resulting in substantial direct savings to the ACO and no initiation of an episode under an episode payment model.

Coexistence of episode-based payment models and ACOs may lead to improved care redesign and coordination strategies, and ultimately, improved quality of care for beneficiaries. While episode-based payment models such as the CJR model target care during a relatively short time span, models incorporating the total cost of care over a longer time period such as ACOs focus on population health and strategies to improve care coordination across the entire spectrum of care. In order to achieve the agency's goals of better care, smarter spending, and healthier people, CMS must engage providers in a variety of models and rigorously evaluate the results of such models and programs in order to identify specific care redesign strategies and payment mechanisms that are effective in reaching these goals. An important feature of such testing and evaluation is also understanding how various models or programs work alongside other initiatives. For this reason, we believe it is appropriate for CMS to allow for the coexistence of various initiatives such as episode-based payment models and ACOs. Doing so will provide robust information on the results of each model, including information on how particular payment structures fare across a variety of regions and in markets with varying levels of provider participation in other models.

In addition, we note that although there are important structural differences between initiatives such as CJR and the Shared Savings Program or other ACO models, the underlying goals are the same. Both CJR and the ACO initiatives target improved quality of care and reduced spending during a defined period of time. Over time, provider organizations participating in one or both types of models will continue to find ways to work together to better coordinate care for beneficiaries, improve clinical efficiencies and reduce unnecessary utilization of health care services, and succeed financially under various types of payment models and programs.

Finally, while we appreciate commenters' suggestion that we test a different method for overlap with ACOs than that used for the BPCI initiative, we do not intend to test a different savings attribution method at this time. Both BPCI and the CJR model share the common episode-initiating event of an inpatient hospitalization and, in the case of each of these models as designed, we have concluded that the same savings attribution policy is appropriate. As we develop other episode payment models in the future and consider the potential for expansion of successful episode payment models, we will consider the perspectives offered by the commenters on the CJR model in the design of those models as we develop overlap policies or consider changes to existing policies.

For the reasons previously stated, we are finalizing our proposal to attribute savings achieved (via reconciliation payments) during CJR episodes to CJR participant hospitals. We refer readers to section III.C.7.e. of this final rule for discussion of the attribution of savings for the CJR discount percentage.

Comment: A commenter requested that CMS not account for overlap between models by including reconciliation payments or savings amounts from one model in the financial calculations for another model. The commenter asserted that any double counting of savings would be offset by compounded efficiencies and clinical integration.

Response: We agree with the commenter that the coexistence of various models and programs is likely to result in compounded efficiencies and clinical integration. However, under all models and programs we believe it is important that Medicare Trust Fund payments made on behalf of beneficiaries be accounted for to the extent feasible and that CMS not pay back savings that should be maintained by the Medicare program. We are finalizing various policies, as outlined elsewhere in this section, to minimize the double payment of savings achieved during CJR episodes and under other models and programs. In addition, we note that under the Shared Savings Program regulations at 425.604(a)(6)(ii), CMS considers all Part A and B expenditures, including payments made under a demonstration or model. Given that CJR reconciliation payments are made from the Trust Funds, and can be attributed to a particular assigned beneficiary, the Shared Savings Program regulations require that such payments be taken into account for the calculation of shared savings or losses.

Comment: Several commenters requested that CMS provide CJR hospitals with a list of beneficiaries prospectively aligned to ACOs. Commenters stated that such information would aid participants in both CJR and the model or program.

Response: We appreciate the commenters' suggestion. However, providing such a list to CJR participants could potentially lead to patient steering. Because we expect hospitals and other providers and suppliers to engage in care redesign activities under both an ACO model or the Shared Savings Program and the CJR model, it would not be appropriate to create incentives for providers and suppliers to

treat beneficiaries differently based on ACO alignment status.

Comment: Numerous commenters requested that CMS allow for Shared Savings Program ACOs or other current or future ACOs participating in risk-bearing ACO models (such as under the Next Generation ACO model) to opt out of the CJR model for beneficiaries aligned to those ACOs. Several commenters suggested allowing Track 2 or Track 3 Shared Savings Program ACOs that had achieved savings in previous performance years to opt out of the CJR model for their aligned beneficiaries.

Response: As previously discussed, we believe it is possible and desirable for the multiple CMS programs and models to coexist. We also believe the coexistence of episode-based payment models and total cost of care models such as ACOs can lead to increased efficiencies for both initiatives and additional coordination among providers. As discussed in section III.A. of this final rule, we do not believe it would be appropriate to allow ACOs to opt their aligned hospitals out of the CJR model. Such a policy could significantly diminish the number of participants in the CJR model, eroding our ability to evaluate the CJR model. As discussed in section I.A. of this final rule, CJR is intended to test the effect of episode payment across a variety of hospitals. Significantly limiting the scope of the model by allowing ACOs to opt their hospitals out of participation in CJR would impact our ability to achieve the goals of the model.

Comment: A commenter requested that if precedence is not given to Shared Savings Program ACOs for savings arising from CJR episodes initiated at unrelated hospitals, CMS should require CJR hospitals to sign agreements with ACOs in the same MSA to coordinate care for such beneficiaries. The commenter suggested such mandated agreements include specific requirements for the CJR hospital to coordinate a beneficiary's care, such as documented use of clinical practice guidelines and a care plan.

Response: Requiring this type of agreement would be inappropriate at this time because it is inconsistent with current CMS policies and practices. While we offer opportunities for providers participating in models such as CJR to enter into financial arrangements with other providers and suppliers and encourage model participants to form clinical partnerships or financial arrangements with other providers and suppliers where appropriate, we do not require specific care coordination agreements or arrangements between entities participating in different CMS models or programs. For further information on our policies regarding agreements and relationships between providers and suppliers coordinating care for beneficiaries under the CJR model, we refer readers to section III.C.10. of this final rule for discussion of financial arrangements under the CJR model.

Summary of Final Decisions: After consideration of the public comments we received, we are finalizing our policy to make reconciliation and repayment amounts under the CJR model available to other models and programs to include in their financial reconciliation calculations.

This policy is set forth at § 510.305.

d. Accounting for PBPM Payments in the Episode Definition

There are currently five CMS models that pay PBPM payments to providers for new or enhanced services as displayed in Table 17. These PBPM payments vary as to their funding source (Medicare Trust Funds or Innovation Center appropriation), as well as to their payment methodology.

In general, these PBPM payments are for new or enhanced provider or supplier services that share the goal of improving quality of care overall and reducing Medicare expenditures for services that could be avoided through improved care coordination. Some of these PBPM payments may be made for services furnished to a beneficiary that is in another Innovation Center model at the that same time that the beneficiary is in a CJR LEJR episode, but the clinical relationship of services paid by the PBPM payments to the CJR episode will vary. For purposes of CJR, we consider clinically related those services paid by PBPMs that are for the purpose of care coordination and care management of any beneficiary diagnosis or hospital readmission not excluded from the CJR episode definition, as discussed in section III.B.2. of this final rule.

We would determine whether the services paid by PBPM payments are excluded from the CJR episode on a model by model basis based on their funding source and clinical relationship to CJR episodes. If we determine a model's PBPM payments are for new or enhanced services that are clinically related to the CJR episode and the PBPM payment is funded through the Medicare Part A or B Trust Fund, we would include the services paid by the PBPM payment to the extent they otherwise meet the proposed episode definition for the CJR model. That is, we would include the clinically related services paid by a PBPM payment if the services would not otherwise be excluded based on the principal diagnosis code on the claim, as discussed in section III.B.2 of the proposed rule. The PBPM payments for clinically related services would not be excluded from the historical CJR episodes used to calculate target prices when the PBPM payments are present on Part A or Part B claims, and they would not be excluded from calculation of episode actual expenditures during the performance period. PBPM model payments that we determine are clinically unrelated would be excluded, regardless of the funding mechanism or diagnosis codes on claims for those payments. We note that in the case of PBPM model payments, principal diagnosis codes on a Part B claim (which are used to identify exclusions from CJR episodes, as discussed in section III.B. of this final rule), would not denote the only mechanism for exclusion of a service from the CJR episode. All such PBPM model payments we determine are clinically unrelated would be excluded as discussed in this proposal. Finally, all services paid by PBPM payments funded through the Innovation Center's appropriation under section 1115A of the Act would be excluded from CJR episodes, without a specific determination of their clinical relationship to CJR episodes. We believed including such PBPM payments funded under the Innovation Center's appropriation and not included on claims would be operationally burdensome and could significantly delay any reconciliation payments and repayments for the CJR model. In addition, because these services are not paid for from the Medicare Part A or B Trust Fund, we are not confident that they would be covered by Medicare under existing law. Therefore, we believed the services paid by these PBPM payments are most appropriately excluded from CJR episodes. Our proposal for the treatment of services paid through model PBPM payments in CJR episodes would pertain to all existing models with PBPM payments, as well as future models and programs that incorporate PBPM payments. We believed that this proposal is fully consistent with our goal of including all related Part A and Part B services in the CJR episodes, as discussed in section III.B.2. of the proposed rule.

Under this proposal, only one of the active models displayed in Table 17 include services paid by PBPM payments that would not be excluded from CJR episodes. The MAPCP model makes PBPM payments that are funded

through the Trust Fund for new or enhanced services that coordinate care, improve access, and educate patients with chronic illnesses. We expect these new or enhanced services to improve quality and reduce spending for services that may have otherwise occurred, such as hospital readmissions, and consider them to be clinically related to CJR episodes because the PBPM payments would support care coordination for medical diagnoses that are not excluded from CJR episodes. Thus, we proposed that services paid by PBPM payments under the MAPCP model not be excluded from CJR episodes to the extent they otherwise meet the proposed episode definition. While the OCM model will pay for new or enhanced services through PBPM payments funded by the Medicare Part B Trust Fund, we did not believe these services are clinically related to CJR episodes. The OCM model incorporates episode-based payment initiated by chemotherapy treatment, a service generally reported with ICD–9–CM and ICD–10–CM codes that are specifically excluded from the CJR episode definition in section III.B.2. of this final rule. We believed the care coordination and management services paid by OCM PBPM payments would be focused on chemotherapy services and their complications, so the services would be clinically unrelated to CJR episodes. Therefore, we proposed that services paid by PBPM payments under the OCM model be excluded from CJR episodes. Similarly, we proposed to exclude services paid by PBPM payments under the Medicare Care Choices Model (MCCM) from the CJR episode spending calculations. The MCCM focuses on providing care coordination and palliative care services for beneficiaries with certain conditions certified as terminally ill with a life expectancy of 6 months or less that have not elected the Medicare hospice benefit. The MCCM seeks to test whether providing palliative care services, without beneficiaries having to forgo curative care, incentivizes beneficiaries to elect hospice sooner. This is aimed at addressing the large percentage of hospice beneficiaries who elect the hospice benefit too late to fully benefit from the range of services that hospice has to offer at end of life. Since the purpose of the MCCM is to test whether providing palliative care services to beneficiaries who are otherwise eligible to elect the Medicare hospice benefit without requiring the beneficiary to forgo curative care results in beneficiaries electing the hospice benefit sooner, we are not including such payments in the CJR episode spending calculations at this time. In addition, unlike the regular hospice benefits, which are furnished to beneficiaries in lieu of curative care and which therefore can be coordinated during a LEJR episode, as described in section III.B.2.b. of this final rule, the services furnished under the MCCM will be in addition to curative services. We note that we are including such curative services in the episode, as they are consistent with our episode definition described in III.B.2.of this final rule, but not the services represented by the PBPM, which are provided in addition to curative services. Beneficiaries electing the hospice benefit could have lower episode spending because they have forgone curative care, however beneficiaries included in the MCCM may have higher episode spending because they are receiving both curative care and the services represented by the PBPM. We do not want to create incentives that deter providers from enrolling beneficiaries in the MCCM model. We note that Part A and Part B services would be included in episodes in both the historical and performance periods used for spending calculations, while the inclusion of PBPM payments would only occur for those time periods (historical and performance periods) during which the relevant model was active. Given that the MCCM was not active during the CJR initial historical period, if we were to include MCCM PBPM payments they would only be included in CJR performance period spending calculations. Excluding MCCM payments also ensures that we do not incentivize providers to avoid enrolling beneficiaries in the MCCM to minimize the effect of the PBPM payment amounts on episode spending during CJR performance periods.

We acknowledge there may be new models not included in Table 17 that could incorporate a PBPM payment for new or enhanced services. We would plan to make our determination about whether services paid by a new model PBPM payment that is funded under the Medicare Trust Funds are clinically related to CJR episodes through the same subregulatory approach that we are proposing to use to update the episode definition (excluded MS–DRGs and ICD–10–CM diagnosis codes). We would assess each model's PBPM payment to determine if it would be primarily used for care coordination or care management services for excluded clinical conditions under the LEJR episode definition for CJR based on the standards we proposed to use to update the episode definition that are discussed in section III.B.2 of the proposed rule.

If we determine that the PBPM payment would primarily be used to pay for services to manage an excluded clinical condition, we would exclude the PBPM payment from the CJR episode on the basis that it pays for unrelated services. If we determine that the PBPM payment could primarily be used for services to manage an included clinical condition, we would include the PBPM payment in the CJR episode if the diagnosis code on the claim for the PBPM payment was not excluded from the episode, following our usual process for determining excluded claims for Part B services in accordance with the episode definition discussed in section III.C.2 of the proposed rule. We would post our proposed determination about whether the PBPM payment would be included in the episode to the CMS Web site to allow for public input on our planned application of these standards, and then adopt changes to the overlap list with posting to the CMS Web site of the final updated list after our consideration of the public input.

We sought comment on our proposals to account for Innovation Center model PBPM payments under CJR.

The following is a summary of the comments received and our responses.

Comment: A commenter supported the proposal to exclude CPCi, OCM, and MCCM PBPM payments and the proposal to seek future public input on PBPM payments that are clinically related to CJR.

Response: We thank the commenter for support of our proposal to exclude CPCi, OCM, and MCCM PBPM payments from CJR episode spending calculations.

Final Decision: After consideration of the public comments we received, we are finalizing the proposed policy, without modification, to include PBPM payments that are funded with Trust Fund dollars, if the services would not otherwise be excluded under the model episode definition. Included PBPM payments would be included in CJR model financial calculations only for historical and performance periods during which the model with a PBPM is active and the PBPM is funded with Trust Fund dollars.

This policy is set forth at § 510.200.

e. Accounting for Overlap With Medicare Initiatives Involving Shared Savings and Total Cost of Care Models

In addition to the Medicare Shared Savings Program under section 1899 of the Act, there are several ACO and other Innovation Center models that make or will make, once implemented, providers

accountable for total cost of care over 6 to 12 months, including the Pioneer ACO Model, Next Generation ACO Model, Comprehensive ESRD Care (CEC) Model, CPCi, OCM, and the MAPCP Demonstration. Some of these are shared savings models (or programs, in the case of the Shared Savings Program), while others do not involve shared savings but still hold participating providers accountable for the total cost of care during a defined episode of care, such as OCM. Note that as discussed in section III.C.7.a. of this final rule, ''total cost of care'' models refer to models in which episodes or performance periods include participant financial responsibility for all Part A and Part B spending, as well as some Part D spending in select cases. Each of these payment models holds providers accountable for the total cost of care over the course of an extended period of time or episode of care by applying various payment methodologies. In the proposed rule, we stated our belief that it is important to simultaneously allow beneficiaries to receive care under broader population-based and other total cost of care models, as well as episode payment models that target a specific episode of care with a shorter duration, such as CJR. Allowing beneficiaries to receive care under both types of models may maximize the potential benefits to the Medicare Trust Funds and participating providers and suppliers, as well as beneficiaries. Beneficiaries stand to benefit from care redesign that leads to improved quality for LEJR episodes of care even while also receiving care under these broader models, while entities that participate in other models and programs that assess total cost of care stand to benefit, at least in part, from the cost savings that accrue under CJR. For example, a beneficiary receiving an LEJR procedure may benefit from a hospital's care coordination efforts with regard to care during the inpatient hospitalization. The same beneficiary may be attributed to a primary care physician affiliated with an ACO who is actively engaged in coordinating care for all of the beneficiary's clinical conditions throughout the entire performance year, beyond the 90-day post-discharge LEJR episode.

We proposed that a beneficiary could be in a CJR episode, as defined in section III.B. of this final rule, by receiving an LEJR procedure at a CJR hospital, and also attributed to a provider participating in a model or program in Table 17. For example, a beneficiary may be attributed to a provider participating in the Pioneer ACO model for an entire performance year, as well as have a CJR episode during the ACO's performance year. Each model incorporates a reconciliation process, where total included spending during the performance period or episode are calculated, as well as any potential savings achieved by the model or program. Given that we proposed to allow for such beneficiary overlap, we stated our belief that it would be important to account for savings under CJR and the other models and programs with potential overlap in order that CMS can apply the respective individual savings-related payment policies of the model or program, without attributing the same savings to more than one model or program. In the proposed rule, we stated our belief that when overlap occurs, it is most appropriate to attribute Medicare savings accrued during the CJR time period (hospitalization plus 90 days post-discharge) to CJR to the extent possible. The CJR episode has a shorter duration and is initiated by a major surgical procedure, requiring an inpatient hospitalization. In contrast, the total cost of care models listed in Table 17 incorporate 6 to 12 month performance periods for participants and, in general, have a broader focus on beneficiary health. Our intention was to ensure that CJR episodes are attributed the full expected savings to Medicare to the extent possible. As such, we proposed the following policies to ensure that other programs and models are able to account for the reconciliation payments paid to CJR hospitals to the extent possible prior to performing their own reconciliation calculations and that, in all appropriate circumstances, the CJR model or the other program or model would make an adjustment for savings achieved under the CJR model and partially paid back through shared savings/performance payments under other initiatives to ensure that the full CJR model savings to Medicare is realized.

We proposed that the total cost of care calculations under non-ACO total cost of care models would be adjusted to the extent feasible to account for beneficiaries that are aligned to participants in the model and whose care is included in CJR in order to ensure that the savings to Medicare achieved under CJR (the discount percentage) are not paid back under these other models through shared savings or other performance-based payment. Thus, the non-ACO total cost of care models would adjust their calculations to ensure the CJR discount percentage is not paid out as savings or other performance-based payment to the other model participants. As previously discussed, we believe that the efficiencies achieved during the CJR episode should be credited to the entity that is closest to that care for the episode of care in terms of time, location, and care management responsibility, rather than the broader entity participating in a total cost of care model that spans a longer duration. We proposed that the non-ACO total cost of care models to which this policy would apply would include CPCi, OCM, and MAPCP. We sought comment on our proposal to account for overlap with those non-ACO total cost of care models and any other current or forthcoming models.

We received no comments on our proposed policy to account for the potential for the discount percentage to be paid out as savings by a non-ACO total cost of care model.

We proposed a different policy for accounting for overlap with Shared Savings Program and other ACO models. We noted that given the operational complexities and requirements of the Shared Savings Program reconciliation process, it would not be feasible for the Shared Savings Program to make an adjustment to account for the discount to Medicare under a CJR episode under existing program rules and processes. Additionally, for programmatic consistency across the Shared Savings Program and other ACO models, given that our ACO models generally are tested for the purpose of informing future potential changes to the Shared Savings Program, in the proposed rule we stated our belief that the ACO model overlap adjustment policy should be aligned with the Shared Savings Program policy. Thus, we proposed that under CJR, we would make an adjustment to the reconciliation amount if available to account for any of the applicable discount for an episode resulting in Medicare savings that is paid back through shared savings under the Shared Savings Program or any other ACO model, but only when a CJR participant hospital also participates in the ACO and the beneficiary in the CJR episode is also assigned to that ACO. This adjustment would be necessary to ensure that the applicable discount under CJR is not reduced because a portion of that discount is accounted for in shared savings to the ACO and thus, indirectly, is paid back to the hospital.

However, we proposed not to make an adjustment under CJR when a beneficiary receives an LEJR procedure at a participant hospital and is assigned

to an ACO in which the hospital is not participating. While this proposal would leave overlap unaccounted for in such situations, we did not believe it would be appropriate to hold responsible for repayment the hospital that managed the beneficiary during the episode through a CJR adjustment, given that the participant hospital may have engaged in care redesign and reduced spending during the CJR episode and may be unaware that the beneficiary is also assigned to an ACO. However, we recognized that as proposed this policy would allow an unrelated ACO full credit for the Medicare savings achieved (via the discount percentage) during the episode. The evaluation of the CJR model, as discussed in section IV. of this final rule, would examine overlap in situations where there is overlap between ACOs and CJR to the extent feasible and the potential effect on Medicare savings.

We note that our proposed policy would entail CJR reclaiming from the participant hospital any discount percentage paid out as shared savings under the Shared Savings Program or ACO models only when the hospital is participating in an ACO as a participant or provider/supplier and the beneficiary is assigned to that ACO, while other total cost of care models such as CPCi would adjust for the discount percentage in their calculations to the extent feasible. While it is operationally feasible for smaller total cost of care models in testing, such as CPCi, to make an adjustment to account for any CJR discount percentage paid out as sharing savings or other performance-based payments, the operational complexities and requirements of the large permanent Medicare ACO program, the Shared Savings Program, make it infeasible for that program to make an adjustment in such cases, and in the proposed rule we stated our belief that other ACO models in testing that share operating principles with the Shared Savings Program should follow the same policies as the Shared Savings Program adjustment for certain overlapping ACO beneficiaries. As the landscape of CMS models and programs changes, we may revisit this policy through future rulemaking.

We sought comment on our proposal for adjustments to account for overlap of the discount percentage between CJR and ACO models or programs.

The following is a summary of the comments received and our responses.

Comment: A commenter suggested that the proposal could create a disincentive for health systems to expand participation in ACO initiatives due to the more favorable treatment of non-ACO participating hospitals. The commenter also requested that CMS not recoup the portion of the discount percentage paid out as savings, regardless of whether the CJR hospital is participating in an ACO as a participant or provider/supplier.

Response: As discussed in section III.C.7.c. of this final rule, we proposed to make CJR reconciliation and repayment amounts available for other models and programs to include in their financial calculations. As commenters noted, the effect of this proposed policy is that savings achieved during the CJR episode would generally be attributed to the CJR model. This proposed policy does not distinguish between ACO and non-ACO entities. In contrast, this section outlines our proposal to make an adjustment to CJR reconciliation amounts in certain situations when a portion of the CJR discount percentage was paid out as savings to an ACO.

For purposes of limiting the instances in which a portion of the discount percentage is doubly counted as savings, we proposed the following. When a beneficiary has a CJR episode and is also assigned to an ACO, it is possible that a portion of the CJR discount percentage could be paid out as savings through the ACO's financial reconciliation. The reconciliation or repayment amounts shared with other models for incorporation into their financial calculations are based on the episode target price, which does not include the spending amount equal to the discount percentage as the discount represents potential savings to Medicare. We proposed that when overlap occurs between CJR hospitals that are participating in an ACO model or program as a participant or provider/supplier, we would make an adjustment to the reconciliation payment (if available) to account for the portion of the discount that was paid to the ACO as shared savings. For example, through the subsequent reconciliation calculation, described in section III.C.6. of this final rule we would reduce a CJR hospital's reconciliation payment by the dollar amount that would have been saved by CMS under the applicable CJR discount percentage, but was determined to have been paid to the ACO as shared savings. In cases where the CJR hospital is not participating in the Shared Savings Program or an ACO model, we would not make such an adjustment. We believe it is reasonable to minimize the situations in which the CJR discount percentage is double counted as savings. We also believe our policy not to make this adjustment in the case of an unrelated ACO is appropriate, given that the ACO may be unaware of the beneficiary's care pathway or that the beneficiary's LEJR episode is included in the CJR model because the CJR hospital and the ACO are not related. We also note that while making an adjustment to a CJR hospital's reconciliation payment is within the scope of the CJR model, adjusting shared savings amounts for ACO entities would necessitate changes to agreements to the Shared Savings Program and other ACO model agreements and methodologies. For the reasons previously stated, we believe unrelated ACOs should not be required to repay the amount of the CJR discount percentage included in the ACO's financial reconciliation.

We do not believe our proposed policy would create a disincentive for health systems to participate in an ACO. Hospitals that are not participating in the Shared Savings Program or other ACO models are treated the same as those participating in an ACO for purposes of determining attribution of savings during the CJR episode represented by the reconciliation payments, as previously discussed in section III.C.7.c. of this final rule. As discussed in that section, after performing the financial reconciliation calculations for CJR, we will put the reconciliation or repayment amounts, as applicable, in a shared repository for other models or programs to use in their own financial calculations. The reconciliation or repayment amounts would be taken into account as if they were FFS payments made for a covered service furnished to a beneficiary, to the extent that such inclusion of payments is consistent with the other model or program's policies. In applying this policy, we will not make a distinction between hospitals or other providers based on participation in an ACO or other initiative. The reconciliation or repayment amounts will be available for all other models or programs to use in their financial calculations as appropriate. In cases where the other initiative includes the CJR reconciliation or repayment amounts in their financial calculations, the savings achieved during an episode would be attributed to CJR, except in cases where the discount percentage is paid out as savings to another model or program participant, as discussed later in this section. In addition, in cases where some or all of the CJR discount percentage is paid out to an ACO hospital through the ACO's financial reconciliation, making an adjustment to the reconciliation payment where available to account for the discount percentage does not penalize the hospital participating in an ACO. Such

adjustment ensures that the discount percentage is not paid out as savings to the same or a related entity.

Comment: A commenter questioned the methodology CMS proposed for accounting for such overlap, requesting that the calculation be pro-rated for the 90-day episode and only include the portion related to CJR model participants.

Response: Although our calculations to determine reconciliation or repayment amounts would be done in aggregate across all CJR episodes for a given participants, overlap adjustments and calculations would be done at the beneficiary level. Therefore, we do not believe proration is necessary.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal, without modification, to account for overlap with non-ACO total cost of care models and ACO models and programs. In cases where a portion of the CJR discount percentage is paid out as savings to a non-ACO model participant, the other model will make an adjustment to their financial reconciliation calculation to the extent feasible. In the case of such overlap with an entity participating in the Shared Savings Program or an ACO model, the CJR model would require repayment of the portion of the discount percentage paid out as savings through the subsequent reconciliation process, by making an adjustment to the reconciliation amount if available. If a CJR hospital did not earn a reconciliation payment, the adjustment would not be made. That is, we will not increase the amount of a hospital's repayment amount in order to account for the portion of the discount percentage paid out as savings. This adjustment would only be undertaken when the CJR hospital is also aligned to an ACO as a participant or a provider/supplier and the beneficiary in the CJR episode was assigned or aligned to the ACO. We may revisit our approach to accounting for overlap with the Shared Savings Program and ACO models in future rulemaking.

Summary of Final Decisions: After consideration of the public comments we received, we are finalizing our proposal, without modification, for non-ACO total cost of care models to adjust their financial reconciliation calculations to the extent feasible to ensure that a portion of the CJR discount is not paid out as savings under that model. We are also finalizing our proposal, without modification, to make an adjustment to a CJR hospital's subsequent reconciliation calculation, when the CJR hospital also participates in the ACO and the beneficiary in the CJR episode is also assigned to that ACO, to account for when a portion of the CJR discount percentage is paid out as shared savings the ACO.

This policy is set forth at § 510.305.

8. Limits or Adjustments to Hospital Financial Responsibility

a. Overview

As discussed in section III.A. of the proposed rule, we proposed designating as the financially responsible providers in CJR all acute care hospitals paid under the IPPS that are located in the selected geographic areas for this test of 90-day post-discharge LEJR episodes, with the exception of some hospitals that we proposed to exclude because of participation in BPCI (Models 1, 2, or 4) for LEJR episodes. We are interested in ensuring a broad test of episode payment for this clinical condition among different types of hospitals, including those who may not otherwise choose to participate in an episode payment model. Many of the participant hospitals would likely be key service providers in their communities for a variety of medical and surgical conditions extending well beyond orthopedic procedures. We want to gain experience with this model before extending it to hospitals in uncommon circumstances. In addition, we acknowledge that hospitals designated for participation in CJR currently vary with respect to their readiness to function under an episode payment model with regard to their organizational and systems capacity and structure, as well as their beneficiary population served. Some hospitals may more quickly be able to demonstrate high quality performance and savings than others, even though we proposed that the episode target prices be based predominantly on the hospital's own historical episode utilization in the early years of CJR.

We also note that providers may be incentivized to excessively reduce or shift utilization outside of the CJR episode, even with the quality requirements discussed in section III.C.5. of the proposed rule. In order to mitigate any excessive repayment responsibility for hospitals or reduction or shifting of care outside the episode, especially beginning in performance year 2 of the model when we proposed to begin to phase in responsibility for repaying Medicare for excess episode spending, we proposed several specific policies that are also referenced in section III.C.6.b. of the proposed rule.

b. Limit on Raw NPRA Contribution to Repayment Amounts and Reconciliation Payments

(1) Limit on Raw NPRA Contribution to Repayment Amounts

When hospital repayment responsibility begins in the second performance year of CJR, under this final rule, hospitals would be required to repay Medicare for episode expenditures that are greater than the applicable target price. As discussed in the section III.C.3.c of the proposed rule regarding our proposed pricing adjustment for high payment episodes, hospitals participating in CJR would not bear financial responsibility for actual episode payments greater than a ceiling set at two standard deviations above the mean regional episode payment. Nevertheless, hospitals would begin to bear repayment responsibility beginning in performance year 2 for those episodes where actual episode expenditures are greater than the target price up to the level of the regional episode ceiling. In aggregate across all episodes, the money owed to Medicare by a hospital for actual episode spending above the applicable target price could be substantial if a hospital's episodes generally had high payments. As an extreme example, if a hospital had all of its episodes paid at two standard deviations above the mean regional episode payment, the hospital would need to repay Medicare a large amount of money, especially if the number of episodes was large.

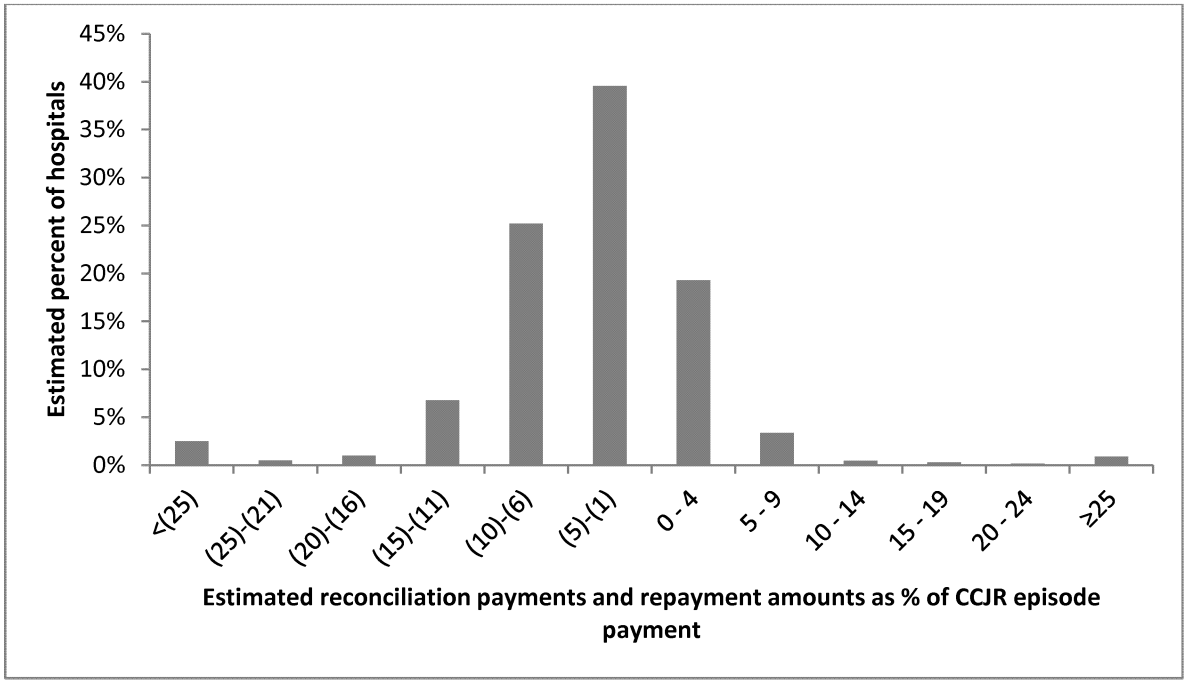
To limit a hospital's overall repayment responsibility for the raw NPRA contribution to the repayment amount under this model, we proposed a 10 percent limit on the raw NPRA contribution to the repayment amount in performance year 2 and a 20 percent limit on the raw NPRA contribution to the repayment amount in performance year 3 and subsequent years. Hereinafter we refer to these proposed repayment limits as stop-loss limits. In performance year 2 as we phase in repayment responsibility, the hospital would owe Medicare under the proposed CJR payment model no more than 10 percent of the hospital's target price for the anchor MS–DRG multiplied by the number of the hospital's CJR episodes anchored by that MS–DRG during the performance year, for each anchor MS–DRG in the model. Ten percent provides an even transition with respect to maximum repayment amounts from performance year 1, where the hospital bears no repayment responsibility, to the proposed stop-loss limit in performance years 3 through 5 of 20 percent. In performance years 3

through 5 when repayment responsibility is fully phased in, no more than 20 percent of the hospital's target price for the MS–DRG multiplied by the number of the hospital's CJR episodes with that MS–DRG in that performance year would be owed by the hospital to Medicare under the proposed CJR payment model. The proposed stop-loss percentage of 20 percent would be symmetrical in performance years 3 through 5 with the proposed limit on the raw NPRA contribution to reconciliation payments discussed in the following section.

We had believed that a stop-loss limit of 20 percent is appropriate when the hospital bears full repayment responsibility, based on our assessment of the changes in practice pattern and reductions in quality of care that could lead to significant repayment responsibility under the CJR model, as compared to historical LEJR episode utilization. We estimate that the IPPS payment for the anchor hospitalization makes up approximately 50 percent of the episode target price, and we expect that the anchor hospitalization offers little opportunity for efficiencies to be achieved by reducing Medicare expenditures. In contrast, we expect significant episode efficiencies could be achieved in the 90 days following discharge from the anchor hospitalization through reductions in related hospital readmissions and increased utilization of appropriate lower intensity PAC providers, specifically increased utilization of home health services and outpatient therapy and reduced utilization of SNFs and IRFs. Hospital readmissions and facility-based PAC increase the typical Medicare episode payment by 30 to 45 percent over episodes that do not include these services. The proposed 20 percent stop-loss limit related to the total episode payment corresponds to approximately 40 percent of episode payment for the post-discharge period only, where the major opportunities for efficiency through care redesign occur. Thus, taking into consideration the historical patterns used to set target prices, we believed it is reasonable to hold participant hospitals responsible for repayment of actual episode spending that is up to 20 percent greater than the target price. If a participant hospital's repayment amount due to the raw NPRA would otherwise have exceeded the stop-loss limit of 20 percent (comparable to 40 percent of Medicare payment for the post-discharge period), the hospital's episodes would include much poorer episode efficiency as compared to the hospital's historical episodes, with large proportions of episodes including related readmissions and facility-based PAC, costly services that we do not expect to be necessary for most beneficiaries whose care is well-coordinated and appropriate throughout a high quality LEJR episode.

The following hypothetical example illustrates how the proposed stop-loss percentage would be applied in a given performance year for the episodes of a participant hospital. In performance year 3, a participant hospital had ten episodes triggered by MS–DRG 469, with a target price for these episodes of $50,000. The hospital's episode actual spending for these ten episodes was $650,000. The hospital's raw NPRA that would otherwise be $150,000 ((10 × $50,000) − $650,000) would be capped at the 20 percent stop-loss limit of $100,000 (0.2 × 10 × $50,000) so the hospital would owe CMS $100,000, rather than $150,000. In performance year 3, the same participant hospital also has 100 episodes triggered by MS–DRG 470, with a target price for these episodes of $25,000. The hospital's episode actual spending for these 100 episodes was $2,800,000. The hospital's raw NPRA would be $300,000 ((100 × $25,000) − $2,800,000), an amount that would be due to CMS in full as it would not be subject to the 20 percent stop-loss limit of $500,000 (0.2 × 100 × $25,000).

FIGURE 4: ESTIMATED DISTRIBUTION OF RECONCILIATION PAYMENTS AND REPAYMENT AMOUNTS UNDER PERFORMANCE YEAR 2 POLICIES, BEFORE CONSIDERATION OF CHANGES IN UTILIZATION, WITHOUT APPLICATION OF STOP-LOSS OR STOP-GAIN LIMITS, BEFORE CONSIDERATION OF QUALITY THRESHOLDS



Source: Medicare Parts A and B claims, CJR episodes as proposed, between October 1, 2013 and September 30, 2014. Assumes no change in utilization patterns, 2 percent discount factor, 33 percent/66 percent regional and hospital-specific blended target price, and 20 episode threshold for using low historical volume pricing approach. Assumes all participant hospitals with actual episode spending below target prices meet minimum quality thresholds.

As illustrated in Figure 4 where we display results from our national model for the proposed CJR performance year 2 policies when the phase-in of repayment responsibility begins and under the assumption that utilization remains constant, we estimate that the 10 percent stop-loss limit would impact the amount of repayment due to the raw NPRA for about 11 percent of hospitals. For performance year 3, the 20 percent stop-loss limit would affect significantly fewer hospitals, only about 3 percent. We note that the stop-loss limit for years 3 through 5 where repayment responsibility is fully implemented is consistent with the BPCI Model 2 policy. While Figure 3 assumes no change in utilization patterns, under the model test we expect that the proposed stop-loss limits could actually affect a smaller percentage of hospitals in each performance year because we expect LEJR episode care redesign incentivized by the model's financial opportunities to generally reduce unnecessary utilization, thereby reducing actual episode spending and, correspondingly, any associated repayment amounts due to the raw NPRA. We note that we would include any post-episode spending amount due to Medicare according to the policy proposed in section III.C.8.d. of the proposed rule in assessing the total repayment amount due to the raw NPRA against the stop-loss limit for the performance year to determine a hospital's total payment due to Medicare, if applicable.

We sought comment on our proposal to adopt a 10 percent stop-loss limit in performance year 2 and 20 percent stop-loss limit in performance year 3 and beyond in CJR as hospital repayment responsibility for excess episode spending above the target price is phased in and then maintained in the model. The following is a summary of the comments received and our responses.

Comment: Several commenters commented on our proposal for stop-loss limits and expressed support of our proposal to establish stop-loss limits on financial responsibility to 10 percent in year 2, 20 percent in years 3 through 5 that aligned with BPCI and comments in support of the premise of phase-in risk under a mandatory model. However, we also received several comments in opposition of our approach for stop-loss limits. Several commenters requested that we either delay downside risk until Performance Year 3 or set the maximum stop-loss limit at 10 percent, as opposed to 20 percent. Several commenters suggested that we phase in downside risk more slowly with various permutations of the transition to downside risk such as 3 percent in year 3, 6 percent in year 4 and 10 percent in year 5 which aligned more with the Shared Savings Program Track 2 or that we phase in risk with no repayment in year 1 and 2 and stop loss limit set at intervals leading up to 10 percent by performance year 5. Commenters found the stop loss limit to be high considering that the IPPS payment for an LEJR episode comprised 50 percent of a payment, so a 10 percent stop-loss limit would actually represent 20 percent of DRG payment and a 20 percent stop-loss limit would represent 40 percent of DRG payment. Additionally, a commenter was concerned that if hospitals only treat

outlier cases, episode costs could be highly skewed, resulting in repayment. Commenters requested for a more gradual transition to downside risk and a lower stop-loss limit to allow for hospitals to have more time to gain experience under a mandatory model. Additionally, commenters were concerned with the downward pressures faced by hospitals under Medicare reimbursement such as penalties under HRRP, HAC, HITECH and sequestration, and that hospitals need to manage moving to ICD–10 and changes under MACRA. The commenter requested that given the other competing Medicare payment policies that are affecting hospitals, we should provide for a lower stop-loss limit.

Response: We thank the commenters for the concerns they raised regarding the proposed stop-loss limit. As described earlier in this final rule, we acknowledge that it may take time for the hospitals to make changes in response to this model and to assume downside risk. We have made several changes in response to such concerns, including delaying the start date of this model to April 1, 2016. Additionally, we have provided safeguards for high cost outlier episodes where we are finalizing capping episodes that are two standard deviations above the mean regional price when determining episode target prices and actual episode payments. Similarly, we agree with commenters that we can provide a more gradual transition to downside risk as hospitals make changes to infrastructure, care coordination, and financial alignment in response to this model. Additionally, we believe a gradual transition to downside risk may reduce the effect of random variation in the early years of the model that could result in highly skewed episode costs that would result in hospital repayment. We are finalizing our policy for no downside risk in Performance Year 1, a stop-loss limit of 5 percent in Performance Year 2, a stop-loss limit of 10 percent in Performance Year 3 and full downside risk with a stop-loss limit of 20 percent in Performance Years 4 and 5. We believe that as we move to regional pricing, hospitals will gain more experience with the model and reduce unnecessary utilization, allowing them better manage additional downside risk capped at 20 percent in Performance Year 4 and 5.

Comment: We received a comment that we should align our stop-loss limit policy with BPCI such that we allow hospitals to choose their level of risk among different tracks such as 5 percent stop loss/stop gain, 10 percent stop loss/stop gain or 20 percent stop loss/stop gain limits. The commenter suggested that as hospitals have more control over the risk they take on, they can get more benefit in terms of stop-gain. Commenter suggested that, similar to BPCI, hospitals should be able to change their risk level on a quarterly basis.

Response: While this may be similar to how the BPCI model operates, we do not believe it would be appropriate to allow for that option at this time. One of the goals of this model is to evaluate the generalizability of a bundled payment model for selected hospitals and we are interested in evaluating the effects on hospitals for assuming financial responsibility of an episode of care that include downside risk with limits over time. If we allow hospitals to choose their risk level over time, it adds to the operational complexity of this model and may limit the generalizability of the findings.

Comment: We received a comment that we should use dollar thresholds to set the stop-loss limits as opposed to percentages. The commenter was concerned that depending on the amount of volume at a hospital, the proposed 10 percent stop-loss limit in Performance Year 2 or 20 percent stop-loss limit in Performance Year 3 through 5 could be difficult to absorb.

Response: We believe that it would be operationally complex to establish a stop-loss limit based on a dollar amount given the payment policies finalized in this rule. It would be difficult to establish a dollar amount stop-loss limit as selected hospitals have varying volumes for LEJR episodes that we are not able to predict over the course of the model. Additionally, we are finalizing to adjust target episode prices twice a year in accordance with updates to the Medicare FFS schedules so it would be challenging to additionally adjust stop-loss limits based on a dollar amount. We believe the percentage based stop-loss limits are easier for the public to understand.

Final Decision: After consideration of the public comments we received, we are finalizing to apply stop-loss limits of 5 percent in performance year 2, 10 percent in performance year 3 and 20 percent for performance years 4 and 5. This is a change from the proposed rule where we had proposed to apply stop-loss limits of 10 percent in Performance Year 2 and 20 percent in Performance Years 3 through 5. We are codifying these changes at § 510.305(e)(1)(v)(C).

(2) Limit on Raw NPRA Contribution to Reconciliation Payments

We believed a limit on reconciliation payments for CJR would be appropriate for several reasons. Due to the proposed nature of the CJR model during performance year 1, when hospitals have no repayment responsibility for excess episode spending above the target price, CMS bears full financial responsibility for Medicare actual episode payments for an episode that exceed the target price, and we believed our responsibility should have judicious limits. Therefore, we believed it would be reasonable to cap a hospital's reconciliation payment due to the raw NPRA as a percentage of episode payment on the basis of responsible stewardship of CMS resources. In addition, we note that beginning in performance year 1, participant hospitals would be eligible for reconciliation payments due to the NPRA if actual episode expenditures are less than the target price, assuming the proposed quality thresholds are met. This proposal for reconciliation payments due to the NPRA provides a financial incentive to participant hospitals from the beginning of the model to manage and coordinate care throughout the episode with a focus on ensuring that beneficiaries receive the lowest intensity, medically appropriate care throughout the episode that results in high quality outcomes. Therefore, we also believed it would be reasonable to cap a hospital's reconciliation payment due to the raw NPRA based on concerns about potential excessive reductions in utilization under the CJR model that could lead to beneficiary harm.

In determining what would constitute an appropriate reconciliation payment limit due to the raw NPRA, we believed it should provide significant opportunity for hospitals to receive reconciliation payments for greater episode efficiency that includes achievement of quality care and actual episode payment reductions below the target price, while avoiding creating significant incentives for sharply reduced utilization that could be harmful to beneficiaries. Thus, for all 5 performance years of the model, we proposed a limit on the raw NPRA contribution to the reconciliation payment of no more than 20 percent of the hospital's target prices for each MS–DRG multiplied by the number of the hospital's episodes for that MS–DRG. Hereinafter we refer to this proposed reconciliation payment limit as the stop-gain limit. This proposed stop-gain limit is parallel to the 20 percent stop-loss limit proposed for performance year 3 and beyond. We believed that a parallel stop-gain and stop-loss limit is important to provide proportionately similar protections to CMS and participant hospitals for their financial

responsibilities under CJR, as well as to protect the health of beneficiaries.

As illustrated in Figure 3 where we displayed results from our national model for the proposed CJR performance year 2 policies under the assumption that utilization remains constant, we estimate that the 20 percent stop-gain limit would impact the reconciliation payment amount due to the raw NPRA of almost no hospitals. We note that a stop-gain limit of 20 percent is consistent with BPCI Model 2 policy. While Figure 3 assumes no change in utilization patterns, under the model test we expect that the proposed stop-gain limit could actually affect a few hospitals in each performance year because we expect LEJR episode care redesign incentivized by the model's financial opportunities to generally reduce unnecessary utilization, thereby reducing actual episode spending and, correspondingly, increasing any associated reconciliation payment amounts due to the raw NPRA. Nevertheless, we believed the proposed stop-gain limit of 20 percent provides substantial opportunity for hospitals to achieve savings over the target price without excessive reductions in utilization, and those savings would be paid back to hospitals fully in most cases without being affected by the stop-gain limit. We sought comment on our proposal to adopt a 20 percent stop-gain limit for all performance years of CJR.

We note that we plan to monitor beneficiary access and utilization of services and the potential contribution of the stop-gain limit to any inappropriate reduction in episode services. We refer readers to section III.F. of the proposed rule for our proposals on monitoring and addressing hospital performance under CJR.

The following is a summary of the comments received and our responses.

Comment: Commenters were generally supportive of the proposed stop-gain limit policy at 20 percent as it aligns with BPCI. Another commenter supported the 20 percent stop-gain limit but noted that it is not proportional to the stop-loss limit of 20 percent that was proposed to begin in Performance Year 3 because hospitals have to invest and achieve a minimum 2 percent savings for the Medicare discount from a blend of regional and provider spend which may represent a higher cost savings. Some commenters requested that we remove a stop-gain limit as there are sufficient safeguards in the rule that a stop gain limit was not necessary. Additionally, commenters found a stop-gain limit could serve as a disincentive for hospitals and hospital systems to undertake those reforms that truly transform care.

Response: As described earlier, in response to comments that hospitals need a more time to assume downside risk, we are similarly finalizing a more gradual transition the stop-loss limit of 20 percent such that in Performance Year 2, the stop-loss limit is 5 percent, in Performance Year 3, the stop loss limit is 10 percent and in Performance Year 4 and 5, the stop-loss limit is 20 percent. As described in the proposed rule, we proposed parallel stop-loss and stop-gain limits in order to provide proportionately similar protections to CMS and participant for their financial responsibilities under CJR, as well as to protect the health of beneficiaries. Because we are changing our stop-loss limits in this final rule to provide for a more gradual transition to a stop-loss limit of 20 percent, we are believe it would be similarly appropriate to implement a gradual transition to the full stop-gain limit of 20 percent. We believe that the commenters' arguments for requiring additional time to make changes to adapt to the model and to take on financial responsibility similarly applies to hospitals' ability to obtain upside risk under this model. We want to ensure that any repayments in the early years of the model are not due to random variation and accordingly, we have applied a transition to downside risk with more gradual stop-loss limits during the course of the model. We similarly want to ensure that any savings achieved by the hospitals in the early years of the model are also not due to random variation and believe it would be appropriate to apply a parallel transition with more gradual stop-gain limits during the course of the model. Additionally, we want to ensure that changes that the hospitals undertake to improve efficiency that include achievement in quality care and episode payment reductions below the target episode price also do not result in sharp decreases in utilization that could be harmful to beneficiaries. Implementing parallel stop-loss and stop-gain limits provides significant opportunity for hospitals to reduce episode spending through care redesign and care coordination, with appropriate safeguards to ensure that such redesign and coordination activities are clinically appropriate and do not result in reduced quality of care. We recognize that while some hospitals may already be adept at such coordination activities, given that we are requiring participation in the CJR model, such safeguards are necessary to protect beneficiaries and the Trust Funds while hospitals less experienced with care redesign adapt to the model and begin to engage in care redesign activities. While we are implementing various mechanisms to monitor for inappropriate changes in utilization as discussed later in this rule, we believe it would also be appropriate to transition to upside risk in the same manner as we are finalizing to transition to downside risk. In addition, we believe parallel stop-loss and stop-gain limits are appropriate for the CJR model in order to ensure that both CMS and hospitals in the model are similarly at risk for episode spending. Accordingly, we are finalizing a 5 percent stop-gain limit in Performance Year 1 and 2, 10 percent stop-gain limit in Performance Year 3 and 20 percent stop-gain limit in Performance Years 4–5. We believe that it is appropriate that as participant hospitals increase their downside risk, they can similarly increase their opportunity for additional payments under this model.

Additionally, we acknowledge the comment that hospitals need to achieve a certain percent savings, representing the Medicare discount before they are able to receive a reconciliation payment and be subject to the stop-gain limits. As discussed in section III.C.4.b.(9) of this final rule, we are modifying our policy in this final rule so as to use lower discount factors for purposes of determining the hospital's responsibility for excess episode spending not only in performance year 2, but also in performance year 3. Additionally, as discussed in section III.C.5. of this final rule, we are modifying the proposed rule so as to provide different levels of quality incentive payments that would modulate participant hospitals' effective target price discount factor based on their quality performance. We expect participant hospitals to have significant opportunity to improve the quality and efficiency of care furnished during episodes in comparison with historical practice, because this model would facilitate the alignment of financial incentives among providers and suppliers caring for beneficiaries throughout the episode. This discount would serve as Medicare's portion of reduced expenditures from the episode, with any episode expenditure below the target price potentially available as reconciliation payments to the participant hospital where the anchor hospitalization occurred.

Final Decision: After consideration of the public comments we received, we are finalizing to establish stop-gain limits that correspond to the finalized stop-loss limits such that the stop-gain limit is 5 percent in Performance Years 1 and 2, 10 percent in Performance Year

3 and 20 percent in Performance Year 4 and 5. We are codifying the establishment of stop-gain limits in this model at § 510.305(e)(1)(v)(D).

c. Policies for Certain Hospitals To Further Limit Repayment Responsibility

As discussed in section III.C.3. of the proposed rule, we proposed that participant hospitals would be subject to repayment responsibility for episode actual spending in excess of the applicable target price beginning in performance year 2. Hospitals participating in CJR would not be responsible for actual episode payments greater than a ceiling set at two standard deviations above the mean regional episode payment as described earlier in this section. Additionally, we proposed a 10 percent limit on the raw NPRA contribution to the repayment amount in performance year 2 and a 20 percent limit on the raw NPRA contribution to the repayment amount in performance year 3 and beyond, as described in the previous section of this final rule.

Though our proposals provide several safeguards to ensure that participant hospitals have limited repayment responsibility due to the raw NPRA, we are proposing additional protections for certain groups of hospitals that may have a lower risk tolerance and less infrastructure and support to achieve efficiencies for high payment episodes. Specifically, we are proposing additional protections for rural hospitals, SCHs, Medicare Dependent Hospitals and Rural Referral Centers (RRCs). We note that these categories of hospitals often have special payment protections or additional payment benefits under Medicare because we recognize the importance of preserving Medicare beneficiaries' access to care from these hospitals. In MedPAC's Report to the Congress in June 2012, MedPAC examined issues related to rural Medicare beneficiaries and found that ''The primary objective of rural special payments is to ensure that Medicare does its part to support the financial viability of rural providers that are necessary for beneficiaries' access to care. Some form of special payments will be needed to maintain access in areas with low population density where providers inevitably have low patient volumes and lack economies of scale.'' [44]

We proposed that a rural hospital would have additional protections under the stop-loss limit proposal. For the purpose of this model, we are proposing to define a rural hospital as an IPPS hospital that is either located in a rural area in accordance with § 412.64(b) or in a rural census tract within an MSA defined at § 412.103(a)(1) or has reclassified to rural in accordance with § 412.103. Such rural hospitals would have additional protections under the stop-loss limit proposal. Consistent with the findings in MedPAC's June 2012 Report to the Congress, we believed rural hospitals may have a lower risk tolerance and less infrastructure and support to achieve efficiencies for high payment episodes, particularly if they are the only rural hospital in an area.

Our preliminary analysis examining national spending for MS–DRGs 469 and 470 from October 1, 2013 to September 30, 2014 showed that MS–DRGs 469 and 470 cases represent a slightly higher proportion of cases and spending for rural hospitals than the national average (for example, MS–DRG 470 episode spending represents 12 percent of IPPS spending for rural hospitals and represents 9 percent of IPPS spending nationally).[45] Additionally, our analysis on the distribution of national spending of MS–DRGs 469 and 470 episodes by service type (that is inpatient, outpatient, SNF, Home Health, Physician Part B, DME), found that on average, inpatient services account for the most spending for an MS–DRGs 469 and 470 episode (53 percent of spending for an MS–DRG 469 episode and 55 percent of spending for MS–DRG 470 episode). SNF services account for 27 percent of spending for MS–DRG 469 and 18 percent of spending for MS–DRG 470. The spending distribution for all rural IPPS hospitals also differs from the national average. For rural hospitals, inpatient services for CJR episodes account for more spending than the national average (56 percent for MS–DRG 469 and 57 percent for MS–DRG 470 for rural hospitals) and SNF spending is higher than the national average (29 percent for MS–DRG 469 and 21 percent for MS–DRG 470 for rural hospitals). It is evident that this category of hospitals has different spending patterns than the national average. Furthermore, hospitals in rural areas often face other unique challenges. Rural hospitals may be the only source of healthcare services for beneficiaries living in rural areas, and beneficiaries have limited alternatives should rural hospitals be subject to financial changes under this model. Additionally, because rural hospitals may be in areas with fewer providers including fewer physicians and PAC facilities, rural hospitals may have more limited options in coordinating care and reducing spending while maintain quality of care under this model. We believed that urban hospitals may not have similar concerns as they are often in areas with many other providers and have greater opportunity to develop efficiencies under this model. Given that rural hospitals have different episode spending patterns, have different challenges in coordinating care and reducing cost than urban hospitals and serve as a primary access to care for beneficiaries, we believed that we should have a more protective stop-loss limit policy as described later in this section.

Additionally, we proposed to provide additional protections for SCHs as defined in § 412.92, Medicare Dependent Hospitals as defined in § 412. 108 and RRCs as defined in § 412.96. Hospitals paid under the IPPS can qualify for SCH status if they meet one of the following criteria:

- Located at least 35 miles from other like hospitals.
- Located in a rural area, located between 25 and 35 miles from other like hospitals, and no more than 25 percent of residents or Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35-mile radius of the hospital or the hospital has fewer than 50 beds and would meet the 25 percent criterion if not for the fact that some beneficiaries or residents were forced to seek specialized care outside of the service area due to the unavailability of necessary specialty services at the hospital.
- Hospital is rural and located between 15 and 25 miles from other like hospitals but because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each of 2 out of 3 years.
- Hospital is rural and the travel time between the hospital and the nearest like hospital is at least 45 minutes.

If an IPPS hospital qualifies to be a SCH, the hospital can be paid the higher of the federal payment rate paid to IPPS hospitals or a cost-based hospital-specific rate as described in § 412.78. Under OPPS, a rural SCH can receive a 7.1 percent add on payment for most services with certain exceptions, in accordance with § 419.43(g). These criteria to qualify for SCH status demonstrate that SCHs are likely to be the sole hospital in an area. Furthermore, additional payments

[44] MedPAC Report to Congress June 2012, Chapter 5, page 121.

[45] Medicare FFS Parts A and B claims, CJR episodes as proposed, between October 1, 2013 and September 30, 2014.

provided under Medicare FFS for SCHs, demonstrates Medicare's interest in ensuring these hospitals are able to provide services to the Medicare beneficiaries who may have limited access to providers in their area. As a result, we believed that we should provide SCHs additional protections from hospital responsibility for repayment in this model. We note that we proposed to exclude these add-on payments for SCHs, as described in section III.C.3.a. of the proposed rule.

MDHs are defined as a hospital that meets the following criteria:

- Located in a rural area.
- Has 100 beds or less.
- Is not a SCH.
- Sixty percent of the hospital's inpatient days or discharges were attributable to individuals entitled to Medicare Part A benefits during specified time periods as provided in § 412.108.

MDHs also qualify for special additional payments under the IPPS where an MDH can receive the higher of a payment under the federal standard rate for IPPS hospitals or the payment under federal standard rate for IPPS hospitals plus 75 percent of the difference in payments between a cost based hospital-specific rate and the federal standard rate as described in § 412.108(c). These criteria demonstrate that MDHs are small, rural hospitals that have a high Medicare case mix percentage and receive additional payments under the IPPS to ensure financial stability and preserve beneficiary access to care to these hospitals. Thus, we believed these factors demonstrate that we should provide additional safeguards from hospital responsibility for repayment in order to preserve access to care. We note that we proposed to exclude these payment enhancements for MDHs, as described in section III.C.3.a. of the proposed rule.

RRCs are defined as IPPS hospitals with at least 275 beds that meet the following criteria:

- Fifty percent of the hospital's Medicare patients are referred from other hospitals or from physicians who are not on the staff of the hospital.
- At least 60 percent of the hospital's Medicare patients live more than 25 miles from the hospital.
- At least 60 percent of all services the hospital furnishes to Medicare patients are furnished to patients who live more than 25 miles from the hospital.

If a hospital does not meet the criteria described previously, a hospital can also qualify for RRC status if a hospital meets the following criteria:

- For specified period of time, the hospital has a case-mix that equals the lower of the median case mix index (CMI) value for all urban hospitals nationally; or the median CMI value for urban hospitals located in its region, excluding those hospitals receiving indirect medical education payments.
- Its number of discharges is at least—

++ 5,000 (or 3,000 for an osteopathic hospital); or

++ The median number of discharges for urban hospitals in the census region in which it is located, set by the CMS through IPPS rulemaking.

- Additionally, a hospital must meet one of the following criteria:

++ More than 50 percent of its active medical staff are specialists who meet the conditions specified at§ 412.96(c)(3).

++ At least 60 percent of all discharges are for inpatients who reside more than 25 miles from the hospital.

++ At least 40 percent of all inpatients treated are referred from other hospitals or from physicians who are not on the hospital's staff.

As an RRC, a hospital can qualify for several additional payments under the IPPS. For example, an RRC is not subject to the 12 percent cap on Medicare Disproportionate Share Hospital payments that a rural hospital would otherwise be subject to, in accordance with § 412.106(d). Although RRCs are larger and have a higher Medicare patient mix, they often serve as the sole provider to treat higher acuity cases, as demonstrated by the RRC qualification criteria. As a result of these unique characteristics of these hospitals, RRCs can receive additional payments under Medicare FFS. Thus, it is also important to provide additional protections for RRCs such that participation in this model does not result in significant financial loss that may reduce access for Medicare beneficiaries.

For these reasons, we proposed a stop-loss limit of 3 percent of episode payments for these categories of hospitals in performance year 2 and a stop-loss limit of 5 percent of episode payments for performance years 3 through 5. More specifically, in performance year 2, a rural hospital, SCH, RRC or MDH that is a participant hospital would owe Medicare due to the raw NPRA no more than 3 percent of the hospital's target price for the anchor MS–DRG multiplied by the number of the hospital's CJR episodes with that anchor MS–DRG in the performance year. Additionally, in performance years 3 through 5, a rural hospital, SCH, RRC or MDH that is a participant hospital would owe Medicare due to the raw NPRA no more than 5 percent of the hospital's target price for the anchor MS–DRG multiplied by the number of the hospital's CJR episodes with that anchor MS–DRG in the performance year. We believed a different stop-loss limit policy is warranted given the different spending patterns and the unique hospital characteristics for these groups of hospitals as described earlier. We believed this proposal strikes an appropriate balance between protecting hospitals that often serve as the only access of care for Medicare beneficiaries and having these hospitals meaningfully participate in the model. We note that this proposal does not impact the proposed stop-gain policy for these categories of hospitals. Rural hospitals, SCHs, MDHs and RRCs would still have the opportunity to participate in full gains at 20 percent similar to other hospitals.

Hospitals can apply for SCH, MDH and RRC status through their MACs and Regional Office at any time. MACs maintain the list of SCHs, MDHs, and RRCs in the CMS Provider Specific File, which they update on a quarterly basis. The special hospital designations recorded in the Provider Specific File are used in Medicare claims pricing to ensure that these hospitals are paid according to their special hospital designation. Additionally, CMS can identify which hospitals are considered rural for the purpose of this policy, using the Provider Specific File to identify physical geographic location of a hospital and the MACs to identify whether an urban hospital has reclassified to rural under § 412.103 or located in a rural census tract of an MSA defined under § 412.103(a)(1). Thus, we proposed to identify rural hospitals, MDHs, SCHs and RRCs at the time of reconciliation using the Provider Specific File updated in December of the end of the performance year and information from the MACs, and those hospitals would be subject to the 3 percent stop-loss limit policy for that performance year 2, and 5 percent stop-loss limit policy in performance years 3 through 5. For example, to identify the hospitals that would receive a 3 percent stop-loss limit for performance year 2, we would use the Provider Specific File updated in December 2017. We note that the special Medicare payment designation of MDH status has been extended through FY 2017 by legislation under the MACRA. As a result, the proposed additional protections for hospital responsibility for repayment for MDHs would only apply to the extent that MDH status exists under Medicare.

In other words, should MDH expire on or after September 30, 2017, we would not identify hospitals as MDHs to receive the 5-percent stop-loss limit policy for performance year 3. Though MDH status is set to expire after the third quarter of 2017, we would still identify MDHs to receive the 3-percent stop loss limit policy for all of performance year 2.

We note that we also considered excluding rural hospitals, SCHs, MDHs and RRCs from the CJR model altogether due to our concerns of placing significant responsibility for actual episode payment above the target price on these hospitals. Additionally, we were also concerned that from an evaluation perspective, we would not have sufficient sample size of CJR episodes from these categories of hospitals to have significant results of how these groups of hospitals perform under this model. We weighed our reasons for excluding these hospitals with the potential qualitative information we would gain from payment innovation tests on rural hospitals in this model. We concluded that because the CJR model strives to test episode payment for a broad variety of hospitals, it would be preferable to include these hospitals in the CJR model and provide additional protections from a large repayment responsibility. We welcome public comment on our proposed stop-loss limit for rural hospitals, SCHs, MDHs and RRCs and on our alternative consideration to exclude these hospitals entirely from the CJR model.

Comment: Several commenters commented on our proposal to provide a more protective stop-loss for rural hospitals, SCHs, MDHs and RRCs. and support of the more protective stop-loss for rural hospitals, SCHs, MDHs and RRCs in order to preserve access to care. Some commenters suggested even more protective stop-loss for these categories of hospitals such as delaying downside risk until Performance Year 3, not providing for downside risk to these hospitals or reducing downside to 1 percent in Performance Year 3, 3 percent in Performance Year Four, and 5 percent in Performance Year Five. We also received comments that we should exclude all-together rural hospitals, SCHs, MDH and RRCs, because as we had acknowledged in the proposed rule, these hospitals may not be able to take on financial risk under this model.

Response: We are interested in including these categories of hospitals in our model to see the impact of a bundled payment model in providers that may not otherwise participate in a voluntary program and to better understand the generalizability of this model. However, we recognize the concerns that these categories of hospitals may be less equipped to take on risk and may be the only access of care in their areas. Thus, we proposed to provide for a more limited stop-loss for these categories of hospitals at 3 percent for Performance Year 2 and 5 percent for Performance Years 3 through 5. We had proposed that rural hospitals, MDHs, SCHs and RRCs would still have the opportunity to participate in full gains at 20 percent similar to other hospitals in the model. While we would provide for more limited downside risk for these categories of hospitals for the reasons previously stated, we believe rural hospitals, MDHs, SCHs and RRCs should have the opportunity to receive the gains to the same extent as the other hospitals in the model. We note that we are finalizing to provide for a more gradual stop-loss limit for all other hospitals in the model where the stop-loss limit is 5 percent in Performance Year 2, 10 percent in Performance Year 3 and 20 percent in Performance Years 4–5. Additionally, we are finalizing that the stop-gain limit would be proportional to the stop-loss limit such that in Performance Year 1–2, the stop-gain limit would be 5 percent; in Performance Year 3, the stop-gain limit would be 10 percent; and in Performance Years 4–5, the stop gain limit would be 20 percent We believe the our rationale described earlier in this section to provide for a more gradual transition to stop-gain limits over the course of the model should similarly apply to rural hospitals, SCHs, MDHs and RRCs, particularly in light of our concerns that these categories of hospitals have lower risk tolerance and less infrastructure and support to achieve efficiencies for high payment episodes. We want to ensure that any performance gains by these categories of hospitals are not based on random variation but rather due to implementing changes to achieve efficiencies for high payment episodes. Thus, we are finalizing a more gradual stop-gain limit where the stop-gain limit is 5 percent in Performance Year 2, 10 percent in Performance Year 3 and 20 percent in Performance Years 4–5 for all hospitals in the model, including rural hospitals, SCHs, MDHs and RRCs.

Comment: Some commenters recommended that we apply the protective stop-loss limits to other categories of providers with similar low-risk tolerance as rural hospitals, SCHs, MDHs and RRCs. A commenter suggested that we apply the protective stop-loss limit to hospitals in bankruptcy, or undergoing major restructuring under State oversight like safety net hospitals under the Medicaid DSRIP waiver in New York. Another commenter suggested that we provide a protective stop-loss limit for urban referral centers. Another commenter requested that we provide risk corridors for providers that partner with participant hospitals such as IRFs and SNFs.

Response: As described in the proposed rule and finalized in this final rule, we are providing additional protections on repayment through more limited stop-loss to certain categories of hospitals that are financially responsible for the 90-day episode spending in this model. Because the provider at risk in this model is the hospital, we believe it is appropriate to provide for limits on financial gain and repayment. We do not believe it would be appropriate to provide risk corridors for other types of providers that may be involved in the continuum of care in a 90 day episode for LEJR such as PAC providers since we will not be making a reconciliation payment or recoupment to those providers. Additionally, we have provided more protective stop-loss limits for certain categories of hospitals that have been recognized by Medicare through additional Medicare FFS payment incentives as often being the only access of care for Medicare beneficiaries and thus it is in our interest to both be able to keep them in the model but recognizing their lower risk tolerance. We do not believe it would be appropriate to provide a limited stop-loss to safety net hospitals under the Medicaid DSRIP waiver in New York. The CJR model addresses a defined population (FFS Medicare beneficiaries undergoing LEJR procedures) for which there are potentially avoidable expenditures (arising from less than optimal care coordination). We believe the DSRIP waiver in New York, which is a waiver provided under the Medicaid program, does not directly impact Medicare FFS payments or a hospital's ability to be in the CJR model at this time. If healthcare transformation initiatives led by States raise concerns about a participant hospital's ability to be in the model, we would address the issue in future rulemaking as necessary. Additionally, we do not believe it would be appropriate to carve out additional protections for other types of hospitals at this time because we want to evaluate, in part, the model's generalizability, which becomes challenging if we add more exceptions. We will continue to monitor the effects

of this model on different categories of hospitals.

Comment: We received a comment regarding our proposal to provide MDHs with the more limited stop-loss until the MDH payment status expires under statute in 2017. The commenter requested that we continue to provide the more limited-stop loss for hospitals currently classified as MDHs in the final rule, if MDH status expires. The commenter stated that while the higher payments afforded to MDHs are set to expire in 2017, the concerns on their ability to bear risk and infrastructure capacity issues will remain.

Response: We had proposed that hospitals that maintain SCH, MDH or RRC status during the performance year would be subject to the protective stop-loss limit. We understand the concern that with the expiration of MDH status under legislation in September 30, 2017, hospitals will lose their MDH designation and additional Medicare FFS payments provided under the MDH designation. Additionally, under the expiration of MDH status, hospitals would no longer qualify for the protective stop-loss limit tied to that status under this model. Should the MDH payment status expire, some MDHs may apply with their MACs to determine if they qualify as an RRC or SCH and would be able to maintain the protective stop-loss limit in this model. However, we believe it would be inconsistent to apply the additional benefit of protective stop-loss limits to former MDHs when by law, those hospitals are not permitted to retain the other Medicare payment benefits provided to MDHs. Additionally we proposed and are finalizing to identify MDHs at the time of reconciliation in the Provider Specific File updated in December of the end of the performance year and information from the MACs and the MDHs identified in that file would be subject to the protective stop-limits. Should the MDH payment status expire, the Provider Specific File would no longer be updated by MACs to identify hospitals that would have met the expired MDH criteria as it would no longer be a Medicare payment policy. As a result, it would be operationally challenging to appropriately identify the hospitals that would have met the criteria to receive MDH status and to apply protective stop-loss to those hospitals. In general, we recognize that hospitals may change their status on an annual basis during the course of this model based on whether or not a hospital can continue to meet the criteria for the special payment designation, and should a hospital no longer meet the rural, SCH, MDH or RRC designation, it would no longer receive the protective stop-loss limit.

Comment: Some comments requested that urban hospitals that reclassify to rural hospitals should be considered rural and be subject to the more protective stop-loss limits. The commenters stated that we generally consider hospitals that undergo urban-to-rural reclassification pursuant to § 412.103 as rural for all Medicare payment purposes and we should consistently treat them as rural under this model and provide this category of hospitals with the more protective stop-loss limit.

Response: We agree with the commenters that urban hospitals that reclassify to rural under § 412.103 should be considered a rural hospital for the purposes of this model and receive the more limited stop-loss. We note that we proposed to define rural hospitals as an IPPS hospital that is either located in a rural area in accordance with § 412.64(b) or in a rural census tract within an MSA defined at § 412.103(a)(1) or has reclassified to rural in accordance with § 412.103 and to provide a more limited stop-loss for such rural hospitals. However, we note that rural hospitals were inadvertently excluded from the proposed regulation language at § 510.305(e)(1)(v)(E) defining which categories of hospitals would be subject to a lower stop-loss limit. Thus, we are finalizing our proposal to provide a more protective stop-loss limit to rural hospitals as previously defined, as well as MDHs, SCHs and RRC, and will revise the regulatory language at § 510.305(e)(1)(v)(E) to reflect our final policy.

Comment: Some commenters were concerned that hospitals with low volume of LEJR episodes have a lower risk tolerance, similar to rural hospitals, SCHs, MDHs and RRCs, may be subject to greater volatility in episode payments and would not have adequate volume to spread the risk of high cost episodes. A commenter's analysis showed that volume is an important determinant of per-episode spending where the average loss was higher for hospitals with fewer episodes. Commenters raised concerns that hospitals with fewer episodes per year may have fewer resources in terms of capital to invest in data infrastructure or care redesign. Commenters suggested that we exclude low volume hospitals from the model, remove downside risk for low volume hospitals or provide a lower stop-loss limit for these hospitals. Commenters provided varying definitions for what qualifies as a low volume hospital ranging from 35 LEJR episodes per year to 100 LEJR episodes per year.

Response: We believe that we can address these concerns for low volume hospitals by the other design changes that we are finalizing in this final rule to mitigate risk as participant hospitals implement the necessary changes to improve efficiencies for LEJR episodes and quality of care. These changes made in this final rule would alleviate concerns for low volume hospitals such that special policies for low volume hospitals are not necessary. First, we believe that the policy finalized in this rule in response to public comments to allow for a more gradual transition to the stop-loss limit of 20 percent beginning in Performance Year 4 will alleviate the concerns of hospitals bearing financial risk in a mandatory model. Participant hospitals, including low volume hospitals, will have additional time to make changes in response to the model and gradually take on more upside and downside risk. Second, we believe that our policy, finalized in this rule, to risk stratify MS–DRG 469 and MS–DRG 470 for hip fractures will reduce the variability in the episode costs. We acknowledge that hip fractures can increase the 90 day episode spend so by risk stratifying for hip fracture, we are creating an episode target price for MS–DRG 469 and MS–DRG 470 with and without hip fractures. For a hospital with a lower volume of cases, the risk stratification for hip fractures will mitigate variability in episode costs if a hospital that has fewer episodes treats higher proportion of hip fracture cases. We disagree with commenters that we should exclude low volume hospitals from the model because we are interested in evaluating the experience of small providers and the inclusion of these hospitals in the model is part of our overall desire to see the impact of a bundled payment model in providers who would not otherwise participate in a voluntary program. We would be concerned that setting a threshold for low volume could result in hospital gaming in order to be below that threshold and be excluded from the model.

We are finalizing our proposal to provide for a lower stop-loss limit for rural hospitals, RRCs, MDHs and SCHs and codifying this policy at § 510.305(e)(1)(v)(E). Additionally, we are finalizing to provide a stop-gain limit that correspond to the finalized stop-loss limits for other hospitals in the model such that the stop-gain limit is 5 percent in Performance Years 1 and 2, 10 percent in Performance Year 3 and 20 percent in Performance Years 4 and 5 that would apply to all hospitals in

the model including rural hospitals, MDHs, SCHs and RRCs. We are codifying the establishment of stop-gain limits in this model at § 510.305(e)(1)(v)(D).

d. Hospital Responsibility for Increased Post-Episode Payments

We noted that while the proposed CJR episode would extend 90-days post-discharge from the anchor hospitalization, some hospitals may have an incentive to withhold or delay medically necessary care until after an episode ends to reduce their actual episode payments. We did not believe this would be likely, especially given the relatively long episode duration. However, in order to identify and address such inappropriate shifting of care, we proposed to calculate for each performance year the total Medicare Parts A and B expenditures in the 30-day period following completion of each episode for all services covered under Medicare Parts A and B, regardless of whether the services are included in the proposed episode definition (section III.B. of the proposed rule), as is consistent with BPCI Model 2. Because we base the proposed episode definition on exclusions, identified by MS–DRGs for readmissions and ICD–9–CM diagnosis codes for Part B services as discussed in section III.B. of the proposed rule, and Medicare beneficiaries may typically receive a wide variety of related (and unrelated) services during the CJR episode that extends 90 days following discharge from the anchor hospitalization, there is some potential for hospitals to inappropriately withhold or delay a variety of types of services until the episode concludes, without attending carefully to the episode definition, especially for Part B services where diagnosis coding on claims may be less reliable. This inappropriate shifting could include both those services that are related to the episode (for which the hospital would bear financial responsibility as they would be included in the actual episode spending calculation) and those that are unrelated (which would not be included in the actual episode spending calculation), because a hospital engaged in shifting of medically necessary services outside the episode for potential financial reward may be unlikely to clearly distinguish whether the services were related to the episode or not in the hospital's decisions.

This calculation would include prorated payments for services that extend beyond the episode as discussed in section III.C.3.b. of the proposed rule. Specifically, we would identify whether the average 30-day post-episode spending for a participant hospital in any given performance year is greater than three standard deviations above the regional average 30-day post-episode spending, based on the 30-day post-episode spending for episodes attributed to all CJR regional hospitals in the same region as the participant hospital. We proposed that beginning in performance year 2, if the hospital's average post-episode spending exceeds this threshold, the participant hospital would repay Medicare for the amount that exceeds such threshold, subject to the stop-loss limits proposed elsewhere in the proposed rule. We sought comment on this proposal to make participant hospitals responsible for making repayments to Medicare based on high spending in the 30 days after the end of the episode and for our proposed methodology to calculate the threshold for high post-episode spend.

The following is a summary of the comments received and our responses.

Comment: Some commenters opposed the proposal entirely, finding that it represented excessive monitoring of LEJR episodes. Other commenters supported monitoring 30 day post-episode spending, but requested certain modifications to the proposal. Other commenters supported our rationale to monitor a hospital's 30 day post-episode spending to identify potential inappropriate shifting of care, but they opposed our proposal to require participant hospitals to repay Medicare for the amount of post-episode spend that exceeds the threshold. Commenters also requested that the categories of services excluded from the episode definition should also be excluded when determining the 30 day post-episode spending because they found it to be inappropriate to hold a hospital responsible for unrelated services, particularly those related to high-cost conditions like the onset of therapy for cancer or the sudden inclusion of clotting factors for hemophilia. Lastly, we received comments in support of our proposal, agreeing that this approach could help identify participant hospitals that withhold or delay medically necessary care until after an episode ends in order to reduce their actual episode spending. A commenter suggested that rather than requiring a participant hospital to repay Medicare up to the stop-loss limit if they are found to have excessive 30 day post-episode spending, we implement an additional financial penalty for participant hospitals that are found to inappropriately delay care. The commenter suggested that the penalty should not be capped at the proposed stop-loss limit arguing that a hospital that has already substantially exceeded target prices and had to repay CMS under the stop-loss limit will have little incentive to refrain from stinting on care unless a separate penalty exists.

Response: We continue to believe that monitoring for 30 day post-episode spending is an appropriate tool to identify inappropriate shifts in care based on our experience with BPCI. We disagree with commenters that we should exclude the same set of services that are excluded from the episode definition in the 30 day post-episode spend because of concern that this model could lead to shifting of both related and unrelated (those not included in the episode definition) services due to some providers encouraging delays of services for beneficiaries that are not immediately necessary, without discriminating between those services that are in and out of the episode definition. Additionally, our experience with BPCI that similarly includes all costs when monitoring for 30 day post-episode spending has helped to inform our policy for the CJR model. Based on our experience with BPCI, we have not found that by including all costs to measure 30 day post-episode spending, that we are inappropriately penalizing hospitals. While we understand commenters' concerns that hospitals could be held responsible for high costs conditions that are not included in the episode definition, our policy aims to strike a balance to hold participating hospitals accountable for inappropriate shifts or delays in care and to provide hospitals with safeguards on financial risk for 30 day post-episode spend. To that end, we are setting a high threshold where only hospitals that have a 30 day post-episode spending average that is three standard deviations above the regional average would be subject to repay that difference to Medicare, and in the case where the hospital's average 30 day post-episode spending exceeds regional average 30 day post-episode spending, the participant hospital would repay Medicare for the amount that exceeds such threshold, subject to the stop loss limits. Additionally, we disagree with the commenter that the penalty for high post-episode spending should not be capped at the proposed stop-loss limit because we still want to provide safeguards for high cost spending for participant hospitals. We note that, as described earlier, we are finalizing to reduce the stop-loss limits for Performance Year 2 and 3 to provide participating hospitals a more gradual transition to assume downside risk

under this model so that repayment under the 30 day post-episode spending policy will be even more limited. We note that participant hospitals that are eligible for reconciliation payments in a performance year that also have an average 30 day post-episode spend that is higher than three standard deviations from the regional average 30 day post-episode spend would have their reconciliation payments reduced by the amount by which spending exceeds three standard deviations.

Final Decision: After consideration of the public comments we received, we are finalizing the proposal as proposed and codifying this policy at § 510.305(e)(1)(v)(A). We note that the term ''CJR eligible hospitals'' is being renamed to ''CJR regional hospitals'' as discussed in response to comments in section III.C.4.b.(4) of this final rule. CJR regional hospitals are all IPPS hospitals located in a region, including IPPS hospitals that are participants in BPCI Model 1 or in the risk bearing period of Models 2 or 4 for LEJR episodes. Accordingly, 30-day post-episode spending for episodes attributed to all IPPS hospitals including BPCI hospitals in the same region as the participant hospital would be included to determine the value that is three standard deviations greater than the regional average 30 day post-episode spend and to determine if a participant hospital has excessive average 30 day post-episode spending.

9. Appeal Procedures

Under the CJR model, we proposed that we would determine target prices for episodes of care using the methodology described in section III.C. of the proposed rule. We proposed to institute a reconciliation payment process as described in section III.C.6. of the proposed rule, and we proposed to retrospectively calculate a participant hospital's actual episode performance relative to its target price after the completion of each performance year. The difference between the actual episode spending of each CJR episode and the target price of that episode (calculated as target price subtracted by CJR actual episode payment) would be aggregated for all episodes initiated at a participant hospital during each performance year. This calculation for a participant hospital would be adjusted for post-episode payment increases and stop gain and stop loss limits, as described in section III.C.6.a. of the proposed rule. We proposed to use quality measure percentiles to determine hospital eligibility to receive the reconciliation payment and use the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment, as described in section III.C.5. of the proposed rule. The NPRA would be reflected in a report sent to the participant hospital called the CJR Reconciliation Report.

We also proposed to institute appeals processes for the CJR model that would allow participant hospitals to appeal matters related to reconciliation and payment (that are previously discussed in this section), as well as non-payment related issues, such as enforcement matters detailed in section III.C.12. of this final rule.

a. Payment Processes

The proposed processes with regard to reconciliation, payment, use of quality measures to determine payment, and stop-loss and stop-gain policies are set forth in detail in sections III.C.5. through 8. of this final rule. In this section, we proposed an appeals process that will apply to the matters addressed in sections III.C.5 through 8. of this final rule, as well as matters not related to payment or reconciliation. These appeals processes will apply to the following payment and reconciliation processes:

- Starting with the CJR Reconciliation Report for performance year 1, if the CJR Reconciliation Report indicates the reconciliation amount is positive, CMS would issue a payment, in a form and manner specified by CMS, for that amount to the awardee within 30 calendar days from the issue date of the CJR Reconciliation Report, unless the participant hospital selects to pursue the calculation error and reconsideration review processes, in which case payment will be delayed as detailed later in this section.
- For performance year 1, if the CJR reconciliation report indicates a repayment amount, the participant hospital would not be required to make payment for that amount to CMS, as we have finalized our proposal not to hold hospitals financially responsible for negative NPRAs for the first performance year. In addition, if it is determined that a CJR hospital has a positive NPRA for performance year 1, and the subsequent calculation for performance year 1 the following year, as described in section III.C.6. of the proposed rule, determines that in aggregate the performance year 1 NPRA and the subsequent calculation amount for performance year 1 is a negative value (adding together the NPRA amount from the reconciliation for performance year 1 as well as the amount determined in the subsequent calculation, which would be detailed on the CJR reconciliation report for performance year 2), the hospital would only be financially responsible for a repayment amount that would net the performance year 1 NPRA and subsequent calculation for performance year 1 to zero. This would be true for performance year 1 only, given our proposal to begin phasing in financial responsibility in year 2 of the model as discussed in section III.C.2.c. of the proposed rule. For performance years 2 through 5 of the model, for example, if there was a positive NPRA for performance year 1 for a given hospital of $3,000, and the subsequent calculation performed in Q2 2018 to account for claims run-out and overlaps determined a repayment amount of $3,500 for claims incurred and overlap during performance year 1, $3,000 would be applied to the CJR reconciliation report for performance year 2. If the positive NPRA for performance year 2 were $5,000, the repayment amount of $3,000 would be netted against the $5,000, and the reconciliation payment for performance year 2 would be $2,000. Given that downside risk has been waived for performance year 1, the remaining $500 would not be added to the CJR reconciliation report for performance year 2. However, beginning with the reconciliation process for performance year 3, any repayment amounts generated through the subsequent calculation process detailed in section III.C.6.b. of this final rule would be netted against any repayment or reconciliation amount on the respective CJR reconciliation reports for performance years 2, 3, 4, and 5. Starting with the reconciliation for performance year 2, if the CJR Reconciliation Report indicates the NPRA is negative, the participant hospital would make payment for the absolute value of that amount to CMS within 30-calendar days from the issue date of the CJR Reconciliation Report, in a form and manner specified by CMS. For example, if there was a positive NPRA for performance year 3 for a given hospital of $1,000, and the subsequent calculation performed in Q2 2019 to account for claims run-out and overlaps determined a repayment amount of $2,500 for claims incurred and overlap during performance year 3, the full $2,500 would be applied to the CJR reconciliation report for performance year 4, subject to the stop loss/stop gain limits detailed in section III.C.8. of this final rule. Thus, if the positive NPRA for performance year 4 were $2,000, the repayment amount of $2,500 would be netted against the $2,000, and a repayment amount for performance year

4 would be $500. Where the participant hospital does not issue payment within 30-calendar days, we will issue a demand letter requiring payment be made immediately.

• The reconciliation or repayment amount may include adjustments, arising from matters from the previous performance year, as necessary to account for subsequent calculations performed for performance years that were specified in earlier CJR Reconciliation Reports, as discussed in section III.C.6. of the proposed rule. For example, we would potentially make determinations of additional monies owed by Medicare to participant hospitals or vice versa in subsequent periods based on the availability of updated Medicare administrative data. These subsequent calculations would be contained in the succeeding reconciliation report. For example, the subsequent calculations applicable to performance year 1 would be contained in the reconciliation report for performance year 2.

• If the participant hospital fails to pay CMS the amount owed by the date indicated in the demand letter, CMS will recoup owed monies from participant hospital's present and future Medicare payments to collect all monies due to CMS. While we proposed that a participant hospital may enter into financial arrangements with CJR collaborators that allow for some risk-sharing, as discussed in section III.C. of the proposed rule, the participant hospital would be solely liable for the repayment of the negative repayment amount to CMS. Where the participant hospital fails to repay CMS in full for all monies owed, CMS would invoke all legal means to collect the debt, including referral of the remaining debt to the United States Department of the Treasury, pursuant to 31 U.S.C. 3711(g).

b. Calculation Error

We proposed the following calculation error process for participant hospitals to contest matters related to payment or reconciliation, of which the following is a non-exhaustive list: The calculation of the participant hospital's reconciliation amount or repayment amount as reflected on a CJR reconciliation report; the calculation of NPRA; the calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment; and the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment. Participant hospitals would review their CJR reconciliation report and be required to provide written notice of any error, in a notice of calculation error that must be submitted in a form and manner specified by CMS. Unless the participant provides such notice, the reconciliation report would be deemed final within 30 calendar days after it is issued, and CMS would proceed with payment or repayment. If CMS receives a timely notice of an error in the calculation, CMS would respond in writing within 30 calendar days to either confirm or refute the calculation error, although CMS would reserve the right to an extension upon written notice to the participant hospital. We proposed that if a participant hospital does not submit timely notice of calculation error in accordance with the timelines and processes specified by CMS, the participant hospital would be precluded from later contesting any of the following matters contained in the CJR reconciliation report for that performance year: Any matter involving the calculation of the participant hospital's reconciliation amount or repayment amount as reflected on a CJR reconciliation report; any matter involving the calculation of NPRA; the calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment; and the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment.

c. Dispute Resolution

(1) Limitations on Review

In accordance with section 1115A(d) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

• The selection of models for testing or expansion under section 1115A of the Act.

• The selection of organizations, sites or participants to test those models selected.

• The elements, parameters, scope, and duration of such models for testing or dissemination.

• Determinations regarding budget neutrality under subsection 1115A(b)(3) of the Act.

• The termination or modification of the design and implementation of a model under subsection 1115A(b)(3)(B) of the Act.

• Decisions about expansion of the duration and scope of a model under subsection 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection.

(2) Matters Subject To Dispute Resolution

We proposed that a participant hospital may appeal an initial determination that is not precluded from administrative or judicial review by requesting reconsideration review by a CMS official. The request for review must be submitted for receipt by CMS within 10 days of the notice of the initial determination, in a form and manner specified by CMS.

(3) Dispute Resolution Process

We proposed the following dispute resolution process. First, we proposed that only a participant hospital may utilize the dispute resolution process. Second, in order to access the dispute resolution process a participant hospital must have timely submitted a notice of calculation error, as previously discussed, for any matters related to payment. We proposed these matters would include any amount or calculation indicated on a CJR reconciliation report, including calculations not specifically reflected on a CJR reconciliation report but which generated figures or amounts reflected on a CJR reconciliation report. The following is a non-exhaustive list of the matters we proposed would need to be first adjudicated by the calculation error process as previously detailed: Calculations of reconciliation or repayment amounts; calculations of NPRA; and any calculations or percentile distribution involving quality measures that we proposed could affect reconciliation or repayment amounts. If a participant hospital wants to engage in the dispute resolution process with regard to one of these matters, we proposed it would first need to submit a notice of calculation error. Where the participant hospital does not timely submit a notice of calculation error, we proposed the dispute resolution process would not be available to the participant hospital with regard to those matters for the reconciliation report for that performance year.

If the participant hospital did timely submit a notice of calculation error and the participant hospital is dissatisfied with CMS's response to the participant hospital's notice of calculation error, the hospital would be permitted to request reconsideration review by a CMS reconsideration official. The reconsideration review request would be submitted in a form and manner and to an individual or office specified by CMS. The reconsideration review request would provide a detailed explanation of the basis for the dispute and include supporting documentation

for the participant hospital's assertion that CMS or its representatives did not accurately calculate the NPRA or post-episode spending amount in accordance with CJR rules. The following is a non-exhaustive list of representative payment matters:

- Calculations of NPRA, post-episode spending amount, target prices or any items listed on a reconciliation report.
- The application of quality measures to a reconciliation payment, including the calculation of the percentiles thresholds of quality measure performance to determine eligibility to receive reconciliation payments, or the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment.
- Any contestation based on the grounds that CMS or its representative made an error in calculating or recording such amounts.

Where the matter is unrelated to payment, such as termination from the model, the participant hospital need not submit a notice of calculation error. We proposed to require the participant hospital to timely submit a request for reconsideration review, in a form and manner to be determined by CMS. Where such request is timely received, we proposed CMS would process the request as discussed later in this section.

We proposed that the reconsideration review would be an on-the-record review (a review of briefs and evidence only). The CMS reconsideration official would make reasonable efforts to notify the hospital in writing within 15 calendar days of receiving the participant hospital's reconsideration review request of the date and time of the review, the issues in dispute, the review procedures, and the procedures (including format and deadlines) for submission of evidence (the ''Scheduling Notice''). The CMS reconsideration official would make reasonable efforts to schedule the review to occur no later than 30 calendar days after the date of the Scheduling Notice. The provisions at § 425.804(b), (c), and (e) will apply to reviews conducted pursuant to the reconsideration review process for CJR. The CMS reconsideration official would make reasonable efforts to issue a written determination within 30 days of the review. The determination would be final and binding.

We solicited comment on our proposals related to appeals rights under this model. The two-step appeal process for payment matters—(1) Notice of calculation error, and (2) reconsideration review—is used broadly in other CMS models. We sought comment on whether we should develop an alternative appeal process. We are also interested in whether there should be appeal rights for reductions or eliminations of NPRA as a result of enforcement actions, as discussed in section III.C.12. of the proposed rule, and if so, whether the process for such appeals should differ from the processes proposed here.

The following is a summary of the comments received and our responses.

Comment: The comments we received on the calculation error process varied widely. Multiple commenters were supportive of the process, including commenters that have experience in BPCI, in which an identical calculation error process is used. A majority of the comments recommended that CMS extend the timeframe for appeals under the calculation error process. Commenters indicated that they appreciated CMS providing details of an appeal procedure, but many suggested that the 30-day timeframe for submission of a notice of calculation error is too short. Some commenters offered proposals for longer periods; specifically, we received separate comments indicating that 45 days, 60 days, or 180 days would be acceptable timeframes. With regard to the proposal to allow for 180 days, multiple commenters noted that this timeframe is similar to the timeframe afforded hospitals to appeal adjustments in the Medicare Cost Report. Multiple commenters also noted that a longer timeframe for notices of calculation error may benefit participant hospitals in providing additional time to identify and understand calculation errors.

Response: We appreciate these comments and are sympathetic to the requests from commenters for more time to review reconciliation reports and submit notices of calculation error. We agree with commenters that providing additional time may benefit some participant hospitals in identifying and understanding calculation errors. We are committed to paying participant hospitals accurately and correctly and believe that the calculation error process serves an important function in achieving that goal.

CMS uses the following processes for appeals that we are finalizing in section III.C.9. of this final rule. The procedures for processing and issuing reconciliation payments and repayments require that we submit the payment files for participant hospitals to the payment systems in batches. CMS uses these processes for several reasons. It is administratively more efficient to continue to use MACs to issue payments to all providers and suppliers that furnish services to beneficiaries during a CJR episode, so as not to disrupt the timing of FFS payments that providers and suppliers normally receive. For reconciliation payments and repayments, CMS has developed a process for processing these payments, which is used for other CMS models. This current process is the result of a substantial number of infrastructure changes to payment and recoupment procedures that were made over a period of several years. As a result, we believe it is appropriate to utilize those processes for the CJR model, given that the challenges associated with establishing these processes, as well as the fact that they were created for other CMS models.

The effect of these processes is that the batches are sent at specified intervals. The first batch is sent after the calculation error timeframe closes. The second batch is sent after CMS has responded to the notices of calculation error of participant hospitals and those hospitals choose to not proceed with the dispute resolution process detailed in section III.C.9.b.(3) of this final rule. The final batch is sent after CMS has adjudicated all of the reconsideration reviews for those participant hospitals that selected to utilize the dispute resolution process.

Given these processes, any extension in the timeframe allowed for submission of notices of calculation error delays payment not only to participant hospitals that choose to utilize the calculation error and dispute resolution processes, but even those participant hospitals that choose not to engage in these processes. As such, we believe the need for extending the deadline for submission of notices of calculation error should be balanced with CMS' goal to issue reconciliation payments and repayments promptly, as an extension for these submissions would delay the processing of reconciliation payments for all participant hospitals for a significant period of time. However, we acknowledge the commenters' concerns and the need for participant hospitals to have adequate time to analyze and prepare notices of calculation error.

Therefore, we believe that a longer timeframe for submission of the calculation error form is appropriate for the CJR model, given that CMS is reconciling on an annual basis, as opposed to quarterly for the BPCI initiative. Given that participant hospitals in CJR are likely have a larger subset of data to review on their annual reconciliation reports than their BPCI counterparts who receive quarterly reconciliation reports, we believe it is

prudent for CMS to allow additional time for participant hospitals to review their reconciliation reports for calculation errors. We agree with the commenters who suggested that 45 days would allow sufficient time for participant hospitals to review reconciliation reports, and if they choose, submit notices of calculation error. We believe that 45 days is the appropriate timeframe to allow for this process, as it responds to the requests for more time than our proposal of 30 days, but does not seriously delay payment of reconciliation payments, in the way in which a submission timeframe of 180 days would do. We considered the recommendations for 60 days, but we rejected these recommendations because we note that the calculation error form represents the first step in a two-step appeals process. Where a participant hospital submits a calculation form and is dissatisfied with CMS' response, the dispute resolution option is available to the participant hospital via a reconsideration review request. Upon receipt of a reconsideration review request, the date of such a review would be scheduled by CMS approximately 130 days from the issue date of the reconciliation report. Thus, we believe that the option for reconsideration review, at a much later date, provides participant hospitals with adequate additional time to analyze the date on reconciliation reports, that a 60-day submission deadline for the calculation error form is unnecessary. Finally, we believe that extending this period to 45 days appropriately balances the goal of CMS to process reconciliation payments on a timely basis with the needs of participant hospitals to have adequate time to review their reconciliation reports and submit notices of calculation error.

Final Decision: After consideration of the public comments we received, we are finalizing the proposal with one modification to allow participant hospitals 45 days to submit a calculation error form. We are finalizing our proposal to process and issue reconciliation payments and collect repayments as described in section III.C.6. of this final rule, and to allow for an optional appeals process, as previously described in this section, in which participant hospitals may submit a calculation error form, as well as have an opportunity to engage in dispute resolution.

With regard to the calculation error process, we are finalizing our proposal with one modification. Participant hospitals may submit a calculation error form to contest matters related to payment or reconciliation, of which the following is a non-exhaustive list: The calculation of the participant hospital's reconciliation amount or repayment amount as reflected on a CJR reconciliation report; the calculation of NPRA; the calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment; and the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment. Upon receipt of its CJR reconciliation report, the participant hospital may choose to submit a calculation error form. The form must be submitted in a form and manner specified by CMS. Unless the participant provides such notice, the reconciliation report will be deemed final within 45 calendar days after it is issued, and CMS will proceed with payment or repayment. If CMS receives a timely notice of an error in the calculation, CMS will respond in writing within 30 calendar days to either confirm or refute the calculation error, although CMS reserves the right to an extension upon written notice to the participant hospital. If a participant hospital does not submit timely notice of calculation error in accordance with the timelines and processes specified by CMS, the participant hospital is precluded from later contesting any of the following matters contained in the CJR reconciliation report for that performance year: any matter involving the calculation of the participant hospital's reconciliation amount or repayment amount as reflected on a CJR reconciliation report; any matter involving the calculation of NPRA; the calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment; and the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment.

With regard to the dispute resolution process, we are finalizing our proposal without modification. In accordance with section 1115A(d) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

- The selection of models for testing or expansion under section 1115A of the Act.
- The selection of organizations, sites or participants to test those models selected.
- The elements, parameters, scope, and duration of such models for testing or dissemination.
- Determinations regarding budget neutrality under subsection 1115A(b)(3) of the Act.
- The termination or modification of the design and implementation of a model under subsection 1115A(b)(3)(B of the Act.
- Decisions about expansion of the duration and scope of a model under subsection 1115A(c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection.

We are also finalizing our proposal without modification regarding the matters subject to dispute resolution, and the process CMS will use to adjudicate dispute resolution matters. Thus, a participant hospital may appeal an initial determination that is not precluded from administrative or judicial review by requesting reconsideration review by a CMS official. The request for review must be submitted for receipt by CMS within 10 days of the notice of the initial determination, in a form and manner specified by CMS. Only a participant hospital may utilize the dispute resolution process.

In order to access the dispute resolution process, a participant hospital must timely submit a calculation error form, as previously discussed, for any matters related to payment. These matters include any amount or calculation indicated on a CJR reconciliation report, including calculations not specifically reflected on a CJR reconciliation report but which generated figures or amounts reflected on a CJR reconciliation report. The following is a non-exhaustive list of the matters that we are requiring must be first adjudicated by the calculation error process as previously detailed: Calculations of reconciliation or repayment amounts; calculations of NPRA; and any calculations or percentile distribution involving quality measures that we proposed could affect reconciliation or repayment amounts. If a participant hospital wants to engage in the dispute resolution process with regard to one of these matters, the participant hospital must first submit a calculation error form. Where the participant hospital does not timely submit a calculation error form, the dispute resolution process is not available to the participant hospital with regard to those matters for the reconciliation report for that performance year.

If the participant hospital does timely submit a calculation error form and the participant hospital is dissatisfied with CMS's response to the participant hospital's calculation error form, the hospital is permitted to request reconsideration review by a CMS reconsideration official. The reconsideration review request must be submitted in a form and manner and to

an individual or office specified by CMS. The reconsideration review request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the participant hospital's assertion that CMS or its representatives did not accurately calculate the NPRA or post-episode spending amount in accordance with CJR rules. The following is a non-exhaustive list of representative payment matters:

- Calculations of NPRA, post-episode spending amount, target prices or any items listed on a reconciliation report.
- The application of quality measures to a reconciliation payment, including the calculation of the percentiles thresholds of quality measure performance to determine eligibility to receive reconciliation payments, or the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment.
- Any contestation based on the grounds that CMS or its representative made an error in calculating or recording such amounts.

Lastly, we are finalizing our proposal without modification that the reconsideration review is an on-the-record review (a review of briefs and evidence only). The CMS reconsideration official will make reasonable efforts to notify the hospital in writing within 15 calendar days of receiving the participant hospital's reconsideration review request of the date and time of the review, the issues in dispute, the review procedures, and the procedures (including format and deadlines) for submission of evidence (the ''Scheduling Notice''). The CMS reconsideration official will make reasonable efforts to schedule the review to occur no later than 30 calendar days after the date of the Scheduling Notice. The provisions at § 425.804(b), (c), and (e) will apply to reviews conducted pursuant to the reconsideration review process for CJR. The CMS reconsideration official will make reasonable efforts to issue a written determination within 30 days of the review. The determination will be final and binding.

This modification is set forth in § 510.310(a)(1). The remainder of the proposal is finalized as proposed and set forth in § 510.310.

10. Financial Arrangements and Beneficiary Incentives

a. Financial Arrangements

As previously noted, in the proposed rule we stated our belief that given the financial incentives of episode payment in CJR, participant hospitals in the model might want to engage in financial arrangements to share reconciliation payments or hospital internal cost savings or both, as well as responsibility for repaying Medicare, with providers and suppliers making contributions to the hospital's episode performance on spending and quality. Such arrangements would allow the participant hospitals to share all or some of the reconciliation payments they may be eligible to receive from CMS, or the participant hospital's internal cost savings that result from care for beneficiaries during a CJR episode. Likewise, such arrangements could allow the participant hospitals to share the responsibility for the funds needed to repay Medicare with providers and suppliers engaged in caring for CJR beneficiaries, if those providers and suppliers have a role in the hospital's episode spending or quality performance. We use the term ''CJR collaborator'' to refer to such providers and suppliers, who we proposed may include the following:

- SNFs.
- HHAs.
- LTCHs.
- IRFs.
- PGPs.
- Physicians, nonphysician practitioners, and providers or suppliers of therapy services.

We stated our belief that CJR collaborators should have a role in the participant hospital's episode spending or quality performance. Accordingly, we proposed that the CJR collaborator would directly furnish related items or services to a CJR beneficiary during the episode and/or specifically participate in CJR model LEJR episode care redesign activities, such as attending CJR meetings and learning activities; drafting LEJR episode care pathways; reviewing CJR beneficiaries' clinical courses; developing episode analytics; or preparing reports of episode performance under the direction of the participant hospital or a CJR collaborator that directly furnishes related items and services to CJR beneficiaries. We also stated that in addition to playing a role in the participant hospital's episode spending or quality performance, physician, nonphysician, and PGP CJR collaborators must directly furnish services to CJR beneficiaries in order to receive a gainsharing payment as result of their financial arrangement with the participant hospital. We sought comment on our proposed definition of CJR collaborators, as well as our proposed definition of a provider's or supplier's role in the participant hospital's episode spending or quality performance.

We proposed that certain financial arrangements between a participant hospital and a CJR collaborator be termed a ''CJR sharing arrangement,'' and that the terms of each CJR sharing arrangement be set forth in a written agreement between the participant hospital and the CJR collaborator. We proposed to use the term ''Participation Agreement'' to refer to such agreements. We proposed that a ''CJR sharing arrangement'' would be a financial arrangement contained in a Participation Agreement to share only the following: (1) CJR reconciliation payments (as that term is defined in section III.C. of the proposed rule); (2) the participant hospital's internal cost savings (as that term is defined later in this section); and (3) the participant hospital's responsibility for repayment to Medicare, as discussed later in this section. Where a payment from a participant hospital to a CJR collaborator is made pursuant to a CJR sharing arrangement, we proposed to define that payment as a ''gainsharing payment.'' A gainsharing payment may only be only composed of the following: (1) Reconciliation payments; (2) internal cost savings; or (3) both. Where a payment from a CJR collaborator to a participant hospital is made pursuant to a CJR sharing arrangement, we proposed to define that payment as an ''alignment payment.'' We proposed that CJR sharing arrangements that provide for alignment payments would not relieve the participant hospital of its ultimate responsibility for repayment to CMS. Many of the programmatic requirements discussed later in this final rule for gainsharing payments and alignment payments are similar to those in Model 2 of the BPCI initiative.

CJR sharing arrangements must be solely related to the contributions of the CJR collaborators to care redesign that achieve quality and efficiency improvements under this model for CJR beneficiaries. All gainsharing payments or alignment payments between participant hospitals and CJR collaborators resulting from these arrangements must be auditable by HHS, as discussed later in this section, to ensure their financial and programmatic integrity. We emphasized that any CJR collaborator that receives a gainsharing payment or makes an alignment payment must have furnished services included in the episode to CJR beneficiaries. Furthermore, the payment arrangements for gainsharing payments or alignment payments contained in a CJR sharing arrangement must be actually and proportionally related to

the care of beneficiaries in a CJR episode, and the CJR collaborator must be contributing to the care redesign strategies of the participant hospital.

We considered whether CJR collaborators should be termed ''participants'' in this model, or whether the term ''participant'' should refer only to the participant hospitals located in MSAs selected for participation. If CJR collaborators are participants in the model, we proposed that their activities with regard to CJR beneficiaries would be regulated directly by CMS. However, if CJR collaborators are not participants, but rather are participating entities and individuals in the CJR model through signed agreements with participant hospitals, their activities with regard to CJR beneficiaries would be governed by the Participation Agreement between a CJR collaborator and a participant hospital. Given the large number of potential CJR collaborators, the expected varied nature of their respective arrangements with participant hospitals, and the potential administrative burden in reporting information to CMS, we believed the activities of CJR collaborators with regard to CJR beneficiaries would be best managed by participant hospitals. As we discussed earlier in this final rule, one justification for proposing that acute care hospitals be the provider type financially responsible under the CJR model is the position of the hospital with respect to other providers and suppliers, in terms of coordinating care for CJR beneficiaries. Given that position, we proposed that where participant hospitals enter into Participation Agreements that contain CJR sharing arrangements, the participant hospital must also be responsible for ensuring that those providers and suppliers comply with the terms and requirements of the proposed rule. We sought comments on this proposal; specifically, whether CJR collaborators should be termed participants in this model and subject to the applicable requirements, or whether the responsibility for compliance with the model's requirements is better managed by participant hospitals. We were particularly interested in comments that address the advantages and disadvantages of making CJR collaborators participants in the model, and whether there are certain provider or supplier types that CMS should consider including as ''participants'' in the model.

The following discussion outlines our proposed requirements and responsibilities of participant hospitals that engage in such CJR sharing arrangements. In the proposed rule, we stated our belief that these proposed requirements and responsibilities are essential to ensuring that all CJR sharing arrangements are for the sole purpose of aligning the financial incentives of collaborating providers and suppliers with those of the participant hospital toward the CJR model goals of improved LEJR episode care quality and efficiency. We believed that the rationale for and details of these arrangements must be documented and auditable by HHS, with a direct connection to the arrangements and the participant hospital's episode performance. Finally, we believed that the proposed limitations to the arrangements, as described later in this section, are necessary to ensure the integrity of the CJR model by minimizing incentives for problematic behaviors, such as patient steering. We sought comments on all proposed requirements regarding CJR sharing arrangements.

With respect to whether certain entities or individuals should be prevented from participating in the CJR model, either as participant hospitals or CJR collaborators, we considered whether CMS should conduct screening for program integrity purposes. Many CMS models conduct screening during the application process and periodically thereafter. These screenings examine provider and supplier program integrity history, including any history of Medicare program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues. Where a screening reveals that a provider or supplier has a history of program integrity issues or affiliations with individuals or entities that have a history of program integrity issues, we may remove that provider or supplier from the model. We utilize these screening processes for many CMS models, including the BPCI initiative.

For several reasons, in the proposed rule we stated our belief that this type of screening for participant hospitals would be inapplicable to the CJR model. Most importantly, this model seeks to evaluate the performance in the model of hospitals located in a particular MSA. We believed it is important that all hospitals that meet the criteria for participation in the model be included. Further, in section III.F. of the proposed rule we proposed that CMS would evaluate the quality of care and institute beneficiary protections via a monitoring plan that in ways that would go beyond some of the efforts of previous or existing CMS models. We solicited comments on this proposal, including whether screening of participant hospitals or CJR collaborators might be appropriate or useful in aiding HHS' program integrity efforts and identifying untrustworthy parties or parties with program integrity history problems.

(1) CJR Sharing Arrangement Requirements

We proposed that each CJR sharing arrangement must include and set forth in writing at a minimum—

- A specific methodology and accounting formula for calculating and verifying internal cost savings, if the participant hospital elects to share internal cost savings through gainsharing payments with CJR collaborators. We proposed to define internal cost savings as the measurable, actual, and verifiable cost savings realized by the participant hospital resulting from care redesign undertaken by the participant hospital in connection with providing items and services to beneficiaries within specific CJR episodes of care. Internal cost savings would not include savings realized by any individual or entity that is not the participant hospital. Each CJR sharing arrangement must include specific methodologies for accruing and calculating internal cost savings of the participant hospital, where the hospital intends to share internal cost savings through a CJR sharing arrangement. The specific methodologies for accruing and calculating internal cost savings must be transparent, measurable, and verifiable in accordance with Generally Accepted Accounting Principles (GAAP) and Government Auditing Standards (The Yellow Book). The methodology must set out the specific care redesign elements to be undertaken by the participant hospital or the CJR collaborator or both;
- A description of the methodology and accounting formula for calculating the percentage or dollar amount of a reconciliation payment received from CMS that will be paid as a gainsharing payment from the participant hospital to the CJR collaborator;
- A description of the methodology, frequency or dates of distribution, and accounting formula for distributing and verifying any and all gainsharing payments;
- A description of the arrangement between the participant hospital and the CJR collaborator regarding alignment payments, where the hospital and CJR collaborator agree through a CJR sharing arrangement to share risk for repayment amounts due to CMS, as reflected on a CJR reconciliation report. The description of this arrangement must include safeguards to ensure that such alignment payments are made solely for

purposes related to sharing responsibility for funds needed to repay Medicare in the CJR model. This description should also include a methodology, frequency of payment, and accounting formula for payment and receipt of any and all alignment payments;

• A provision requiring the participant hospital to recoup gainsharing payments paid to CJR collaborators if gainsharing payments were based on the submission of false or fraudulent data;

• Plans regarding care redesign, changes in care coordination or delivery that are applied to the participant hospital or CJR collaborators or both, and any description of how success will be measured;

• Management and staffing information, including type of personnel or contactors that will be primarily responsible for carrying out changes to care under the model;

• The participant hospital must maintain records identifying all CJR collaborators, and the participant hospital's process for determining and verifying the eligibility of CJR collaborators to participate in Medicare; and

• All CJR sharing arrangements must require compliance, from both the participant hospital and the CJR collaborator, with the policies regarding beneficiary notification set forth in section III.F. of the final rule.

With respect to these requirements for Participation Agreements and CJR sharing arrangements, we considered whether we should require participant hospitals and CJR collaborators to periodically report this information to CMS for purposes of enforcement of these proposed regulations. However, we are mindful of the administrative burden in reporting this information as well as the challenges associated with creating a universal collection tool that would account for all the various iterations of financial arrangements into which participant hospitals and CJR collaborators may enter. We sought comment on this proposal as well as whether CMS should require participant hospitals and CJR collaborators to periodically report data such as: Gainsharing payments and/or alignment payments distributed and received; name and identifier (NPI, CCN, TIN) of all CJR collaborators; and any other relevant information related to Participation Agreements and CJR sharing arrangements that would assist HHS with enforcement of these regulations.

We solicited comments about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(2) Participation Agreement Requirements

We proposed that the Participation Agreement must obligate the parties to comply, and must obligate the CJR collaborator to require any of its employees, contractors or designees to comply, without limitation, with the following requirements:

• Each individual's or entity's participation in the CJR sharing arrangement is voluntary and without penalty for nonparticipation.

• Any gainsharing payments made pursuant to a CJR sharing arrangement must be made only from the participant hospital to the CJR collaborator with whom the participant hospital has signed a Participation Agreement containing a CJR sharing arrangement. Additionally, we proposed to require the following for all CJR sharing arrangements between a participant hospital and a CJR collaborator that is a PGP:

+ Where a gainsharing payment is made to a CJR collaborator that is a PGP, all monies contained in such a gainsharing payment must be shared only with physician or nonphysician practitioners that furnished a service to a CJR beneficiary during an episode of care in the calendar year from which the Net Payment Reconciliation Amount (NPRA), as that term is defined in section III.C.6. of this final rule, or internal cost savings was generated, either or both of which are the only permitted sources of funds for a gainsharing payment. We further proposed that each CJR sharing arrangement between a participant hospital and a CJR collaborator that is a PGP must stipulate that the PGP may not retain any portion of a gainsharing payment or distribute, by any method, any portion of a gainsharing payment to physician or nonphysician practitioners who did not furnish a service to a CJR beneficiary during an episode of care in the calendar year from which the NPRA or internal cost savings was generated.

• Any alignment payments made pursuant to a CJR sharing arrangement may be made only to the participant hospital from the entity or individual with whom the participant hospital has signed a Participation Agreement containing a CJR sharing arrangement.

• Each CJR sharing arrangement must require that the CJR collaborator be in compliance with all Medicare provider enrollment requirements at § 424.500 *et seq.,* including having a valid and active TIN or NPI.

• Any internal cost savings or reconciliation payments that the participant hospital seeks to share through CJR sharing arrangements must meet the requirements set forth in the final CJR rule (as finalized) and be administered by the participant hospital in accordance with GAAP. In no event may the participant hospital distribute any amounts pursuant to a CJR sharing arrangement that are not comprised of either internal cost savings or a reconciliation payment, as those terms are defined in this final rule. All amounts determined to be internal cost savings by the participant hospital must reflect actual, internal cost savings achieved by the participant hospital through implementation of care redesign elements identified and documented by the participant hospital. In no case may internal cost savings reflect ''paper'' savings from accounting conventions or past investment in fixed costs.

• Any alignment payments that the participant hospital receives through a CJR sharing arrangement must meet the requirements set forth in the final CJR rule (as finalized) and be administered by the participant hospital in accordance with GAAP.

• CJR sharing arrangements must not include any amounts that are not alignment payments or gainsharing payments.

• Further, we proposed that each Participation Agreement—

++ Between the participant hospital and a CJR collaborator must obligate the CJR collaborator to provide the participant hospital and HHS access to the CJR collaborator's records, information, and data for purposes of monitoring and reporting and any other lawful purpose. Records, information, and data regarding the CJR sharing arrangement must have sufficient detail to verify compliance with all material terms of the CJR sharing arrangement and the terms of the CJR model;

++ Must require the participant hospital and the CJR collaborator to include in their compliance programs specific oversight of their Participation Agreements and compliance with the requirements of the CJR model;

++ If the participant hospital or CJR collaborator does not have a compliance program, each party must create one and incorporate the provisions described in this part in that program;

++ Must require compliance, from both the participant hospital and the CJR collaborator, with the policies regarding beneficiary notification set

forth in section III.F.2. of this final rule; and

++ Must require the board or other governing body of the participant hospital to have responsibility for overseeing the participant hospital's participation in the model, its arrangements with CJR collaborators, its payment of gainsharing payments and receipt of alignment payments, and its use of beneficiary incentives in the CJR model.

• Participation Agreements must require all CJR collaborators to comply with any evaluation, monitoring, compliance, and enforcement activities performed by HHS or its designees for the purposes of operating the CJR model.

• Each Participation Agreement must require the CJR collaborator to permit site visits from CMS, or one of its designees, for purposes of evaluating the model.

We solicited comments about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(3) Gainsharing Payment and Alignment Payment Conditions and Restrictions

We proposed the following conditions and restrictions concerning gainsharing payments and alignment payments made pursuant to a CJR sharing arrangement:

• No entity or individual, whether or not a party to a Participation Agreement, may condition the opportunity to give or receive gainsharing payments in CJR on the volume or value of past or anticipated referrals or other business generated to, from, or among a participant hospital, any CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

• Participant hospitals would not be required to share reconciliation payments, internal cost savings, or responsibility for repayment to CMS with other providers and suppliers. However, where a participant hospital elects to engage in those activities, we proposed that such activities be limited to the provisions prescribed in the proposed rule.

• We proposed that gainsharing payments must be distributed on an annual basis, and are required to meet the following criteria:

++ Must be clearly identified and comply with all provisions in the proposed rule, as well as all applicable laws, statutes, and rules;

++ Must not be a loan, advance payments, or payments for referrals or other business; and

++ Must be made by electronic funds transfer (EFT).

• We proposed that alignment payments from a CJR collaborator to a participant hospital may be made at any interval, and are required to meet the following criteria:

++ Must be clearly identified and comply with all provisions in the proposed rule, as well as all applicable laws, statutes, and rules;

++ Must not be issued, distributed, or paid prior to the calculation by CMS of a reconciliation report reflecting a negative NPRA;

++ Must not be a loan, advance payments, or payments for referrals or other business; and

++ Must be made by EFT.

• We proposed that each CJR sharing arrangement stipulate that any CJR collaborator that is subject to any action involving noncompliance with the provisions of the proposed rule, engaged in fraud or abuse, providing substandard care, or have other integrity problems not be eligible to receive any gainsharing payments related to NPRA generated during the time that coincides with the action involving any of the issues previously listed until the action has been resolved in a forum or manner that constitutes a final determination, either by the state or federal court of last resort, as applicable, or by CMS, HHS, or its designees.

• No entity or individual, whether or not a party to a Participation Agreement, may condition the opportunity to make or receive alignment payments in CJR on the volume or value of past or anticipated referrals or other business generated to, from, or among a participant hospital, any CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

• In a calendar year, the aggregate amount of the total gainsharing payments distributed by the participant hospital that are derived from a CJR reconciliation payment may not exceed the amount of the reconciliation payment that the participant hospital received from CMS.

• In a calendar year, the aggregate amount of the total alignment payments received by the participant hospital may not exceed 50 percent of the participant hospital's repayment amount due to CMS. If no repayment amount is due, then no alignment payments may be received by the participant hospital.

• We proposed that the participant hospital must retain at least 50 percent of its responsibility for repayment to CMS, pursuant to the repayment amount reflected in each annual reconciliation report, under the CJR model. Given that the participant hospital will be responsible for developing and coordinating care redesign strategies in response to its participation in the CJR model, we believed it is important that the participant hospital retain a significant portion of its responsibility for repayment to CMS. For example, upon receipt of a reconciliation report indicating that the participant hospital owes $100 to CMS, the participant hospital would be permitted to receive no greater than $50 in alignment payments, in the aggregate, from its CJR collaborators.

• Further, we proposed that a CJR sharing arrangement must limit the amount a single CJR collaborator may make in alignment payments to a single participant hospital. We proposed that a single CJR collaborator not make an alignment payment to a participant hospital that represents an amount greater than 25 percent of the repayment amount reflected on the participant hospital's annual reconciliation report. For example, upon receipt of a reconciliation report indicating that the participant hospital owes $100 to CMS, the participant hospital would be permitted to receive no more than $25 in an alignment payment from a single entity or individual who is a CJR collaborator of the participant hospital.

• Gainsharing payments and alignment payments must not induce the participant hospital, CJR collaborators, or the employees, contractors, or designees of the participant hospital or CJR collaborators to reduce or limit medically necessary services to any Medicare beneficiary.

• Individual physician and nonphysician practitioners, whether or not a party to a CJR sharing arrangement, must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

• Entities furnishing services to beneficiaries during a CJR episode, whether or not a party to a CJR sharing arrangement, must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

• Gainsharing methodologies for determining gainsharing payments and alignment payments must not directly account for volume or value of referrals, or business otherwise generated, between or among a participant hospital, any CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

• Gainsharing payments must be derived solely from reconciliation payments or internal cost savings or both.

• The total amount of gainsharing payments for a calendar year paid to an individual physician or nonphysician practitioner who is a CJR collaborator must not exceed a cap. The cap is 50 percent of the total Medicare approved amounts under the Medicare Physician Fee Schedule (MPFS) for services furnished to the participant hospital's CJR beneficiaries during a CJR episode by that physician or nonphysician practitioner. This cap of 50 percent on gainsharing payments to individual physician or nonphysician practitioner is consistent with the same policy for the BPCI initiative. The purpose of this cap is to limit the amount of gainsharing payments an individual practitioner may receive due to his/her provision of services included in the CJR model.

• The total amount of gainsharing payments for a calendar year paid to a PGP that is a CJR collaborator must not exceed a cap. The cap is 50 percent of the sum of the total Medicare approved amounts under the MPFS for services furnished by physician or nonphysician practitioner members of the PGP to the participant hospital's CJR beneficiaries during a CJR episode by those physicians or nonphysician practitioners.

We solicited comments about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(4) Documentation and Maintenance of Records

We proposed to require participant hospitals and CJR collaborators to comply with audit and document retention requirements similar to those required by the Medicare Shared Savings Program, BPCI Model 2, and other Innovation Center models. Specifically, with respect to all Participation Agreements and CJR sharing arrangements, the participant hospital and CJR collaborator must:

• Comply with the retention requirements regarding Participation Agreements and CJR sharing arrangements set forth in subsection III.C.10.(a) of this final rule.

• Maintain and give CMS, the Office of Inspector General of the Department of Health and Human Services (OIG), and the Comptroller General or their designee(s) access to all books, contracts, records, documents, and other evidence (including data related to utilization and payments, quality performance measures, billings, and CJR sharing arrangements related to CJR) sufficient to enable the audit, evaluation, inspection, or investigation of the participant hospital's compliance, as well as the compliance of any CJR collaborator that has a CJR sharing arrangement with the participant hospital, with CJR rules and requirements, the Participation Agreement, the quality of services furnished, the obligation to repay any reconciliation payments owed to CMS, the determination, distribution, receipt, or recoupment of gainsharing payments or alignment payments.

• Maintain such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the participant hospital's participation in the CJR model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

++ CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the participant hospital or CJR collaborator at least 30 calendar days before the normal disposition date; or

++ There has been a dispute or allegation of fraud or similar fault against the participant hospital or any CJR collaborator in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

• Notwithstanding any CJR sharing arrangements, the participant hospital must have ultimate responsibility for adhering to and otherwise fully complying with all provisions of the CJR model.

• OIG Authority is not limited or restricted by the provisions of the CJR model, including the authority to audit, evaluate, investigate, or inspect the participant hospital, CJR collaborators, or any other person or entity or their records, data, or information, without limitation.

• None of the provisions of the CJR model limits or restricts any other government authority permitted by law to audit, evaluate, investigate, or inspect the participant hospital, CJR collaborators, or any other person or entity or their records, data, or information, without limitation.

We solicited comments about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

The following is a summary of the comments received and our responses.

Comment: Many commenters requested clarification regarding the application of the fraud and abuse laws to arrangements contemplated by the CJR model.

Response: We understand the commenters' interest in the availability of fraud and abuse waivers for the CJR model. However, as indicated in the proposed rule, such waivers would be issued separately by OIG (as to sections 1128A and 1128B of the Act) and CMS (as to section 1877 of the Act). Any fraud and abuse waivers issued in connection with the CJR model will be available at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html* and on OIG's Web site. No waivers of any fraud and abuse authorities are being issued in this final rule.

Comment: Some commenters recommended that CMS rename the proposed ''Participation Agreements'' as ''collaborator agreements.'' The justification for this recommendation was that CJR collaborators, unlike the participant hospital, will not have responsibility for managing the compliance of other CJR collaborators with terms of the CJR sharing arrangement, and that it would be, therefore, appropriate to differentiate ''participant hospitals'' from entities or individuals signing a ''Participation Agreement.''

Response: We agree that changing the term from Participation Agreement to collaborator agreement is appropriate and may help to eliminate confusion about the type and purpose of such agreements. To avoid confusion, throughout the remainder of this final rule we are substituting the term collaborator agreement in all instances where the term Participation Agreement was used in the proposed rule. All instances in this final rule in which the term Participation Agreement appears have the same meaning as collaborator agreement.

For the same reason, we are also revising the term ''CJR sharing arrangement,'' to ''sharing arrangement.'' Given that a sharing arrangement is contained in a collaborator agreement that has been created solely for the purpose of establishing a financial arrangement between a participant hospital and a CJR collaborator, we believe the inclusion of the acronym CJR in the term for sharing arrangement is unnecessary. Therefore, to avoid confusion, throughout the

remainder of this final rule we are substituting the term sharing arrangement in all instances where the term CJR sharing arrangement was used in the proposed rule. All instances in this final rule in which the term CJR sharing arrangement appears have the same meaning as sharing arrangement.

Comment: Many commenters expressed support for CMS' proposal to allow participant hospitals to enter into financial arrangements with other providers and suppliers to share the participant hospital's reconciliation payments or hospital internal cost savings or both, as well as a portion of the participant hospital's responsibility for repayment to Medicare. Some commenters claimed that past and current experience with gainsharing or risk-sharing have yielded positive results for many hospitals, particularly with regard to aligning the financial incentives of various providers and suppliers that furnish services during an episode of care. For example, A commenter noted that a prior program involving gainsharing yielded significant cost reductions to the hospital participants, while maintaining, and in many cases improving, the quality of care. The commenter noted that it had observed through participation in that gainsharing program that it takes time, discipline, and vigilance to change provider behavior, and that gainsharing was one method of attempting to effectuate such change.

Several commenters supported CMS' proposal to define ''CJR collaborators'' to include only certain providers and suppliers, including that CJR collaborators that are physicians, nonphysicians, or PGPs must furnish services to CJR model beneficiaries. Some of these commenters suggested that these particular provider and supplier types, given the nature of the services they furnish to beneficiaries, have increased commitments to clinical responsibility, to sustainable change, and to a long-term investment in the communities in which they operate, as opposed to entities that do not furnish these types of services to beneficiaries.

By contrast, some commenters expressed disappointment that the list of CJR collaborators did not include individuals such as Infectious Disease Specialists, or entities such as accountable care organizations (ACOs), medical device companies, and other third parties, such as the types of convening organizations participating in other CMMI models. Some of the commenters suggested that CMS should expand the list of potential CJR collaborators to include non-provider or non-supplier entities, particularly given that these entities in many cases have a track record of providing Medicare providers and suppliers participating in other models with support services such as care redesign, data analytics, and general program support. A commenter noted that were device manufacturers allowed to be CJR collaborators, those manufacturers might collaborate with health care providers to make a meaningful contribution to the success of the CJR model and the individual initiatives of participant hospitals. Multiple commenters added that entities like ACOs and conveners might provide such services at a reduced cost through economies of scale—as these organizations could spread the expense of developing this infrastructure over many clients. These commenters also noted that some entities that are not providers or suppliers might be willing to assume a high percentage of downside risk, in order to reduce that risk to participant hospitals.

Additionally, a commenter shared its perspective that CMS failed to indicate whether the proposed list of CJR collaborators is exhaustive, and requested clarification as to whether that was the case. Finally, another commenter requested clarification on the status of episodes in which services are furnished by physicians who opt out of Medicare.

Response: We have noted the positive feedback from commenters indicating their support for CMS' proposed list of CJR collaborators. We also value the input from other commenters requesting that CMS expand the list of CJR collaborators to include additional entities, some of which may be neither Medicare providers nor suppliers, and the justifications to consider allowing these entities to participate in gainsharing. We want to point out that infectious disease specialists are physicians and, therefore, could potentially be CJR collaborators based on our proposed list. We also are clarifying that with the exception of PGPs that are CJR collaborators (as discussed later in this section), all other CJR collaborators (SNF, HHAs, LTCHs, IRFs, physicians, nonphysician practitioners, and providers or suppliers of outpatient therapy services) must actually furnish a billable service to CJR beneficiaries during CJR episodes in the calendar year in which the savings or loss was created in order to be eligible to receive a gainsharing payment or make an alignment payment.

Although we are open to reconsidering the eligibility of additional entities to be CJR collaborators in the future based on the early implementation experience with the CJR model, at this time we will not adopt a final policy that includes additional entities or individuals beyond those listed as CJR collaborators in the proposed rule. As we stated in section III.A. of the proposed rule, we selected acute care hospitals as the financially responsible entity because we are interested in evaluating the impact of bundled payment and care redesign across a broad spectrum of hospitals with varying levels of infrastructure and experience in entering into risk-based reimbursement arrangements. We also stated our belief that it is most appropriate to identify a single type of provider to bear financial responsibility for making repayment to CMS under the CJR model; given that hospitals perform a central role in coordinating episode-related care and ensuring smooth transitions for beneficiaries undergoing LEJR procedures, this role factored in our decision to select IPPS hospitals as the financially responsible entity for this model. Given this structure, we believe that limiting the testing of gainsharing relationships to solely those between hospitals and providers and suppliers enrolled in Medicare is most appropriate because we expect enrolled providers and suppliers to be most directly and specifically engaged with the participant hospitals in care redesign and episode care for beneficiaries who have LEJR surgery at the hospital.

We also note that many of the potential reasons that were suggested by commenters for us to consider allowing individuals and entities other than providers and suppliers to be CJR collaborators eligible for gainsharing payments, such as data analytics and general program support, can be achieved outside of the context of gainsharing through other relationships between the participant hospital and those entities. With the exception of PGPs (as discussed in detail later in this section), we continue to believe that any CJR collaborator that receives a gainsharing payment must have furnished a billable service included in the episode to CJR beneficiaries, that the payment arrangements for gainsharing payments must be actually and proportionally related to the care of beneficiaries in a CJR episode, and that the CJR collaborator must be contributing to the care redesign strategies of the participant hospital. We further note that we operate many models concurrently, and not all providers and suppliers are eligible for participation in all models. Models have

different design features and, therefore, the permitted financial arrangements under the models vary. Testing different financial arrangements in various models provides additional information about important factors in success of models in improving care quality and reducing costs.

Given our experience to date with the intersection between Medicare ACO programs, Medicare ACO models, and bundled payment models, we believe it important to note that financial arrangements between non-Medicare providers and suppliers, such as ACOs or other third parties, are allowed under existing laws, rules, and regulations, outside of the context of the CJR model. While we agree that the potential for leveraging the economies of scale of services offered by many entities that are not Medicare providers or suppliers may be significant, we do not believe their involvement necessitates CMS allowing for gainsharing relationships between hospitals and these entities at this time. In many circumstances, financial arrangements between hospitals and these entities may be possible outside the context of gainsharing under a sharing arrangement in the CJR model. For example, a hospital may pay an ACO for care coordination services the ACO provides during or after a beneficiary's stay in the hospital, in the event that a hospital and the ACO are collaborating and agree to that arrangement. In the event an ACO provides care coordination services to the hospital, the hospital is not precluded from compensating the ACO for the services. In other words, if an ACO hires a case manager to work in the hospital to focus on beneficiaries in CJR episodes, the hospital may contract with the ACO for those case manager services. However, this payment would be outside of the context of the CJR model and would not fall under the categories of a gainsharing payment or alignment payment, as those terms are defined in this final rule. Further, nothing in this section alters the applicable laws, rules, and regulations that apply to such arrangements. Thus, we are maintaining the conditions set forth in the proposed rule, and finalizing the list of CJR collaborators as proposed. This finalized list of CJR collaborators is an exhaustive list—only entities and individuals that meet the criteria listed in this final rule may be eligible as CJR collaborators.

Finally, with regard to the comment regarding physicians that have opted out of Medicare, we note that as discussed in section III.C.3. of this final rule, there are implications related to reconciliation payment when services are furnished by physicians and nonphysician practitioners that have opted out of Medicare. With regard to sharing arrangements, we are clarifying in this final rule that in order to be a CJR collaborator, an individual must not have opted out of Medicare, meaning that the individual physician or nonphysician practitioner must be either enrolled in Medicare as a ''Participating physician/supplier'' or as a ''Non-participating physician/supplier.'' In this model, the payments to physicians and nonphysician practitioners that have opted out of Medicare are not included in a participant hospital's target price and the actual episode spending calculations. Thus, the purpose of this policy is to prevent an individual from receiving a gainsharing payment in the CJR model if he/she has opted out of Medicare.

Comment: Some commenters expressed concern that a participant hospital may steer beneficiaries to certain providers and suppliers, particularly PAC providers, with which the participant has a sharing arrangement. Another commenter opined that sharing arrangements have the potential to result in decisions that are not in the best interest of patient care but rather are in the best interest of increased profit for CJR collaborators. The commenter suggested that this incentive-based arrangement may lead to lower quality of care and restricted access to medically necessary services. Several commenters requested that CMS allow hospitals to steer patients to particular providers and suppliers.

Response: We emphasize that beneficiaries included in a CJR episode retain their full rights to choose their providers and suppliers. Participant hospitals, providers, and suppliers are reminded that patient steering is not permissible and such entities and individuals must continue to comply with current laws. Participant hospitals and CJR collaborators that engage in sharing arrangements may not adversely impede those rights of the beneficiary. Furthermore, we reiterate that sharing arrangements or gainsharing payments must not induce the participant hospital, CJR collaborators, or the employees, contractors, or designees of the participant hospital or CJR collaborators to reduce or limit medically necessary services to any Medicare beneficiary, and that individual physician and nonphysician practitioners, whether or not a party to a sharing arrangement, must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments. For further discussion on this topic, we refer readers to see the provisions addressing beneficiary notification in section III.F. of this final rule.

Comment: A commenter suggested that hospitals located in rural communities may be less likely to have resources to enter into sharing arrangements with CJR collaborators. The commenter stated that in regions where there is not a core group of PAC providers where patients will seek care, rural hospitals may incur additional costs to try to form arrangements with CJR collaborators to support efforts to reduce costs and improve the quality of care.

Response: We appreciate the perspective of the commenter that highlights some of the challenges for providers and suppliers located in rural areas. This model seeks to test episode payment for LEJR procedures initiated at acute care hospitals located in selected Metropolitan Statistical Areas (MSAs). By selecting MSAs as the geographic unit, the majority of participant hospitals located in the selected regions will not be located in rural areas. However, some participant hospitals are located in rural areas, and we agree that these hospitals may face unique challenges in establishing sharing arrangements with CJR collaborators if there are few eligible providers or suppliers, or such providers or suppliers are located across significant distances.

Several studies have shown that Medicare beneficiaries located in rural areas historically have had identifiable patterns pertaining to hospital choice, with results across multiple studies and decades indicating that rural Medicare beneficiaries tend to choose larger hospitals and those offering a broader scope of services.[46] Particularly, patients with complex acute medical conditions have been found to be more likely to bypass their closest rural hospitals for larger, urban hospitals. These patterns have been chronicled across several decades, and we expect that rural hospitals are familiar with many of these studies, as well as related studies demonstrating that patients are more likely to seek care from broader regional networks—comprised of individual rural hospitals—than alternatives with fewer hospitals.[47]

[46] Buczko, W. ''Bypassing of Local Hospitals by Rural Medicare Beneficiaries.'' *Journal of Rural Health.* 1994; 10(4): 237–46.

[47] Tai, Porell, and Adams. ''Hospital Choice of Rural Medicare Beneficiaries: Patient, Hospital Attributes, and the Patient-Physician Relationship.'' *Health Services Research.* 2004; 39(6 Pt 1): 1903–1922.

Perhaps based in part on this research, a number of rural health alliances and rural health networks have been created to address these patient preferences, and we expect these alliances and networks may be useful to rural hospitals in exploring the potential for establishing sharing arrangements with CJR collaborators.

We anticipate that CJR beneficiaries located in rural areas are likely to follow this historical trend, and that some patients will seek care from nonrural hospitals. By contrast, other CJR beneficiaries will initiate CJR episodes at rural hospitals. But this trend is unlikely to be unique to CJR beneficiaries, and we expect that rural hospitals already have established relationships, either on their own or through rural health networks, with providers and suppliers that can furnish services to the hospital's patients upon discharge. Thus, we believe it is possible that rural hospitals may identify a small core group of PAC providers where their model beneficiaries commonly seek care following surgery. We will be providing claims data to assist hospitals in identifying potential CJR collaborators, as discussed in section III.E. of this final rule. Finally, one of the purposes of requiring participation in this model of all hospitals in the selected MSAs is to gain information about the challenges and successes achieved by different types of hospitals in the CJR model, and to share strategies related to success.

Comment: Multiple commenters requested that CMS clarify the relationships between participant hospitals and CJR collaborators. A commenter requested that CMS explain whether these are financial or clinical relationships. Another commenter expressed concern that CJR collaborators that are non-compliant with the requirements of this final rule and/or the terms of a collaborator agreement with a participant hospital might make a participant hospital liable or financially responsible for the conduct of other organizations. The commenter reasoned that it would be unreasonable for a participant hospital to be held responsible for the behavior of CJR collaborators with whom they may enter into a contract for the provision of services under this model.

Response: With respect to the question of whether arrangements between a CJR collaborator and a participant hospital constitute clinical or financial relationships, we note that a CJR collaborator is a specific type of provider or supplier, as previously described, which has signed a written collaborator agreement with a participant hospital. The collaborator agreement must describe a sharing arrangement between the parties. A sharing arrangement, by definition, documents a financial arrangement between the CJR collaborator and the participant hospital that is for the purpose of making gainsharing payments or alignment payments or both. While a collaborator agreement may also address clinical matters, such as care redesign strategies, a provider or supplier is not a CJR collaborator unless the collaborator agreement signed by the provider or supplier contains a sharing arrangement.

As to the second question of provider responsibility, we proposed that participant hospitals in the CJR model that enter into sharing arrangements ''be responsible for ensuring that those providers and suppliers comply with the terms and requirements of this proposed rule.'' We are not suggesting that CJR collaborators be able to escape responsibility for noncompliance with the Medicare Conditions of Participation, or a state or federal law, rule, or regulation merely by entering into a sharing arrangement. Rather, this provision is meant to not only make participant hospitals aware of their responsibility to oversee their CJR collaborators for compliance with the CJR model, but also to inform the participant hospitals of the potential remedial actions that may be taken against them if their CJR collaborators do not comply with all requirements of the CJR model. Specifically, where CMS, HHS, or its designees discovers an instance of noncompliance by a CJR collaborator with the requirements of the CJR model, CMS, HHS, or its designees may take remedial action against the participant hospital, which may include requiring the participant hospital to terminate a collaborator agreement with a CJR collaborator and prohibit further engagement in the CJR model by that CJR collaborator. Furthermore, this provision requires participant hospitals to include in their collaborator agreements provisions requiring compliance from CJR collaborators with the requirements of the CJR model. This provision is discussed further in section III.C.12. of this final rule, in which we detail the enforcement mechanisms that CMS, HHS, or its designees may apply to a participant hospital.

Comment: Several commenters recommended that CMS screen participant hospitals and CJR collaborators to address program integrity concerns.

Response: We appreciate the recommendations of the commenters that we screen participant hospitals and CJR collaborators. However, for several reasons, we continue to believe that this type of screening for participant hospitals would be inapplicable to the CJR model. Most importantly, this model seeks to evaluate the performance in the model of hospitals located in a particular MSA. Given this important objective, we believe it is crucial for evaluation purposes that all hospitals that meet the criteria for participation in the model be included. Further, as discussed in sections III.F and IV, we have finalized our proposal to include evaluation and monitoring provisions that go beyond some of the efforts of previous or existing CMS models.

With regard to screening CJR collaborators, we believe the additional administrative burden on participant hospitals and CMS to periodically prepare, collect, and specifically screen lists of CJR collaborators would not substantially enhance the program integrity protections otherwise built into the model design. We note that CMS will be monitoring for inappropriate behavior of participant hospitals through monitoring efforts specifically for this model. We further note that CMS retains all of its existing mechanisms to directly monitor providers and suppliers, even if they are CJR collaborators. We have included a number of enforcement mechanisms in this final rule that will be available to CMS should a participant hospital or CJR collaborator be out of compliance with the model's requirements.

Comment: Some commenters recommended that CMS provide additional opportunities for entities and individuals other than participant hospitals to assume downside risk under the model. Several commenters indicated that the risk sharing arrangements CMS proposed, via alignment payments from CJR collaborators to participant hospitals, are too limited. In particular, commenters called for PGPs to be able to take on increased risk beyond the 25 percent of a participant hospital's repayment amount that CMS proposed. These commenters suggested that if PGPs were permitted to negotiate sharing arrangements containing provisions for higher gainsharing payments, they would be able to assume greater financial risk as well. Commenters further suggested that transferring risk to PGPs in this manner would be unlikely to result in problematic behaviors such as patient steering, but rather, that such allowances would result in greater provider alignment and better patient care.

Response: We believe the limits proposed on alignment payments perform two important functions. First, as described in section III.A. of this final rule, we seek to test in this model the effects of placing financial responsibility on acute care hospitals for episodes of care initiating with an inpatient stay involving LEJR procedures. While we agree with the commenters that some ability to share downside risk could be useful for participant hospitals and CJR collaborators in creating greater provider alignment and improving patient care, we believe that allowing a participant hospital to shift a majority of its repayment risk under the CJR model to a different entity would fundamentally change the model CMS seeks to test. Further, our experience with other episode payment models, particularly Models 2 and 3 of BPCI, has demonstrated that relatively few PGPs have committed to assuming downside risk in those models. Nearly all of the PGPs participating in Models 2 and 3 of BPCI are participating under another entity that assumes all (or a substantial majority) of the downside risk. Thus, this experience suggests to us that increasing the limits on alignment payments is unlikely to result in many PGPs assuming a greater percentage of risk than what we proposed.

Furthermore, limiting alignment payments as we proposed operates as a safeguard in much the same manner as we discuss later in this section regarding the cap on gainsharing payments. Thus, we do not agree that increasing the limits on alignment payments is appropriate at this time or necessary to test the model.

Finally, we reiterate that beneficiaries included in a CJR episode retain their full rights to choose their providers and suppliers. Participant hospitals and CJR collaborators that engage in sharing arrangements may not adversely impede those rights of the beneficiary. Alignment payments, or the potential for such payments, must not induce the participant hospital, CJR collaborators, or the employees, contractors, or designees of the participant hospital or CJR collaborators to reduce or limit medically necessary services to any Medicare beneficiary. Individual physician and nonphysician practitioners, whether or not a party to a sharing arrangement, must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

Comment: Many commenters opposed the proposed cap on the total amount of gainsharing payments for a calendar year that could be paid to a PGP, or an individual physician or nonphysician practitioner who is a CJR collaborator, arguing that the 50 percent figure is arbitrary and should be removed. Other commenters asserted that a PGP that is a CJR collaborator should have the freedom to determine the most appropriate way to distribute gainsharing payments, given the multiple disciplines involved in patient care. Additionally, some commenters requested that internal cost savings be treated separately from reconciliation payments under the cap on gainsharing payments. These commenters attempted to differentiate these two revenue streams by explaining that while internal cost savings may be achieved by the participant hospital relatively early in the model, reconciliation payments are based upon changes in payment made to providers for services related to episodes in the CJR model. The commenters noted that the financial effects of these latter changes, in the form of positive reconciliation payments, may not be realized for some time. These commenters added that gainsharing payments comprised of internal cost savings are derived from hospital cost improvements and do not result from or impact Medicare payments. Thus, in the commenters' opinion, the cap on gainsharing payments should apply only to the portion of a gainsharing payment derived from a reconciliation payment. A commenter further added that the many requirements that CMS proposed, including that all payments must be auditable by HHS, provide assurance that the distribution will be documented and supported, thus avoiding the possibility of program abuse.

Other commenters acknowledged the necessity for a cap on gainsharing payments, but urged CMS to apply the same cap to the CJR model as is applied to Model 2 of the BPCI initiative, which does not place a cap on gainsharing payments to PGPs. Commenters stated that having different policies between the models could create the potential for an uneven playing field across CJR participant hospitals and BPCI Model 2 episode initiator hospitals. These commenters asserted that the cap on gainsharing payments to PGPs in CJR may work to the detriment of participant hospitals, as compared to hospitals in the same geographic markets that are participating in BPCI. Given the proposed cap on gainsharing payments to PGPs, the commenters stated that participant hospitals in CJR may be placed at a competitive disadvantage within the market, with the potential for PGPs to view hospitals in BPCI Model 2 as more lucrative financial partners.

In addition, some commenters objected to the proposed requirement that only CJR collaborators that actually furnish a service to a CJR beneficiary during an episode of care would be eligible to receive a gainsharing payment. This policy would prohibit, for example, a PGP from distributing any portion of a received gainsharing payment to physicians or nonphysician practitioners who did not furnish a service to the CJR beneficiary during an episode of care. Commenters suggested that such a requirement might be difficult to institute with PGPs and may necessitate group practices amending their particular bylaws and internal contracts. Another commenter acknowledging that CMS' rationale for this proposal was to preserve program integrity and ensure that individuals who did not furnish services to a CJR beneficiary during an episode are not permitted to receive a payment, nevertheless also disagreed with the proposal, stating that billing records do not always capture all of the surgeons who deliver care to each beneficiary, as other PGP members would likely deliver some postoperative services that are not separately recorded and thereby not identifiable from claims data. According to the commenter, only at the PGP level would it be feasible for the group members to most appropriately allocate gainsharing payments.

Response: We acknowledge the many perspectives of the commenters on the proposed cap on gainsharing payments to physicians, nonphysician practitioners, and PGPs in the CJR model. The purpose of the cap is to serve as a safeguard against the potential risks of stinting, steering, and denial of medically necessary care due to financial arrangements specifically allowed under the CJR model by providing an upper limit on the potential additional funds a physician, nonphysician practitioner, or PGP can receive for their engagement with participant hospitals in caring for CJR model beneficiaries beyond the FFS payments that those suppliers are also paid and that are included in the actual episode spending calculation for the episodes.

While we appreciate the distinction being made by the commenters regarding the potential timing differences between internal cost savings and reconciliation payments, as well as that internal cost savings that could be paid to a CJR collaborator would not actually be due to a change in Medicare payment, as would be the

case for reconciliation payments, we do not agree that it would be appropriate to exclude gainsharing payments based on internal cost savings from the cap on this basis. There is the potential for stinting, steering, or denial of medically necessary care to be implicated by the sharing of either internal cost savings or reconciliation payments. For example, if a physician were to discharge a beneficiary from the hospital earlier than medically necessary, and not transfer that beneficiary to PAC services that were medically necessary, such behavior could have impacts on both a hospital's internal cost savings and reconciliation payments. We do not agree that only reconciliation payments should be subject to the cap on gainsharing payments, but rather that the cap on gainsharing payments should apply to all potential dollars that could be transferred to a CJR collaborator subject to the cap. We believe that allowing a physician or nonphysician practitioner to be paid up to 50 percent more for engagement with the episode care of CJR beneficiaries than they are paid for furnishing direct services to those beneficiaries under the MPFS provides participant hospitals with substantial flexibility in developing meaningful financial arrangements that align the financial interests of physicians and nonphysician practitioners with the quality and cost goals of the hospital under the CJR model. Moreover, we note that we have applied the 50 percent cap on gainsharing payments to physicians and nonphysician practitioners in the BPCI initiative, and participants have not voiced significant complaints that this moderate financial limitation has hampered their ability to engage physicians and nonphysician practitioners in care redesign to improve episode quality and reduce costs. Given this feedback, and that the provisions governing financial arrangements for the BPCI initiative and the CJR model are similar, we believe that the 50 percent cap on gainsharing payments is an appropriate condition for this model.

We understand the perspective from some commenters that the cap on gainsharing payments to PGPs may have impacts on revenue sharing within PGPs, particularly for multi-specialty practices. If the CJR model included clinical episodes for many different conditions, such as in the case of a number of BPCI participants who are testing multiple different clinical episodes, we could understand how it might be justified to remove the cap on gainsharing payments to PGPs. However, with CJR, there is only a single episode—LEJR procedures. As such, we believe it is likely that most services to CJR beneficiaries during an episode will be furnished by an identifiable subset of physician and nonphysician practitioners within a PGP. From our experience with other bundled payment models, such as the BPCI initiative, we have found that even in large, multi-specialty PGPs, the majority of services to LEJR patients are furnished by a subset of practitioners.

We proposed that a cap on gainsharing payments made to a PGP that is a CJR collaborator be limited by the aggregate billable services furnished during a calendar year to the participant hospital's CJR beneficiaries during CJR episodes by physicians and nonphysician practitioners that are members of the PGP. This cap on gainsharing payments to PGPs is based on Medicare payments for the services delivered to CJR beneficiaries by PGP members. We also proposed that the only PGP members that could receive all or a portion of the gainsharing payment made to the PGP are those PGP members that furnished a billable service to a CJR beneficiary during a CJR episode. Therefore, we believe that the cap on gainsharing payments as it has been proposed for the CJR model is appropriate, because it ensures that only physicians and nonphysician practitioners within a PGP that may receive all or a portion of a gainsharing payment are those physicians and nonphysician practitioners who actually furnished services to CJR beneficiaries during CJR episodes, and that the amounts those PGP members receive does not exceed the capped amounts that would be applied to those physician and nonphysician practitioners if they were directly engaging with a participant hospital as CJR collaborators.

For example, for a physician or nonphysician practitioner who furnishes billable services in a calendar year to CJR beneficiaries during CJR episodes that amount $1,000 in total Medicare approved amounts under the MPFS, the cap for that physician or nonphysician practitioner would be $500. By comparison, if the physician or nonphysician practitioner furnishes billable services in a calendar year to CJR beneficiaries during CJR episodes that amount $0 in total Medicare approved amounts under the MPFS, the cap for that physician or nonphysician practitioner would be $0. In both scenarios, if the physician or nonphysician practitioner is a PGP member in a PGP that is a CJR collaborator that has a sharing arrangement with a participant hospital, then the maximum gainsharing payment that could be made to the PGP would be the aggregate capped amounts, as previously described, of all physician and nonphysician practitioners that furnished a billable service in a calendar year to a CJR beneficiary during a CJR episode. Similarly, if the physician or nonphysician practitioner has a sharing arrangement directly with a participant hospital (regardless of whether the physician or nonphysician practitioner is a PGP member), the maximum gainsharing payment that could be made to the physician or nonphysician practitioner would be the capped amount, as previously described, for services furnished to the participant hospital's CJR beneficiaries during a CJR episode by that physician or nonphysician practitioner. We believe that the flexibilities inherent in these policies on limits to gainsharing recognize the various levels of engagement from physicians and nonphysician practitioners in a participant hospital's care redesign, and allows for arrangements to be structured accordingly.

Our proposed policies for limits on gainsharing also recognized that the work of care redesign will also likely be carried out by those same physicians caring for model beneficiaries. We further note that MSAs with high proportions of acute care hospitals initiating LEJR episodes in BPCI have not been included in the random selection process for the CJR model, as described in section III.A. of this final rule. This should limit those communities where participant hospitals in CJR and BPCI hospitals initiating LEJR episodes are co-located such that PGPs could consider moving their current practice locations based on financial considerations under a model in testing.

Furthermore, we do not see how allowing all or a portion of a gainsharing payment to be distributed to individual physicians, nonphysician practitioners, or members of PGPs who did not furnish any services to model beneficiaries during a CJR episode is likely to increase the quality of care that was furnished to those beneficiaries or reduce the cost to Medicare. We can, however, see the potential for abuse by allowing such payments to flow freely to any member of a PGP, as PGPs in some markets could potentially funnel portions of a gainsharing payment to practitioners not involved in LEJR care as a means of impacting the referral patterns of those practitioners to particular hospitals or the PGP. As stated previously, the cap on gainsharing payments functions to deter

steering, stinting, and denial of medically necessary care. For these reasons, we believe that the limits on gainsharing payments to certain types of CJR collaborators via the proposed cap are necessary and tailored appropriately to the risks we seek to minimize.

In summation, the cap on gainsharing payments ensures that only physician and nonphysician practitioners that actually furnish a service to a beneficiary during a CJR episode are eligible for gainsharing payments, and that gainsharing payments made to PGPs are limited to the aggregate capped amounts of each physician or nonphysician practitioner member that furnished a service to a CJR beneficiary. We reiterate that while the cap is only applicable to gainsharing payments made to CJR collaborators who are physicians, nonphysician practitioners, providers or suppliers of outpatient therapy services, and PGPs, CJR collaborators that are SNFs, HHAs, LTCHs, IRFs, physicians, nonphysician practitioners, and providers or suppliers of outpatient therapy services that are CJR collaborators must have furnished a billable service during a CJR episode to a CJR beneficiary during the calendar year in which the internal cost savings was generated or to which the NPRA applied (the latter of which are directly reflected in a reconciliation payment), in order to be eligible to receive a gainsharing payment. As discussed later in this section, CJR collaborators that are PGPs need to have participated in care redesign activities that involved the provision of care to CJR beneficiaries during the calendar year in which the internal cost savings was generated or to which the NPRA applied (the latter of which is directly reflected in a reconciliation payment), in order to be eligible to receive a gainsharing payment. We believe this connection to beneficiaries is likely to be important in aligning the financial incentives of the practitioner with those of the participant hospital, as well as the other providers and suppliers involved in the delivery of care to beneficiaries.

Comment: A commenter suggested that outside of large orthopedic groups, few CJR collaborators are likely to have a sufficient volume of cases for gainsharing to be a financially meaningful incentive. The commenter further explained that in the current environment, there is no compelling reason for a CJR collaborator to enter into a sharing arrangement containing provisions for alignment payments.

Many commenters offered related comments regarding CMS' proposed gainsharing policies as applied to PGPs. Commenters vigorously requested that CMS remove the provision prohibiting a PGP that is a CJR collaborator from retaining any portion of a gainsharing payment. CMS' proposal would have required the PGP to distribute 100 percent of the gainsharing payment to the PGP's member physicians and nonphysician practitioners that actually furnished a service to a CJR beneficiary during a CJR episode. In opposing this proposed requirement, commenters stressed that PGPs should have the freedom to determine the most appropriate way to distribute gainsharing payments, given the multiple disciplines involved in patient care, and the potential for clinical and financial involvement of the PGP in the care of CJR beneficiaries. Multiple commenters suggested that if CMS were to finalize this proposal without modification that PGPs would likely be discouraged from participating as CJR collaborators in the model.

Response: We appreciate these perspectives, and have carefully considered the potential consequences of our proposals. With regard to the commenter that recommended that gainsharing will be meaningful for only a small subset of large PGPs, our experience in gainsharing in other models suggests otherwise. For example, we have received extensive feedback from participants in the BPCI initiative that gainsharing can be a highly effective tool in assisting hospitals in aligning financial incentives not only with physician group practices, but also with individual physicians. Second, as we detail in section III.C. of this final rule, PAC spending within a 90-day LEJR episode constitutes a significant portion of the overall episode spending. As a result, we believe that participant hospitals may choose to engage in sharing arrangements with a wide variety of CJR collaborators, including physicians, PGPs, and PAC providers to attempt to reduce unnecessary episode spending during the post-anchor hospital discharge period. Our experience with BPCI suggests these efforts may be best served from involvement by multiple individuals and entities, not just large orthopedic practices.

We considered whether PGPs that are CJR collaborators should be permitted to retain all or a portion of a gainsharing payment. We are concerned by the comments suggesting that some PGPs may be unwilling to engage in care redesign efforts as a CJR collaborator with a participant hospital if the PGP is not permitted to retain a gainsharing payment. We also understand that PGPs might serve a variety of functions that contribute to care redesign and innovations in care furnished to CJR beneficiaries. For example, while a PGP, as an entity, would not furnish a billable service to a CJR beneficiary (that function is performed by the member physician and nonphysician practitioners of the PGP), a PGP that is engaged in care redesign with a participant hospital could serve as an organizing entity for the physician and nonphysician practitioner members of the PGP that are furnishing services to CJR beneficiaries. Further, the PGP might provide care coordination services for CJR beneficiaries or invest in new technologies that improve care for CJR beneficiaries. In this way, a PGP is distinct from the other provider and supplier types eligible to be CJR collaborators in that, although the PGP is a Medicare enrolled entity, it does not furnish billable services to beneficiaries.

Given these considerations, we are persuaded that a PGP that is a CJR collaborator should be permitted to retain all or a portion of a gainsharing payment. Thus, we are finalizing our proposal with a modification to allow PGPs that are CJR collaborators to retain all or a portion of a gainsharing payment that the PGP receives from a participant hospital. We believe that this modification will provide greater financial flexibility to PGPs that are CJR collaborators, and will allow for those PGPs to consider sharing arrangements that contain provisions regarding alignment payments. We note that for purposes of this final rule, a PGP is an entity that furnishes clinical patient care services, including evaluation and management services, or professional surgical services. We do not believe that an entity is a PGP if it merely furnishes supplies or tests to patients.

In order to be eligible to receive a gainsharing payment, the PGP that is a CJR collaborator must meet all of the following:

- The PGP must have at least one member of the PGP that is a physician or nonphysician practitioner, as those terms are defined at § 510.2, that actually furnished a service to a CJR beneficiary during a CJR episode during the calendar year in which the participant hospital's internal cost savings was generated, or to which the NPRA applied (the latter of which is directly reflected in a reconciliation payment), as these funds are the only two sources that may comprise a gainsharing payment;
- The PGP must contribute to a participant hospital's care redesign in CJR and be clinically involved in the care of CJR beneficiaries. The following is a non-exhaustive list of ways in

which a PGP might be clinically involved in the care of CJR beneficiaries:

++ Provide care coordination services to CJR beneficiaries during and/or after inpatient hospital admission;

++ Engage with a participant hospital in developing care redesign strategies, and actually perform a role in implementing such strategies, that are designed to improve the quality of care for LEJR episodes and reduce LEJR episode spending;

++ In coordination with other providers and suppliers (such as the PGP's members, participant hospitals, and PAC providers), implement strategies designed to address and manage the comorbidities of CJR beneficiaries.

Finally, should the PGP wish to distribute all or a portion of a gainsharing payment to its member physicians and nonphysician practitioners, we discuss later in this section, in detail, the requirements for such distributions.

Comment: Multiple commenters raised issues related to participant hospitals' consideration of quality of care in initially selecting CJR collaborators and later determining gainsharing payments for CJR collaborators. While some commenters recommended that CMS require hospitals to engage in sharing arrangements with all providers and suppliers caring for CJR model beneficiaries, other commenters encouraged CMS to maintain participant hospital flexibility in selecting CJR collaborators based on parameters such as contributions to the efficiency and quality of episode care.

With respect to the determination of gainsharing payments, a commenter stated that gainsharing payments should be founded in quality performance, with each CJR collaborator needing to meet minimum thresholds prior to any gains being distributed. Other commenters suggested that the ability of all CJR collaborators to receive a gainsharing payment should be based on the quality performance of the CJR collaborators both as individuals and as a group—essentially recommending that CMS institute a ''quality gate'' that would need to be met by all CJR collaborators in order for any single CJR collaborator to receive a gainsharing payment. The suggested methodologies varied as to how quality would be measured—some commenters suggested that selection should be done by CMS while others recommended that participant hospitals should choose quality criteria important to them. Commenters did not suggest particular quality criteria that CMS should consider, and most commenters did not describe how CMS or participant hospitals would select quality criteria.

Response: We agree with commenters that quality should be a consideration in the participant hospital's selection of CJR collaborators, as well as the determination of gainsharing payments for CJR collaborators. However, we do not believe that we need be as prescriptive on quality criteria used for determining gainsharing payments as some commenters suggested. Participant hospitals are best positioned to determine the quality of care considerations for CJR collaborator selection and the quality criteria for gainsharing payments that are most important to them and that are the most meaningful indicators of the quality of care furnished to CJR model beneficiaries. By way of comparison, BPCI participants are required to report the quality targets they will use in determining gainsharing payments, and providers and suppliers who do not meet the BPCI participant's quality targets are prohibited from receiving gainsharing payments. For the CJR model, we are adopting a more flexible approach to quality considerations in the selection of CJR collaborators and the requirement that quality criteria be described in sharing arrangements under the CJR model, once again balancing our interest in encouraging financial arrangements that consider high quality of care and not the volume and value of referrals, with allowing participant hospitals maximal flexibility to determine the issues related to quality of most importance to their efforts to improve episode quality and efficiency.

With regard to the selection of CJR collaborators, while we do not agree with the commenters suggesting that we require participant hospitals to engage as CJR collaborators with all providers and suppliers caring for CJR model beneficiaries, we believe the providers and suppliers that the participant hospital selects as CJR collaborators should be held to certain standards related to the quality of care for CJR model beneficiaries. Thus, we believe it is appropriate to require the participant hospital to create a written set of policies for selecting providers and suppliers for sharing risks and gains as CJR collaborators. Those policies must be related to, and inclusive of, the quality of care to be delivered to beneficiaries during a CJR episode. We believe these criteria could permit selection of CJR collaborators based on their previous demonstration of the ability to furnish high-quality services to beneficiaries receiving LEJR or based on their expected high quality care due to requirements specified in the hospital's collaborator agreement. For example, some participant hospitals may choose to satisfy this requirement by adopting quality criteria that look at a provider/supplier's past performance on certain quality metrics, such as complication rates, whereas other hospitals may choose to adopt quality criteria that rely primarily on satisfaction of forward-looking requirements that the participant hospital expects to lead to improved quality of episode care, such as attending weekly care coordination meetings, contacting CJR beneficiaries frequently, or following specified clinical care pathways. As previously stated, we believe it is important that participant hospitals have the ability to select the CJR collaborators that are willing to engage in the participant hospital's care redesign strategies, as well as provide high-quality care, so that the CJR collaborators are likely to contribute to improvements in episode quality and efficiency. Thus, with regard to the role of quality in the selection of CJR collaborators, we will require the participant hospital to develop a written set of criteria that it will use to determine the selection of all CJR collaborators.

We also believe the quality of care furnished by CJR collaborators to beneficiaries during an episode should be a factor in determining a gainsharing payment, not just the savings created by the CJR collaborator. We believe that requiring participant hospitals to include quality criteria when determining gainsharing payments will incentivize CJR collaborators to provide high quality, medically necessary care that contributes to the quality of episode care. Because the CJR model incorporates pay-for-performance in the payment methodology, rewarding high quality performance and quality improvement with increased financial opportunity for participant hospitals as discussed in section III.C.5. of this final rule, we believe this same principle should carry through to gainsharing payments, to which episode quality and cost performance should be linked. We further believe that requiring the participant hospital to include quality criteria as a factor in the determination of gainsharing payments should prevent low quality providers and suppliers that have not contributed to the quality of episodes that leads to participant hospital financial opportunity from receiving gainsharing payments in this model.

With regard to the role of quality in the determination of gainsharing

payments, we will require the participant hospital to develop a written methodology included in the collaborator agreement that specifies how the hospital will determine gainsharing payments. To be eligible to receive a gainsharing payment, a CJR collaborator must meet quality criteria, established by the participant hospital and directly related to CJR episodes of care, for the calendar year for which the gainsharing payment is determined. For purposes of this requirement, we note that participant hospitals may utilize a variety of quality criteria depending on their priorities for care redesign and quality improvement, as long as those criteria are directly related to CJR episodes of care. For example, some participant hospitals may choose to incorporate health outcome measures specific to each CJR collaborator in the gainsharing methodology, such as the hospital readmission rate of CJR beneficiaries for each physician or the complication rate of CJR beneficiaries at each SNF, in their quality criteria for gainsharing payments. Other hospitals may choose to incorporate specific process measures that are aligned with the hospital's objectives for care redesign to improve CJR episode quality, such as the rate of attendance by CJR collaborators at weekly care coordination meetings to discuss the care of CJR beneficiaries or performance on patient experience surveys of CJR model beneficiaries. Again, we underscore that the set of quality criteria used to determine gainsharing payments must be directly related to the care of CJR beneficiaries, but we believe that each hospital should be permitted to determine the quality criteria most important to them and which relate to the areas of care redesign on which they seek improvement.

In summary, we will require the participant hospital to develop and maintain a written set of policies for selecting its CJR collaborators. Further, this set of policies must contain criteria for selection of CJR collaborators that include criteria related to, and inclusive of, the quality of care to be delivered to beneficiaries by the CJR collaborator during a CJR episode. The selection criteria cannot be based directly or indirectly on the volume or value of referrals or revenue generated by providers or suppliers. All CJR collaborators must have met, or agree to meet, the quality criteria for selection. In the case of selection criteria regarding an individual's or entity's willingness to engage in activities that are expected to improve the quality of care (such as following specified clinical pathways), such activities must be specified in the collaborator agreement as an obligation of the CJR collaborator. We are also adding a requirement that the participant hospital include in its collaborator agreements with CJR collaborators the methodology the participant hospital will use to determine gainsharing payments, and this methodology must be based, at least in part, on criteria related to, and inclusive of, the quality of care to be delivered to beneficiaries during a CJR episode, and not directly on the volume or value of referrals or business generated by providers and suppliers. Finally, we will require participant hospitals, in considering the quality criteria to incorporate as part of their gainsharing methodologies, to use quality criteria that are directly related to CJR episodes of care, so that the criteria used by the participant hospital are relevant to care for beneficiaries in the model. To be eligible to receive a gainsharing payment, a CJR collaborator must meet quality criteria for the calendar year for which the gainsharing payment is determined by the participant hospital. Any CJR collaborator that does not meet the quality criteria described with specificity in the collaborator agreement is not eligible for a gainsharing payment for the calendar year for which the gainsharing payment is being calculated.

Lastly, with regard to the application of a participant hospital's quality criteria prior to the distribution of gainsharing payments, we are clarifying our proposal by changing the word ''calculation'' to ''determination.'' As previously discussed, we are requiring that participant hospitals use a methodology to determine gainsharing payments, and that this methodology be explained in detail in all sharing arrangements with CJR collaborators. We expect that this methodology may include calculations, but we are clarifying that while quality criteria must be used when determining the gainsharing payment for each CJR collaborator, the quality criteria are not specifically required to be a part of the calculated amount of the gainsharing payment.

Comment: Many commenters recommended specific changes to the gainsharing policies proposed by CMS. First, some commenters recommended that CMS require participant hospitals to offer the same gainsharing arrangement to all CJR collaborators of the same provider or supplier type. For example, MedPAC recommended that CMS allow participant hospitals the flexibility to draft their own risk-sharing arrangements, but require that hospitals have the same gainsharing arrangement with all physicians; the per-episode payment for each physician that is a CJR collaborator in the gainsharing pool would be the same. MedPAC also suggested that physicians in a gainsharing pool should be judged across all CJR beneficiaries treated by all physicians in the pool, which would prevent hospitals from making gainsharing payments on a patient-specific basis. MedPAC stated that these requirements would limit the incentive for physicians to select low-cost patients. With respect to CJR collaborators that are PAC providers, MedPAC and other commenters recommended that participant hospitals should not be required to offer risk sharing to all PAC providers, the arrangements offered should be identical across all selected PAC providers, and the gainsharing payments should be calculated for all PAC providers offered risk sharing by the hospital using a methodology that is not patient-specific or provider/supplier-specific. The commenters recommended that gainsharing methodologies that reward providers or suppliers based on the performance of a group of similar providers or suppliers would limit the incentives for certain CJR collaborators to select low-cost patients over higher cost patients. In addition, the commenters recommended that such methodologies would encourage all CJR collaborators to lower episode spending, improve quality, and reduce Medicare spending for all CJR model beneficiaries.

Second, a number of commenters urged CMS to make sharing arrangements mandatory; in effect suggesting that participant hospitals be required to enter into gainsharing relationships. For example, a commenter recommended that CMS require participant hospitals to enter into sharing arrangements with ACOs in the participant hospital's MSA. Another commenter recommended that CMS require participant hospitals to enter into sharing arrangements with all orthopedic physicians credentialed at the hospital, in order to reduce the potential for hospitals to arbitrarily decide whether or not to enter into such arrangements with a physician. Multiple commenters cautioned that participant hospitals may choose to select only the most ''efficient'' or ''cost effective'' orthopedic surgeons to enter into sharing arrangements, and thus recommended that CMS require participant hospitals to enter into sharing arrangements with all

physicians. Another commenter likewise urged CMS to require, or strongly encourage, participant hospitals to collaborate with independent professionals who can demonstrate effectiveness and efficiency in the rehabilitation treatment of THA and TKA patients in the model. However, many other commenters recommended that CMS retain the provision in the proposed rule to allow participant hospitals the freedom to determine whether they want to enter into gainsharing or risk-sharing arrangements. MedPAC stated that a participant hospital should not be required to offer sharing arrangements to all providers and suppliers in its market, and that participant hospitals should be allowed to exclude providers and suppliers that are not contributing to efficiencies or that are delivering a poor quality of care. Many commenters recommended that CMS allow participant hospitals to discontinue a sharing arrangement with any individual or entity not contributing to savings. Several commenters urged CMS to finalize its proposed policy to prohibit participant hospitals from coercing or requiring physician participation in the CJR model.

Many commenters stated that the proposed sharing arrangement requirements, such as the gainsharing and alignment payment caps, were too limiting. Several commenters noted that certain types of physicians—particularly orthopedic surgeons—serve a critical role in care redesign and creating internal cost savings for a participant hospital and episode savings to Medicare. Thus, these commenters stated, applying the same policies regarding sharing gains and losses to orthopedic surgeons as to other providers and suppliers—such as physical therapists or PAC providers—would be inapplicable. These commenters recommended that CMS allow physicians greater freedom to negotiate sharing arrangements—such as the ability to assume greater financial risk above the 25 percent for alignment payments proposed by CMS in the proposed rule, and removal of the 50 percent cap on gainsharing payments for CJR collaborators that are physicians, nonphysician practitioners, and PGPs.

Several commenters suggested that the proposed caps on gainsharing payments and alignment payments were arbitrary, particularly given the proposed policy that gainsharing payments must be ''actually and proportionally related to the care'' of beneficiaries in CJR episodes and that the CJR collaborator must be contributing to the care redesign strategies of the participant hospital. Other commenters likewise suggested that the capped limits were arbitrary because they may not reflect the efforts that a physician undertook to meet required quality metrics and reduce episode spending. Rather than setting what they argue is an arbitrary limit, these commenters recommended that CMS should allow providers to determine the distribution amounts.

Some commenters noted that gainsharing structures in the private sector allow for more flexibility and are less prescriptive. Other commenters recommended that the participant hospital should be afforded broad discretion to establish its policies for the distribution of gainsharing payments. For example, a commenter suggested that CMS should remove the requirement that gainsharing payments be made annually, and allow participant hospitals to make this payments at any interval, or at a minimum, twice per year. These commenters also noted that hospitals are likely to be experienced business entities and should be able to make independent financial decisions without a regulatory structure for gainsharing like the one proposed. Further, these commenters suggested that in the absence of gainsharing, the participant hospital would retain the full reconciliation payment, and thus the hospitals are unlikely to make distributions of gainsharing payments unnecessarily.

Response: We appreciate the robust response from commenters on these issues. We proposed to allow financial arrangements in this model to incentivize higher quality care and reductions in episode spending through improved financial alignment between providers and suppliers furnishing services to beneficiaries during a CJR episode, while protecting against undue risk from beneficiary steering, care stinting, and inappropriate reductions in access to care that could otherwise result from the financial incentives in an episode payment model.

We appreciate the reasons for the recommendations by some commenters that we require participant hospitals to essentially offer the same gainsharing arrangement to all providers and suppliers of the same type. While we understand the potential benefits of a policy standardizing sharing arrangements to protect against selection of low-cost patients and the resulting patient steering, we believe that participant hospitals may have legitimate reasons to enter into a sharing arrangement with a particular provider or supplier that differs from the hospital's arrangements with other similar providers or suppliers. For example, it is possible there may be instances in which a particular SNF offers certain therapies or has resources that a participant hospital believes will benefit its patients in the model. In these instances, it may be prudent for a hospital to enter into a different sharing arrangement with that SNF, as opposed to other SNFs. Furthermore, participant hospitals may have legitimate reasons to construct different sharing arrangements with CJR collaborators that agree to take on a portion of the participant hospital's financial risk compared to sharing arrangements with CJR collaborators that do not assume downside risk. We believe that the CJR model's policies that require participant hospitals to be financially liable for episodes of care will incentivize participant hospitals to decrease episode spending and increase the quality of care by engaging participant hospitals to seek CJR collaborators that are also supportive of these goals.

We believe that the MedPAC recommendation to require identical per-episode payments for each physician that is a CJR collaborator would likely limit physician commitment to the goals of the model and the model would be less likely to result in reduced episode spending and improved quality of care. Our experience in other models that incorporate gainsharing has indicated that a hospital may have legitimate reasons to construct different sharing arrangements with different physicians, depending on factors such as the involvement of the physician in the hospital's care redesign efforts, adoption of leadership roles requiring direction and instruction of other physicians, and the number and magnitude of disruptions in the physician's existing practice patterns.

We have included safeguards in this final rule to address patient steering, including the requirement that beneficiaries retain their full rights to choose their providers and suppliers, the requirement that hospitals not limit beneficiary choice of providers or suppliers, the cap on gainsharing payments, the requirement that the opportunity to receive gainsharing payments (or the opportunity to make or receive alignment payments) may not be conditioned on the volume or value of past or anticipated referrals or other business generated to, from, or among the participant hospital and any CJR collaborator, the requirement that gainsharing payments be distributed only to CJR collaborators that meet the quality criteria established by the participant hospital, and the

requirement that gainsharing methodologies must not directly account for the volume or value of referrals or business otherwise generated between or among the participant hospital and CJR collaborators. For these reasons, we believe that participant hospitals should be allowed to enter into different sharing arrangements with various CJR collaborators.

While we appreciate the reasons why some commenters recommended that we require participant hospitals to enter into financial relationships with certain entities and individuals, we do not agree that such a requirement is necessary. We agree with the commenters who supported the voluntary nature of sharing arrangements, and we continue to believe that it is essential that sharing arrangements be voluntary and without penalty for nonparticipation. Although we are not requiring participant hospitals to offer sharing arrangements to all providers or suppliers, we are finalizing our proposal prohibiting hospitals from coercing or requiring individuals or entities to enter into a sharing arrangement, and participant hospitals may not penalize or discriminate against physicians and nonphysician practitioners on the grounds that they are not CJR collaborators. However, in response to these comments, we are also modifying our proposal, discussed in detail later in this section, regarding the selection criteria a participant hospital must use in choosing CJR collaborators. We believe that our final requirement for selection criteria for CJR collaborators responds to the concerns from some commenters regarding how a participant hospital selects it CJR collaborators.

In response to the view of some commenters that the provisions for gainsharing and risk-sharing in the CJR model are overly restrictive, we note that we constructed a framework for financial arrangements in the CJR model that we believe leaves participant hospitals and CJR collaborators relatively unconstrained to develop sharing arrangements in a manner they see fit, provided that all the requirements contained in this final rule are met. We have not proposed that participant hospitals would need to use a particular methodology for determining gainsharing payments or alignment payments, other than placing upper thresholds on those payments and a requirement for quality criteria for gainsharing payments, which we discuss in greater detail previously in this section.

With regard to the provision on the annual distribution of gainsharing payments, given that CMS is not requiring participant hospitals to submit gainsharing methodologies for review or to report gainsharing payments to CMS, we believe that the provision allowing for gainsharing payments on an annual basis is appropriately placed, for purposes of tracking by the participant hospital, as well as facilitating any program integrity matters by CMS, HHS, and its designees. We also believe that annual distributions of gainsharing payments are appropriate because reconciliation within the model will occur on an annual basis. Also, because providers and suppliers will continue to be paid according to the existing FFS processes throughout the duration of the model, CJR collaborators will continue to have sources of revenue other than gainsharing payments, which we believe makes distributions of gainsharing payments more often than once per year unnecessary. Finally, while gainsharing arrangements in the private sector may be less restrictive, as suggested by some commenters, other commenters nonetheless noted that a number of Federal laws are implicated by gainsharing, and thus a more prescriptive set of gainsharing policies is an appropriate reflection of the presence and importance of that legal framework. We agree with those commenters, and emphasize that while we have attempted to avoid making the provisions on sharing arrangements and collaborator agreements unnecessarily complex, we believe that the regulatory requirements for these documents are justified, for reasons such as limiting opportunities for patient steering, preserving beneficiary choice, and protecting Federal healthcare dollars.

We continue to believe that the permissible sharing arrangements under the CJR model should allow participant hospitals substantial and appropriate flexibility to develop these arrangements with the care redesign needs of their beneficiaries in mind to achieve the model objective of quality improvement and reduced episode cost, while providing sufficient protections against the possible risks of beneficiary steering, stinting, and inappropriate reductions in access to care under an episode payment model. Therefore, final policies apply certain limited protections to minimize these risks and reduce the opportunities for providers and suppliers to engage in inappropriate behavior, while allowing participant hospitals sufficient flexibility to achieve success in the model, striking an appropriate balance between these two important objectives. These protections fall into the following several categories:

- Requirements that the basis for selection of CJR collaborators be on criteria related to, and inclusive of, the quality of care to be delivered to beneficiaries during a CJR episode, and that the selection criteria cannot be based directly or indirectly on the volume or value of referrals or revenue generated by providers or suppliers. Further, all CJR collaborators must have met, or agree to meet, the quality criteria for selection.
- Requirements that the basis for, and determination of, gainsharing payments include provisions describing with specificity in the collaborator agreement, including the quality criteria that the participant hospital will use in its determination of gainsharing payments, and that such payments be based on criteria other than the volume or value of past or future referrals, or business otherwise generated.
- Contemporaneous documentation requirements to ensure that collaborator agreements between participant hospitals and CJR collaborators are memorialized in writing and comply with all the provisions of this final rule.
- Limits on the absolute amount of dollars in alignment payments to ensure that such payments are made solely for the purposes permitted under this final rule.
- Restrictions on the types of providers and suppliers that may receive gainsharing payments and provisions requiring that those providers and suppliers have actually furnished a service to a beneficiary and/or been involved in care redesign, as required by this final rule.
- Limits on the absolute amount of dollars an individual practitioner or PGP may receive as gainsharing payments.
- Compliance from participant hospitals and CJR collaborators with the requirements of this final rule.

Finally, for the many reasons previously provided, we disagree with commenters who suggested that we proposed an arbitrary structure for financial arrangements in the CJR model. We acknowledge that any protections will inherently provide some limits on the flexibility of participant hospitals to develop certain financial arrangements, but we believe that the CJR model requirements appropriately balance the need for flexibility and program integrity.

Comment: Some commenters expressed confusion about the manner in which gainsharing payments can be distributed from participant hospitals to CJR collaborators. For example, these

commenters inquired about whether a physician who is engaged in CJR model care redesign with a participant hospital and is also a member of a PGP would contract directly with the participant hospital through a collaborator agreement or whether the PGP would contract with the participant hospital, including on behalf of the physician member who is working with the hospital.

Response: We appreciate these requests for clarification. We understand from the comments that some physicians engaged in care redesign with a participant hospital may wish to contract directly with a hospital through a collaborator agreement, and other physicians may prefer to have their PGP contract directly with a participant hospital on behalf of the members of the PGP that furnish services to CJR beneficiaries. We note that as previously discussed, we are finalizing our proposal with a modification to allow PGPs that are CJR collaborators to retain all or a portion of a gainsharing payment, provided that the PGP meets certain conditions. A PGP that does not retain any or all of a gainsharing payment can distribute all or the remaining portion of the gainsharing payment to individual practitioners who are members of the PGP under certain conditions. As such, we are adding new § 510.505 to set forth the requirements for the arrangement between a PGP that is a CJR collaborator and the individual practitioners who are members of the PGP. The section only applies when the PGP chooses to distribute all or a portion of a gainsharing payment to individual physicians or nonphysician practitioners who are members of the PGP.

We specify in § 510.505(a) that a PGP that has entered into a collaborator agreement with a participant hospital may distribute all or a portion of any gainsharing payment it receives from the hospital only in accordance with a ''distribution arrangement,'' which we define as a financial arrangement between a PGP that is a CJR collaborator and a ''practice collaboration agent'' pursuant to which the PGP distributes some or all of a gainsharing payment. We define a ''practice collaboration agent'' as a PGP member who has entered into a distribution arrangement with the same PGP of which he or she is a member and who has not entered into a collaborator agreement with a participant hospital. We are defining the terms ''PGP member'' and ''member of a PGP'' to mean a physician, nonphysician practitioner, or therapist who is an owner or employee of the PGP and who has reassigned to the PGP his or her right to receive Medicare payment. We note that the fact that an entity employs or contracts with physicians, nonphysician practitioners or therapists does not make the entity a PGP. We are adding commonplace definitions of ''physician'' and ''nonphysician practitioner'' and we are defining ''therapist'' to include physical, occupational, and speech therapists.

We emphasize that a PGP that is a CJR collaborator (hereafter in this section, ''a PGP,'' unless noted otherwise) is not obligated under this final rule to distribute (make a ''distribution payment'') of a gainsharing payment to its PGP members. Upon receipt of a gainsharing payment, the PGP may retain some or all of the gainsharing payment. If the PGP chooses to make distribution payments, it must do so only in accordance with a distribution arrangement. This final rule requires at new § 510.505 that all distribution arrangements must comply with all applicable laws and regulations, including the applicable fraud and abuse laws, and the following criteria:

- All distribution arrangements must be in a writing signed by the PGP and practice collaboration agent.
- Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.
- The distribution arrangement must require the practice collaboration agent to comply with the requirements set forth in this final rule.
- The opportunity to receive a distribution payment must not be conditioned directly on the volume or value of past or anticipated referrals or other business generated to, from, or among a participant hospital, the PGP, other CJR collaborator, any practice collaboration agents, and any individual or entity affiliated with a participant hospital, CJR collaborator, or practice collaboration agent.
- Methodologies for determining distribution payments must not directly account for volume or value of referrals, or business otherwise generated, between or among the participant hospital, CJR collaborators, practice collaboration agents, and any individual or entity affiliated with a participant hospital, CJR collaborator, or practice collaboration agent.
- A practice collaboration agent is eligible to receive a distribution payment only if the PGP billed for an item or service furnished by the practice collaboration agent to a CJR beneficiary during a CJR episode that occurred during the calendar year in which the participating hospital accrued the internal cost savings or earned the reconciliation payment that comprise the gainsharing payment made to the PGP.
- Where a PGP receives a gainsharing payment from a participant hospital pursuant to a sharing arrangement, all monies contained in such a gainsharing payment must be shared only with the physician or nonphysician practitioners that are PGP members that furnished a service to a CJR beneficiary during an episode of care in the calendar year from which the NPRA, as that term is defined in section III.C.6. of the final rule, or internal cost savings was generated, either or both of which are the only permitted sources of funds for a gainsharing payment.
- The total amount of distribution payments for a calendar year paid to a practice collaboration agent must not exceed 50 percent of the total Medicare approved amounts under the Medicare Physician Fee Schedule (MPFS) for services billed by the PGP and furnished by the practice collaboration agent to the participant hospital's CJR beneficiaries during a CJR episode.
- With respect to the distribution of any gainsharing payment received by a PGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment.
- All distribution payments must be made through EFTs.
- The practice collaboration agents must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.
- The distribution arrangement must not—

++ Induce a practice collaboration agent to reduce or limit medically necessary services to any Medicare beneficiary; or

++ Reward the provision of items and services that are medically unnecessary.

- The PGP must maintain documentation regarding practitioner distribution arrangements in accordance with § 510.500(e), including the relevant written agreements, documentation of the amount of any distribution payment, the identity of each practice collaboration agent who received a distribution payment, and a description of the methodology and accounting formula for calculating the amount of any distribution payment.
- The PGP may not enter into a distribution arrangement with any member of the PGP that has a collaborator agreement in effect with a participant hospital.

These provisions require distribution payments to be made by a PGP only to individuals who furnished an item or service to a CJR beneficiary during a CJR

episode. As a result, a PGP's existing practice compensation methodology is likely to be inapplicable to the determination and payment of distribution payments. For example, where a PGP retains a gainsharing payment and elects not to make distribution payments to eligible practice collaboration agents, the aforementioned criteria would prohibit the PGP from placing the gainsharing payment in its general funds and distributing those monies to any member of the PGP who did not furnish an item or service to a CJR beneficiary during a CJR episode that occurred during the calendar year in which the participating hospital accrued the internal cost savings or earned the reconciliation payment that comprise the gainsharing payment made to the PGP. We emphasize that such individuals are not permitted under this final rule to receive a distribution payment.

Comment: Some commenters requested that CMS offer additional protections to small businesses, such as some physical therapy or physician group practices, who may desire to engage as CJR collaborators with participant hospitals, but may have limited resources to do so. Recommendations from these commenters were for CMS to ensure that gainsharing payments are paid in a timely manner, that gainsharing payments are distributed fairly and equitably to CJR collaborators according to the provisions in this final rule as well as those agreed upon in a collaborator agreement, and that participant hospitals and CJR collaborators not be permitted to engage in unfair business practices.

Response: It is our intent to construct a model that offers opportunities for providers and suppliers of all sizes to be CJR collaborators, provided they meet the criteria in this final rule. In response to the timely payment comment, we direct those commenters to the requirement that gainsharing payments must be distributed on an annual basis. Accordingly, a gainsharing payment can only be distributed to eligible CJR collaborators once per year. As previously noted, CMS is not requiring participant hospitals to enter into collaborator agreements with all providers and suppliers caring for CJR beneficiaries, but where a hospital does enter one or more collaborator agreements, the participant hospital must not distribute any gainsharing payments more than once per year. We believe that this requirement ensures that gainsharing payments are timed to sufficiently maintain a CJR collaborator's commitment to lowering costs and improving quality of care.

To the extent the commenters were advocating that CMS prohibit late payment of amounts owed to CJR collaborators, we believe that the consequences for breach of contract offer sufficient protection. Regarding the commenters' desire to ensure that gainsharing payments are distributed fairly and equitably to CJR collaborators, we believe that the provisions of this final rule adequately address their comment. For example, this final rule prohibits participant hospitals and all CJR collaborators from reducing or limiting medically necessary services, prohibits conditioning the opportunity to receive gainsharing payments on the volume or value of referrals, requires gainsharing payment eligibility to include quality criteria and gainsharing payment determinations to be based on criteria related to the quality of care to be delivered to CJR beneficiaries during episodes, prohibits gainsharing methodologies that directly account for the volume or value of referrals, and caps the amount a physician or nonphysician practitioner can receive in gainsharing payments as a CJR collaborator. Finally, we agree with the commenters that it is important to deter unfair business practices, but the regulation of such practices is outside the scope of our authority. Accordingly, we decline to add a prohibition against unfair business practices. However, we believe that many of the program integrity provisions regarding sharing arrangements will also serve to deter unfair business practices.

Comment: A few commenters suggested that CMS should encourage participant hospitals and CJR collaborators to establish multi-year collaborator agreements, with the goal of fostering a long-term relationship resulting in optimal program alignment.

Response: Nothing in this final rule prohibits participant hospitals and CJR collaborators from entering into collaborator agreements for a duration of more than one year.

Comment: Several commenters opposed the adoption of reporting requirements for gainsharing and alignment payments, a topic upon which CMS sought comment but did not make a specific proposal. Alternatively, these commenters recommended CMS should not finalize the adoption of reporting requirements without considering the administrative burden such reporting would place on hospitals. However, other commenters recommended that CMS take a more active role in managing the agreements and payments between participant hospitals and CJR collaborators. For example, some commenters recommended that all collaborator agreements should be submitted to CMS and that CMS should perform random audits of these agreements to ensure they comply with current regulations. Another commenter urged CMS to track all gainsharing payments from participant hospitals to each CJR collaborator. Furthermore, multiple commenters recommended that CMS include a requirement that participant hospitals submit to CMS, or publish themselves, a list of all CJR collaborators. These commenters believe that disclosure of all sharing arrangements would foster transparency regarding the business and referral networks of providers and suppliers that may arise through sharing arrangements.

Response: We appreciate the feedback with respect to the potential burden of periodically reporting data to CMS on matters related to gainsharing payments. We proposed to require participant hospitals to retain documentation regarding sharing arrangements and solicited comments on whether we should require participant hospitals and CJR collaborators to periodically report certain data, including gainsharing payments, alignment payments, identification of all CJR collaborators, and other relevant information related to collaborator agreements and sharing arrangements. We also sought comment on whether we should require reporting of any other information that would assist HHS with enforcement of the regulations governing this model and whether additional or different safeguards are needed to protect the program and to ensure that its goals are satisfied.

We agree with the commenters that transparency is important to ensure program integrity and to assist with evaluation of the model. We have tried, where possible, to ensure transparency regarding sharing arrangements and distribution arrangements without imposing undue administrative burden on the individuals and entities that enter into such arrangements.

Because documenting financial arrangements is consistent with general business practices, we believe that our documentation requirement imposes minimal additional administrative burden on participant hospitals and CJR collaborators. To promote transparency, we are modifying our regulation text to require contemporaneous documentation of collaborator agreements. This will discourage gaming by ensuring that these agreements are entered into before care is furnished to CJR beneficiaries.

Further, we are modifying our regulation text to require that the documentation for collaborator agreements must include a description of the sharing arrangement; its date; the purpose; the provisions and scope of the arrangement; and the financial terms of the arrangement. We believe that these requirements will ensure that these agreements are entered into before the care furnished to CJR beneficiaries and will be auditable by the government. We have imposed similar requirements for distribution arrangements.

We do not agree that it is necessary for participant hospitals to submit periodically to CMS documentation regarding sharing arrangements, lists of CJR collaborators, or documentation regarding all gainsharing payments and alignment payments. We are sensitive to the potential burden of such a reporting requirement. We believe that the goals of transparency and program integrity can be achieved by requiring participant hospitals and CJR collaborators to retain contemporaneous documentation of collaborator agreements, gainsharing payments, and alignment payments for at least 10 years following completion of the arrangement and to allow CMS, HHS, or its designee's access to such records. In addition, we are modifying the regulation text to require each participant hospital to maintain accurate, current, and historical lists of CJR collaborators and to publish on its Web site, on a Web page accessible to the general public, an accurate and current list of all CJR collaborators. The hospital must update its published list of CJR collaborators no less frequently than quarterly. The dollar amounts of any gainsharing payments or alignment payments need not be listed on the participant hospital's Web site.

We note that the participant hospital's records associated with tracking gainsharing payments must reflect whether the participant hospital recouped any gainsharing payments received by a CJR collaborator that contain funds derived from a CMS overpayment on a reconciliation report or because such gainsharing payments were the result of the submission of false or fraudulent data. Similarly, this final rule also requires PGPs to maintain documentation regarding distribution arrangements in accordance with § 510.500(e), including the relevant written agreements, documentation of the amount of any distribution payment, the identity of each practice collaboration agent who received a distribution payment, and a description of the methodology and accounting formula for determining the amount of any distribution payment. We have revised the regulation text to reflect these requirements.

We do not believe that the obligation to maintain accurate current or historical lists of CJR collaborators and documentation regarding all gainsharing payments and alignment payments, imposes any significant additional burden on participant hospitals. Participant hospitals will likely maintain such lists for their own operational purposes whether or not they are required by our regulations to do so. We believe that maintaining an accurate list of all CJR collaborators and documentation regarding all gainsharing payments, alignment payments, and distribution payments is a necessary and appropriate provision for purposes of transparency, keeping beneficiaries informed, and ensuring that such information is auditable by CMS, HHS, or its designees. We also believe that such information will help inform both CMS and the public about collaborator agreements.

We leave open the possibility for future rulemaking on the issue of documentation and reporting for this model. CMS may consider additional documentation requirements, including submission of lists of CJR collaborators and practice collaboration agents to CMS at regular, ongoing intervals.

Summary of Final Decisions: After consideration of the public comments we received, we are finalizing the proposal with thirteen modifications. These modifications are:

- The term ''Participation Agreement'' has been changed to ''collaborator agreement''.
- The term ''CJR sharing arrangement'' has been changed to ''sharing arrangement''.
- In order for a physician or nonphysician practitioner to be a CJR collaborator, the physician or nonphysician practitioner must not have opted out of Medicare.
- PGPs that are CJR collaborators may retain all or a portion of a gainsharing payment, provided that the PGP meets all the criteria in this final rule for such retention.
- Sharing arrangements, included in collaborator agreements, must be entered into before care is furnished to CJR beneficiaries under the terms of the arrangement.
- A requirement that the participant hospital develop and maintain a written set of policies for selecting its CJR collaborators. This set of policies must contain criteria for selection of CJR collaborators that include criteria related to, and inclusive of, the quality of care to be delivered to beneficiaries during a CJR episode. The selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the participant hospital and CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator. All CJR collaborators must have met, or agree to meet, the quality criteria for selection.
- A requirement that the participant hospital include in its collaborator agreements with CJR collaborators the methodology the participant hospital will use to determine gainsharing payments, and this methodology must be based, at least in part, on criteria related to, and inclusive of, the quality of care to be delivered to beneficiaries during a CJR episode, and not directly on the volume or value of referrals or business otherwise generated by, between or among the participant hospital and CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator
- A requirement that the participant hospital, in considering the quality criteria to incorporate as part of its gainsharing methodologies, use quality criteria that are directly related to CJR episodes of care, so that the criteria used by the participant hospital are relevant to care for beneficiaries in the model. Any CJR collaborator that does not meet the quality criteria described with specificity in the sharing arrangement is not eligible for a gainsharing payment for the calendar year for which the gainsharing payment is being determined.
- Requirements that the participant hospital keep contemporaneous documentation of collaborator agreements.
- A requirement that the participant hospital maintain accurate current and historical lists of CJR collaborators.
- A requirement that the participant hospital publish on its Web site, on a Web page accessible to the general public, accurate current and historical lists of CJR collaborators.
- A participant hospital must not make a gainsharing payment to a CJR collaborator that is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the provision of substandard care in CJR episodes or other integrity problems.
- A regulatory framework has been created to allow PGPs that are CJR collaborators to share all or portions of gainsharing payments with individual practitioners that are members of the PGP. These requirements are set forth in new § 510.505.

With the exception of new § 510.505, the final policies are set forth in

§ 510.500, which we have reorganized to eliminate redundancy and internal inconsistencies and to more clearly set forth the requirements for CJR sharing arrangements.

''General.'' We are finalizing at § 510.500(a) the following general requirements for all sharing arrangements that a participant hospital may elect to enter into:

- A participant hospital must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement. Any gainsharing payments or alignment payments made pursuant to a sharing arrangement must be made only from the participant hospital to the CJR collaborator with whom the participant hospital has signed a collaborator agreement containing a sharing arrangement.
- CMS may review any sharing arrangement for compliance with the requirements of this part and to ensure that it does not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.
- Notwithstanding any sharing arrangements between the participant hospital and CJR collaborators, the participant hospital must have ultimate responsibility for fully complying with all provisions of the CJR model.
- If a participant hospital enters into a sharing arrangement, it must update its compliance program to include oversight of sharing arrangements and compliance with the requirements of the CJR model.
- The board or other governing body of the participant hospital must have responsibility for overseeing the participant hospital's participation in the model, its arrangements with CJR Collaborators, its payment of gainsharing payments and receipt of alignment payments, and its use of beneficiary incentives in the CJR model.
- Participant hospitals must develop and maintain a written set of policies for selecting its CJR collaborators. This set of policies must contain criteria for selection of CJR collaborators that include criteria related to, and inclusive of, the quality of care to be delivered by the CJR collaborator to beneficiaries during a CJR episode. The selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the participant hospital and CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator. All CJR collaborators must have met, or agree to meet, the quality criteria for selection.

''Sharing Arrangements.'' We have consolidated at § 510.500(b) the criteria that each sharing arrangement must satisfy. Specifically, each sharing arrangement must comply with the following criteria:

- The sharing arrangement must be set forth in a collaborator agreement that complies with the requirements of § 510.500(c).
- The sharing arrangement must comply with all relevant laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.
- An individual or entity's participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.
- The parties must enter into a sharing arrangement before care is furnished to CJR beneficiaries under the terms of the sharing arrangement.
- To be eligible to receive a gainsharing payment, a CJR collaborator must meet quality criteria for the calendar year for which the gainsharing payment is determined by the participant hospital. The quality criteria must be established by the participant hospital and directly related to CJR episodes of care.
- To be eligible to receive a gainsharing payment or make an alignment payment, a CJR collaborator other than a PGP must directly furnish a billable service to a CJR beneficiary during a CJR episode that occurred in the calendar year in which the savings or loss was created.
- To be eligible to receive a gainsharing payment, a PGP that is a CJR collaborator must meet the following criteria:

++ The PGP must have billed for an item or service that was rendered by one or more members of the PGP to a CJR beneficiary during a CJR episode that occurred during the calendar year in which the participant hospital's internal cost savings was generated, or to which the NPRA applied;

++ The PGP must contribute to a participant hospital's care redesign in the CJR model and be clinically involved in the care of CJR beneficiaries. We set forth in the regulation a non-exhaustive list of ways in which a PGP might be clinically involved in the care of CJR beneficiaries.

- No entity or individual, whether a party to a collaborator agreement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments on the volume or value of referrals or business otherwise generated by, between or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.
- Gainsharing payments, if any, must be—

++ Derived solely from reconciliation payments, or internal cost savings, or both;

++ Actually and proportionally related to the care of beneficiaries in a CJR episode;

++ Distributed on an annual basis (not more than once per calendar year); and

++ Not be a loan, advance payments, or payments for referrals or other business.

- Alignment payments from a CJR collaborator to a participant hospital may be made at any interval that is agreed upon by both parties, and must—

++ Not be issued, distributed, or paid prior to the calculation and issuance by CMS of a reconciliation report reflecting a repayment amount; and

++ Not be a loan, advance payments, or payments for referrals or other business.

- A participant hospital must not make a gainsharing payment to a CJR collaborator that is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the provision of substandard care in CJR episodes or other integrity problems.
- In a calendar year, the aggregate amount of all gainsharing payments distributed by a participant hospital that are derived from a CJR reconciliation payment may not exceed the amount of the reconciliation payment the participant hospital receives from CMS.
- In a calendar year, the aggregate amount of all alignment payments received by the participant hospital must not exceed 50 percent of the participant hospital's repayment amount. No alignment payments may be collected by a participant hospital if it does not owe a repayment amount.
- The aggregate amounts of all alignment payments from any one CJR collaborator to a participant hospital must not be greater than 25 percent of the participant hospital's repayment amount.
- A sharing arrangement must not induce the participant hospital, CJR collaborator, or any employees or contractors of the participant hospital or CJR collaborator to reduce or limit medically necessary services to any Medicare beneficiary.
- A sharing arrangement must not restrict the ability of a CJR collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.
- The methodology for determining gainsharing payments must be based, at

least in part, on criteria related to, and inclusive of, the quality of care to be delivered to CJR beneficiaries during an episode and must not directly account for the volume or value of referrals or business otherwise generated by, between or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

• The methodology for determining alignment payments must not directly account for the volume or value of referrals or business otherwise generated by, between or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

• The total amount of a gainsharing payment for a calendar year paid to an individual physician or nonphysician practitioner who is a CJR collaborator must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule (PFS) for services furnished to the participant hospital's CJR beneficiaries during a CJR episode by that physician or nonphysician practitioner.

• The total amount of gainsharing payments for a calendar year paid to a PGP that is a CJR collaborator must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule (PFS) for services that are billed by the PGP and furnished during a calendar year by members of the PGP to the participant hospital's CJR beneficiaries during CJR episodes.

• The participant hospital's determination of internal cost savings must satisfy the following criteria:

++ Internal cost savings are calculated in accordance with generally accepted accounting principles and Government Auditing Standards (The Yellow Book).

++ All amounts determined to be internal cost savings must reflect actual, internal cost savings achieved by the participant hospital through implementation of care redesign elements identified and documented by the participant hospital. Internal cost savings does not include savings realized by any individual or entity that is not the participant hospital.

++ Internal cost savings may not reflect ''paper'' savings from accounting conventions or past investment in fixed costs.

• All gainsharing payments and any alignment payments must meet the requirements set forth in this section and be administered by the participant hospital in accordance with generally accepted accounting principles. In no event may the participant hospital receive any amounts from a CJR collaborator under a sharing arrangement that are not alignment payments.

• All gainsharing payments and alignment payments must be made through electronic funds transfers.

''Participation Agreements.'' We proposed a number of provisions that we believed should be set forth in the sharing arrangement or participation agreement (now termed ''collaborator agreement''). We have finalized and consolidated these provisions under § 510.500(c). Specifically, we are finalizing our proposal to require that each collaborator agreement must include and set forth in writing the following:

• The collaborator agreement must contain a description of the arrangement between the participant hospital and the CJR collaborator regarding gainsharing payments and alignment payments. This description must specify the following:

++ The parties to the sharing arrangement.

++ The date of the sharing arrangement.

++ The purpose and scope of the sharing arrangement; ++ The financial or economic terms of the sharing arrangement, including the frequency of payment, and the methodology and accounting formula for determining the amount of any gainsharing payment or alignment payment.

++ Safeguards to ensure that alignment payments are made solely for purposes related to sharing responsibility for funds needed to repay Medicare in the CJR model.

++ Plans regarding care redesign.

++ Changes in care coordination or delivery that is applied to the participant hospital or CJR collaborators or both.

++ A description of how success will be measured.

++ Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out changes to care under the model.

• The collaborator agreement must contain a requirement that the CJR collaborator and its employees and contractors must comply with the applicable provisions of this part (including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees) and all other applicable laws and regulations.

• The collaborator agreement must require the CJR collaborator to be in compliance with all Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the agreement.

• The collaborator agreement must require the CJR collaborator to have a compliance program that includes oversight of the collaborator agreement and compliance with the requirements of the CJR model.

• The collaborator agreement must set forth a specific methodology for accruing, calculating, and verifying the internal cost savings generated by the participant hospital based on the care redesign elements specifically associated with the particular CJR collaborator.

++ The methodology must set out the specific care redesign elements to be undertaken by the participant hospital or the CJR collaborator or both.

++ The methodology must be based, at least in part, on criteria related to, and inclusive of, the quality of care to be delivered to CJR beneficiaries during an episode and must not directly account for the volume or business otherwise generated by, between, or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

++ The specific methodologies for accruing and calculating internal cost savings must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles and Government Auditing Standards (The Yellow Book).

• The collaborator agreement must set forth the quality criteria established by the participant hospital that will be used in determining the gainsharing payment.

• The collaborator agreement must require the participant hospital to recoup gainsharing payments paid to CJR collaborators if gainsharing payments contain funds derived from a CMS overpayment on a reconciliation report, or were based on the submission of false or fraudulent data.

• Any alignment payments made pursuant to a sharing arrangement may be made only to the participant hospital from the entity or individual with whom the participant hospital has signed a collaborator agreement containing a sharing arrangement.

• The collaborator agreement must require the CJR collaborator to comply with the beneficiary notice requirements specified in § 510.405, as applicable.

• Any internal cost savings or reconciliation payments that the participant hospital seeks to share through sharing arrangements must

meet the requirements set forth in this final rule and be administered by the participant hospital in accordance with GAAP. In no event may the participant hospital distribute any amounts pursuant to a sharing arrangement that are not comprised of either internal cost savings or a reconciliation payment, as those terms are defined in this final rule. All amounts determined to be internal cost savings by the participant hospital must reflect actual, internal cost savings achieved by the participant hospital through implementation of care redesign elements identified and documented by the participant hospital. In no case may internal cost savings reflect ''paper'' savings from accounting conventions or past investment in fixed costs.

• Any alignment payments that the participant hospital receives through a sharing arrangement must meet the requirements set forth in this final rule and be administered by the participant hospital in accordance with GAAP.

• Sharing arrangements must not include any amounts that are not alignment payments or gainsharing payments.

• Each collaborator agreement —

++ Between the participant hospital and a CJR collaborator must obligate the CJR collaborator to provide the participant hospital and HHS access to the CJR collaborator's records, information, and data for purposes of monitoring and reporting and any other lawful purpose. Records, information, and data regarding the sharing arrangement must have sufficient detail to verify compliance with all material terms of the sharing arrangement and the terms of the CJR model;

++ Must require the participant hospital and the CJR collaborator to include in their compliance programs specific oversight of their collaborator agreements and compliance with the requirements of the CJR model;

++ If the participant hospital or CJR collaborator does not have a compliance program, each party must create one and incorporate the provisions described in this part in that program; and

++ Must require the board or other governing body of the participant hospital to have responsibility for overseeing the participant hospital's participation in the model, its arrangements with CJR Collaborators, its payment of Gainsharing Payments and receipt of Alignment Payments, and its use of beneficiary incentives in the CJR model.

• Collaborator agreements must require all CJR collaborators to comply with any evaluation, monitoring, compliance, and enforcement activities performed by HHS (including CMS and OIG) and its designees for the purposes of operating the CJR model.

• Each collaborator agreement must require the CJR collaborator to permit site visits from CMS, and its designees, for purposes of evaluating the model.

''Documentation and Maintenance of Records.'' We are finalizing at § 510.500(d) our proposal with regard to certain documentation requirements, and we are finalizing at new § 510.500(e) our proposal regarding access to documents and record retention. Under § 510.500(d), we require the following documentation:

• Documentation of any collaborator agreement containing a sharing arrangement must be contemporaneous with the establishment of the arrangement.

• A participant hospital must maintain accurate current and historical lists of all CJR collaborators, including their names and addresses. The participant hospital must update the lists on at least a quarterly basis and publicly report the current and historical lists of CJR collaborators on a public-facing Web page on the participant hospital's Web site.

• The participant hospital and CJR collaborator must maintain contemporaneous documentation of the payment or receipt of any gainsharing payment or alignment payment. The documentation must identify at least the following: The nature of the payment (gainsharing payment or alignment payment); the identity of the parties making and receiving the payment; the date of the payment; the amount of the payment; and the date and amount of any recoupment of all or a portion of a CJR collaborator's gainsharing payment.

++ The participant hospital must keep records of the following:

++ Its process for determining and verifying the eligibility of CJR collaborators to participate in Medicare.

++ Information confirming the organizational readiness of the participant hospital to measure and track internal cost savings.

++ The participant hospital's plan to track internal cost savings.

++ Information on the accounting systems used to track internal cost savings.

++ A description of current health information technology, including systems to track reconciliation payments and internal cost savings.

++ The participant hospital's plan to track gainsharing payments and alignment payments.

++ Whether the participant hospital recouped any gainsharing payments received by a CJR collaborator that contain funds derived from a CMS overpayment on a reconciliation report, or were based on the submission of false or fraudulent data.

''Access to Records and Record Retention.'' Section 510.500(e) finalizes our proposal regarding government access to books and records and document retention requirements. Specifically, § 510.500(e) requires that each participant hospital and CJR Collaborator, at a minimum, adhere to the following requirements:

• Provide to CMS, the OIG, and the Comptroller General or their designees scheduled and unscheduled access to all books, contracts, records, documents, and other evidence (including data related to utilization and payments, quality criteria, billings, lists of CJR collaborators, sharing arrangements, and distribution arrangements, and other documentation) sufficient to enable the audit, evaluation, inspection, or investigation of the individual's or entity's compliance with CJR requirements, the quality of services furnished, the obligation to repay any reconciliation payments owed to CMS, or the calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, or distribution payments.

• Maintain such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the participant hospital's participation in the CJR model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

++ CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the participant hospital or CJR collaborator at least 30 calendar days before the normal disposition date; or

++ There has been a dispute or allegation of fraud or similar fault against the participant hospital or any CJR collaborator in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

We are finalizing without modification our proposal that OIG Authority is not limited or restricted by the provisions of the CJR model, including the authority to audit, evaluate, investigate, or inspect the participant hospital, CJR Collaborators, or any other person or entity or their records, data, or information, without limitation. In addition, we are finalizing without change our proposal that none of the provisions of the CJR model limits or restricts any other government authority permitted by law to audit,

evaluate, investigate, or inspect the participant hospital, CJR Collaborators, or any other person or entity or their records, data, or information, without limitation. These provisions are finalized at§ 510.510.

''Distribution Arrangements.'' As previously noted, we are finalizing our proposal with a modification to allow PGPs that are CJR collaborators to enter into distribution arrangements for the purposes of distributing all or a portion gainsharing payment with certain PGP members (practice collaboration agents). We note that we are not requiring the PGP to distribute all or a portion of a gainsharing payment to its member physicians and nonphysician practitioners. But where a PGP chooses to make such distributions, this final rule requires at new § 510.505 that all distribution arrangements must comply with all applicable laws and regulations and the following criteria:

- All distribution arrangements must be in writing and signed by the PGP and practice collaboration agent.
- Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.
- The distribution arrangement must require the practice collaboration agent to comply with the requirements set forth in this part.
- The opportunity to receive a distribution payment must not be conditioned directly or indirectly on the volume or value referrals or business otherwise generated by, between or among a participant hospital, the PGP, other CJR collaborators, any practice collaboration agents, and any individual or entity affiliated with a participant hospital, CJR collaborator, or practice collaboration agent.
- Methodologies for determining distribution payments must not directly account for the volume or value of referrals, or business otherwise generated, by, between or among the participant hospital, CJR collaborators, other CJR collaborators, practice collaboration agents, and any individual or entity affiliated with a participant hospital, CJR collaborator, or practice collaboration agent.
- A practice collaboration agent is eligible to receive a distribution payment only if the PGP billed for an item or service furnished by the practice collaboration agent to a CJR beneficiary during a CJR episode that occurred during the calendar year in which the participating hospital accrued the internal cost savings or earned the reconciliation payment that comprise the gainsharing payment made to the PGP.
- Where a PGP receives a gainsharing payment from a participant hospital pursuant to a sharing arrangement, all monies contained in such a gainsharing payment must be shared only with the physician or nonphysician practitioners that are PGP members that furnished a service to a CJR beneficiary during an episode of care in the calendar year from which the NPRA, as that term is defined in section III.C.6. of the final rule, or internal cost savings was generated, either or both of which are the only permitted sources of funds for a gainsharing payment.
- The total amount of distribution payments for a calendar year paid to an individual physician or nonphysician practitioner who is a practice collaboration agent must not exceed a cap. The total amount of distribution payments for a calendar year paid to a practice collaboration agent must not exceed 50 percent of the total Medicare approved amounts under the Medicare Physician Fee Schedule (MPFS) for services billed by the PGP and furnished by the practice collaboration agent to the participant hospital's CJR beneficiaries during a CJR episode.
- With respect to the distribution of any gainsharing payment received by a PGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment.
- All distribution payments must be made through electronic funds transfers.
- The practice collaboration agents must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.
- The distribution arrangement must not—

++ Induce a practice collaboration agent to reduce or limit medically necessary services to any Medicare beneficiary; or

++ Reward the provision of items and services that are medically unnecessary.

- The PGP must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 510.500(e), including the relevant written agreements, the date and amount of any distribution payment, the identity of each practice collaboration agent who received a distribution payment, and a description of the methodology and accounting formula for determining the amount of any distribution payment.
- The PGP may not enter into a distribution arrangement with any member of the PGP that has a collaborator agreement in effect with a participant hospital.

b. Beneficiary Incentives Under the CJR Model

In the proposed rule, we stated our belief that the CJR model would incent participant hospitals to furnish services directly and otherwise coordinate services throughout the episode that lead to higher quality care for the beneficiary and lower episode spending. We proposed that one mechanism that may be useful to the participant hospital in achieving these goals would be the provision of certain items and services to the beneficiary during the episode of care. We also considered whether this policy on beneficiary incentives should extend to providers and suppliers, other than the participant hospital, that furnish services during the CJR episode of care. In the proposed rule, we stated our belief that hospitals are better suited than other providers and suppliers to provide beneficiary incentives. Thus, we proposed that participant hospitals could choose to provide certain in-kind patient engagement incentives to the beneficiary, subject to a number of conditions, including the following:

- The incentive must be provided by the participant hospital to the beneficiary during CJR episode of care.
- There must be a reasonable connection between the item or service and the beneficiary's medical care.
- The item or service must be a preventive care item or service or an item or service that advances a clinical goal for a CJR beneficiary, including the following: Increasing the beneficiary's engagement in the management of his or her own health care; adherence to a treatment or drug regimen; adherence to a follow-up care plan; reduction of readmissions and complications resulting from LEJR procedures; and management of chronic diseases and conditions that may be affected by the LEJR procedure.
- Items of technology must comply with certain safeguards, as discussed later in this section.
- The participant hospital must maintain contemporaneous documentation of the incentives provided to beneficiaries for a period of 10 years.
- The cost of the incentives must not be shifted to another federal health care program.

For example, under this proposal, participant hospitals could provide incentives such as post-surgical monitoring equipment to track patient weight and vital signs for post-surgical patients discharged directly to home, but they could not provide theater tickets, which would bear no reasonable connection to the patient's medical care.

Similarly, we proposed that participant hospitals might provide post-surgical monitoring equipment, but not broadly used technology that is more valuable to the beneficiary than equipment that is reasonably necessary for the patient's post-surgical care. In such circumstances, a reasonable inference arises that the technology would not be reasonably connected to the medical care of the patient. Among other things, this safeguard precludes incentives that might serve to induce beneficiaries inappropriately to receive other medical care that is not included in the episode.

In addition to the conditions previously noted, we proposed that participant hospitals would be required to maintain contemporaneous documentation of such items and services furnished whose value exceeds $10, including the date and identity of the beneficiary to whom the item or service was provided. We further proposed that the required documentation be maintained for a period of 10 years.

We also proposed that items and services involving technology provided to beneficiaries may not exceed $1,000 in retail value at the time of donation for any one beneficiary in any one CJR episode. Items of technology exceeding $50 in retail value at the time of donation must remain the property of the participant hospital and must be retrieved from the beneficiary at the end of the episode, with the documentation of the date of retrieval. In addition, we proposed that the amount and nature of the technology must be the minimum necessary to achieve the goals previously noted earlier in this section. Finally, we proposed that beneficiary incentives may not be tied to the receipt of services outside the episode of care and that the cost of the incentives cannot be shifted to a federal health care program. Our proposals regarding beneficiary incentives are consistent with the policies on beneficiary incentives in other CMS models, such as the BPCI initiative.

We sought comment on our proposal for beneficiary incentives under CJR. In addition to general comments on the proposal, we described our interest in comments on whether the $1000 retail value limit on technology items and services is necessary, reasonable, and appropriate. We also solicited comment on whether retrieving technology valued at more than $50 would be too burdensome and whether elimination of that requirement would prevent abuse. We also solicited comment on the documentation requirement for items and services furnished that exceed $10, or whether a different amount would be more appropriate and less burdensome. We welcomed comments on additional program integrity safeguards for these arrangements.

We proposed to set forth the CJR beneficiary incentives policies in § 510.505. However, in this final rule, the beneficiary incentives section has been renumbered to § 510.515. Thus, the following discussion incorporates the final beneficiary incentive policies under the new section number.

The following is a summary of the comments received and our responses.

Comment: Many commenters expressed appreciation for CMS' proposal to permit beneficiary incentives to be provided by participant hospitals. The commenters agreed that CMS should establish certain conditions under which beneficiary incentives would be permitted, in order to ensure that beneficiary incentives are used solely to advance the goals of the CJR model for the beneficiary's care. These commenters further agreed that the beneficiary incentives should only be used when a beneficiary was in a CJR episode.

Several commenters expressed concern about the use of beneficiary incentives in a payment model such as the CJR model that commonly includes a substantial period of PAC services which may be furnished by different provider types during the episode, as opposed to the more traditional use of beneficiary incentives in a wellness environment where such incentives are related to prevention and primary care. The commenters urged CMS to maintain the requirement of a reasonable connection between the service and a beneficiary's medical care and that the service advance a meaningful clinical goal for the beneficiary under the CJR model. The commenters suggested that CMS take two further actions to strengthen the protections against hospitals' misuse of beneficiary incentives to influence the beneficiary's choice of providers and types of care. First, they recommended that CMS include strong and specific language prohibiting the formal or informal use of incentives as a way to steer beneficiaries toward a certain provider or type of services. Second, they urged CMS to additionally require that hospitals offer beneficiary incentives in the same way to all patients and that the hospital make their beneficiary incentive policy publicly available.

Response: We appreciate the support of the commenters for our proposal to allow beneficiary incentives under certain conditions in the CJR model, including requirements related to advancing a clinical goal and use of the incentive during the episode. We wish to clarify that beneficiary incentives should be reasonably connected to medical care that is provided during an episode, which is consistent with our proposal that beneficiary incentives not be tied to the receipt of services outside the episode of care. We note that the clinical goals of the model that may be advanced through beneficiary incentives include beneficiary adherence to drug regimens, beneficiary adherence to a care plan, reduction of readmissions and complications resulting from LEJR procedures, and management of chronic diseases and conditions that may be affected by the LEJR procedure. We further note that this final rule defines an episode to include services for chronic diseases and conditions that may be affected by the LEJR procedure or post-surgical care (see section III.B.2.b. of this final rule). To the extent that services for these chronic conditions are included in CJR model episodes, we believe it is appropriate to permit beneficiary incentives to manage these chronic diseases and conditions during the episode. For example, we would consider a beneficiary incentive to advance the clinical goals of the CJR model and to be connected to medical care provided to the beneficiary during the episode if the incentive is related to a chronic condition, such as diabetes or congestive heart failure, that may be affected by the LEJR procedure or post-surgical care and is included in the LEJR episode.

We appreciate the concerns of some commenters about the potential misuse of beneficiary incentives to steer beneficiaries toward a certain type of provider or type of services. We believe that requiring beneficiary incentives to be provided only by a participant hospital partially reduces the likelihood that such an incentive would be used to steer a beneficiary toward a specific PAC provider or type of PAC services. We are accepting the commenters' suggestion to add a requirement that beneficiary incentives must not be tied to the receipt of items or services from a particular provider or supplier. We believe this requirement, which will appear at new § 510.515(a)(5), will further reduce the potential for use of beneficiary incentives to steer a beneficiary toward a specific provider or supplier.

While we agree with the commenters who recommended that we explicitly prohibit the use of beneficiary incentives to steer a beneficiary toward a certain type of provider or types of services, we do not believe that hospitals should be required to offer the incentives in the same way to all

beneficiaries in the model or to make their policies regarding beneficiary incentives publicly available. Hospitals may want to offer beneficiary incentives to those CJR model beneficiaries with the greatest need, even if CJR model beneficiaries have similar clinical goals. In addition, we do not believe it would be appropriate to require hospitals to make their policies regarding beneficiary incentives publicly available because, as later discussed in this section, we do not believe that the availability of beneficiary incentives should be advertised or marketed to beneficiaries.

We believe that certain aspects of our proposal on beneficiary incentives will help to protect the program and beneficiaries from misuse of such incentives, including the requirements that only a hospital may provide patient incentives, that the incentives must be furnished during an episode of care, and that the item or service is either a preventive care item or service or advances a clinical goal for a CJR beneficiary. Accordingly, we are finalizing the conditions that we proposed in § 510.515(a)(1) and (2), but with some modification. First, we wish to clarify that the items and services may be provided by the hospital through an agent who is under the hospital's direction and control. We note that if a reasonable beneficiary would perceive the item or service as being from the agent rather than the hospital, we would not consider the incentive to have been provided by the hospital. Second, as previously noted, we are clarifying in § 510.515(a)(2) that the items and services must be reasonably connected to medical care provided to a beneficiary during an episode. We are separately incorporating the requirement that the item or service be a preventive care item or service or advance a clinical goal for a beneficiary in a CJR episode in new § 510.515(a)(3). In addition, we are also adding a new § 510.515(a)(4) to set forth the proposed requirement that the item or service must not be tied to the receipt of services outside of the episode of care. To clarify, our proposed requirement that the item or service must not be tied to the receipt of services outside of the episode of care should have also referred to the receipt of items outside of the episode of care. Thus, the new § 510.515(a)(4) requires that the item or service must not be tied to the receipt of items or services outside of the episode of care.

Comment: Some commenters recognized that beneficiary incentives have potential value to model beneficiaries, especially the use of new technology that will help beneficiaries better monitor their health. However, they pointed out that the incentives could be a financial burden on hospitals when model beneficiaries can choose any provider for their care. They added that beneficiary incentives would lead to a cost to the hospital, with no guarantee of quality improvement. The commenters expressed concerns that small benefits due to beneficiary incentives would be outweighed by their costs to hospitals and the additional cost to CMS of monitoring their use.

Response: We recognize that the provision of beneficiary incentives may create some additional costs and administrative burden for participant hospitals. However, we believe that it is important to provide participant hospitals with the option to furnish beneficiary incentives in a manner that will not result in patient steering or other abuse. The participant hospitals are not required to offer beneficiary incentives. Thus, hospitals are free to determine whether it will be useful or feasible to provide beneficiary incentives in accordance with the terms of this final rule.

Comment: Several commenters recommended that CMS not permit marketing of beneficiary incentives, similar to the existing requirements for beneficiary incentives in Medicare Advantage plans. The commenters stated that this additional condition would provide further protection against the potential for beneficiary incentives being used to steer beneficiaries to certain providers.

Response: We agree that beneficiary incentives should not be marketed to beneficiaries, because this could unduly influence their selection of a provider or type of service. As discussed previously, we are incorporating the requirement that beneficiary incentives must not be tied to the receipt of items or services from a particular provider or supplier. We believe it would be difficult to meet this requirement if the availability of the items or services was advertised or promoted except in the case where a CJR beneficiary is only made aware of the availability of the items or services at the time the beneficiary could reasonably benefit from them. For example, when a participant hospital initiates post-discharge planning for a CJR beneficiary with a chronic health condition, the participant hospital could discuss providing the beneficiary with an electronic tablet for home use to track certain measurements and health information and to transmit this information periodically to the beneficiary's physician to aid in post-operative recovery and management of the chronic health condition. We are including this condition in new § 510.515(a)(6).

Comment: Many commenters opposed the proposed requirements that hospitals maintain contemporaneous documentation of beneficiary incentive items and services whose value exceeds $10. The commenters recommended that CMS increase the threshold to $50, $100, or a higher value in order to minimize unnecessary administrative burden. Some commenters also suggested that CMS exempt beneficiary incentives from the 10-year documentation requirement to further reduce burden.

Response: We appreciate the perspectives of the commenters on our proposed requirements for contemporaneous documentation of all beneficiary incentive items and services furnished whose value exceeds $10, including the date and the identity of the beneficiary to whom the item or service was provided. We note that, like the $1,000 limit for beneficiary incentives involving technology items and services, our proposed documentation threshold of $10 was intended to represent the retail value of the item or service. We proposed a $10 retail value threshold for documentation because we recognized that a beneficiary could receive many incentives that are each of low dollar value but in the aggregate constitute an excessively high value to the beneficiary. We believe is important to maintain the documentation threshold at a modest level for all beneficiary incentives in order to monitor compliance with the requirements for providing these items and services. We believed that the $10 threshold represented an appropriate balance between the benefits of beneficiary incentives and burden of the documentation requirement.

The commenters did not provide specific examples of items and services that would be commonly furnished as beneficiary incentives such that the cumulative documentation burden on the hospital for CJR model beneficiaries would outweigh the potential benefit to the beneficiary of the item or services. However, after considering the comments, we believe a higher retail value threshold of $25 would strike the appropriate balance between beneficiary and program protections and participant hospital administrative burden. This higher threshold will eliminate the documentation burden for some beneficiary incentives. Therefore, at § 510.515(c)(1), we are finalizing our proposed requirement that participant

hospitals must maintain a contemporaneous list of items and services furnished as beneficiary incentives, including the date the incentive was provided and the identity of the beneficiary to whom it was provided. We specify in that section that this obligation applies only to incentives that exceed $25 in retail value. Under new § 510.515(c)(2), we set forth the requirement that the participant hospital must retain the required documentation in accordance with new § 510.515(e), which we have added to establish our proposed documentation and maintenance of records provision for beneficiary incentives.

We recognize that the 10-year retention requirement imposes some administrative burden, but we note that such a 10-year requirement is commonly used in Medicare. We do not believe it would be appropriate to reduce that document retention period for beneficiary incentives furnished under this model.

Comment: Several commenters provided their perspectives on the proposed $50 retail value threshold for items of technology that must remain the property of the participant hospital and be retrieved at the end of the episode. Some commenters recommended that CMS increase this threshold to $100 or $500. Many commenters expressed particular concern about the proposed requirement to retrieve technology from a beneficiary following the end of the episode because they believed it could be impossible to locate some beneficiaries and/or retrieve the technology from them in some cases. These commenters requested that CMS waive this requirement for hospital demonstration of a good faith effort to retrieve the technology. A number of commenters requested that CMS eliminate the requirement to maintain documentation of the date of retrieval. The commenters generally expressed concerns about the legal, compliance, documentation, and administrative resources associated with the proposed requirements for items of technology provided as beneficiary incentives. While no commenters objected to the proposed retail value limit of $1,000 on items and services of technology, a commenter questioned the meaning of this limit. The commenter inquired whether a hospital could be paid by CMS for the incentive and questioned the use of the term ''donate'' in the proposed rule in the discussion of the ''retail value at the time of donation'' of items involving technology.

Response: The commenters did not provide specific information about the types of technology that they believe should remain the property of the beneficiary at the end of episode. However, we believe that a higher threshold than the one we proposed for items of technology that must remain the property of the participant hospital may result in useful beneficiary incentives that, in light of other regulatory safeguards, would not pose an undue risk of patient steering or other abuse. One important safeguard is the inability of a hospital to advertise or promote the availability of the technology. In addition, we are finalizing our proposed safeguard requiring that items and services involving technology must be the minimum necessary to advance a clinical goal for a CJR beneficiary (as defined in § 510.515(b)). We note that we are finalizing the term ''advance a clinical goal'' in this provision, rather than our proposed language (''achieve a clinical goal''), for consistency with § 510.515(b), which identifies the clinical goals that may be ''advanced'' through beneficiary incentives. Accordingly, in light of these safeguards, we believe it is appropriate to raise the technology retrieval threshold to a retail value of $100 which, for example, would allow some types of electronic tablets that could be furnished to a beneficiary for health monitoring during a CJR model episode to remain the property of the beneficiary following the end of the episode.

We understand the administrative burden on hospitals that tracking and retrieval requires, but believe that a higher retrieval threshold is not warranted. For example, given that the majority of CJR episodes will be elective THA or TKA procedures, we believe it would be inappropriate for participant hospitals to furnish items of technology with a retail value of over $100 for beneficiaries' permanent use because the high value of these items could unduly influence the beneficiary to receive services from the hospital, particularly services outside of the CJR episode of care. We do not believe the administrative burden of retrieving items involving technology with a retail value in excess of $100 outweighs the program integrity benefits of retrieval. Therefore, we are finalizing § 510.515(d)(3) to reflect the $100 retail value threshold for retrieval of items of technology.

We decline to exempt items of technology and their retrieval date from the documentation requirements. We believe that documentation is important to ensure that the provision of items of technology is in compliance with program requirements and is not used by a participant hospital to steer beneficiaries toward one provider or type of service or to engage in other abusive conduct. We stress that hospitals must carefully and completely document all of their attempts to retrieve from a beneficiary at the end of an episode items of technology whose retail value exceeds $100, regardless of whether the hospital is ultimately successful in retrieving the technology. Documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement. These policies are set forth in § 510.515(d)(3)(ii).

Hospitals will not be reimbursed by CMS for the cost of items and services furnished to CJR model beneficiaries as beneficiary incentives. Participant hospitals may choose to provide in-kind patient engagement incentives to beneficiaries in CJR model episodes in accordance with the CJR regulations. Items and services of technology furnished as beneficiary incentives may not exceed $1,000 in retail value at the time they are furnished to any one beneficiary in a single CJR model episode.

Finally, we acknowledge that, in light of our proposal to require retrieval of certain items of technology, our use of the word ''donate'' was imprecise. We intended to refer to the retail value of technology at this time it was ''furnished'' to a model beneficiary.

Comment: Several commenters recommended that CMS allow other types of beneficiary incentives, including waivers of Part B coinsurance amounts and opportunities for participant hospitals to share reconciliation payments with model beneficiaries when actual episode spending is less than the target price.

Response: We appreciate these suggestions for additional beneficiary incentives. However, we are limiting our policies to the incentives as proposed and subsequently modified and finalized in this final rule. We do not believe that waivers of the Part B coinsurance amounts are necessary for the model test to advance clinical goals for model beneficiaries in view of the typical services furnished to beneficiaries in LEJR episodes and the aggregate modest associated coinsurance amounts. We also do not believe that sharing savings would be appropriate as such a policy could unduly influence a beneficiary's choice of types of care.

Comment: Several commenters recommended that CMS or the OIG should establish a dedicated email address or other communication portal

for questions about beneficiary incentives, so that participant hospitals could receive informal compliance advice in order to ensure that their use of beneficiary incentives in the CJR model meets the required conditions. Other commenters requested specific guidance on certain items with respect to the beneficiary incentives conditions, including post-surgical intermittent pneumatic compression devices, the determination of retail prices, supportive services that are in short supply or inadequate such as hot meal delivery, home preparation for a beneficiary who left home urgently, or enhanced homemaker or personal care aide services.

Response: We appreciate the interest of the commenters in understanding the conditions under which beneficiary incentives can be furnished under the CJR model. We believe that this final rule provides sufficient guidance on the requirements for beneficiary incentives under the model. Only beneficiary incentives that meet all of these requirements are permitted under this model. We will not provide informal compliance advice or provide additional advisory information about specific items or services or other definitions and terms in this final rule. Participant hospitals should review the regulations for the conditions and requirements to make sure their plans for beneficiary incentives comply with all of the requirements and conditions set forth in this final rule and any other applicable law. Any guidance from OIG regarding its authorities would be provided outside the scope of this rulemaking.

Comment: Several commenters recommended that CMS prohibit hospitals from shifting the cost of the incentives to government programs generally, including state health care programs, not only federal health care programs. Other commenters suggested that CMS further extend the cost-shifting prohibition to commercial programs.

Response: We intend to prohibit cost shifting to a ''Federal health care program,'' as defined at 42 U.S.C. 1320a–7b(f) (section 1128–7b(f) of the Act), which encompasses the following broad array of government health care programs:

- Any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5, United States Code [5 U.S.C. 8901 *et seq.*]); or
- Any state health care program, as defined in section 1128(h) [42 U.S.C. 1320a-7(h)], which includes the following:
- A state plan approved under title XIX [42 U.S.C. 1396 *et seq.*].
- Any program receiving funds under title V [42 U.S.C. 701 *et seq.*] or from an allotment to a state under such title.
- Any program receiving funds under subtitle 1 of title XX [42 U.S.C. 1397 *et seq.*] or from an allotment to a State under such subtitle.
- A state child health plan approved under title XXI [42 U.S.C. 1397aa *et seq.*].

We do not believe it would be appropriate to expand this cost-shifting prohibition to other government programs generally or to commercial programs. We question whether we have the authority to expand the cost-shifting prohibition to commercial payers. Moreover, we believe it would be very difficult to enforce such a provision in a meaningful manner.

We are finalizing this proposed condition in § 510.515(a)(7).

Final Decision: After consideration of the public comments we received, we are finalizing the proposal for beneficiary incentives under the CJR model, with certain modifications. We are clarifying at § 510.515(a)(1) that the items and services may be provided by the hospital through an agent who is under the hospital's direction and control. We note that if a reasonable beneficiary would perceive the item or service as being from the agent rather than the hospital, we would not consider the incentive to have been provided by the hospital. As previously noted, we are clarifying in § 510.515(a)(2) that the items and services must be reasonably connected to medical care provided to a beneficiary ''during an episode.'' We are separately incorporating at § 510.515(a)(3) the proposed requirement that the item or service be a preventive care item or service or advance a clinical goal for a beneficiary in a CJR episode. In addition, we are also adding a new paragraph(a)(4) at § 510.515 to set forth the proposed requirement that the item or service must not be tied to the receipt of items or services outside of the episode of care. At the suggestion of the commenters, we are adding new provisions to require that—(1) The item or service may not be tied to receipt of items or services from a particular provider or supplier; and (2) the availability of the items or services must not be advertised or promoted, except that a beneficiary may be made aware of the availability of the items or services at the time the beneficiary could reasonably benefit from them. These conditions appear at § 510.515(a)(5) and (6). We are finalizing the proposed requirement in § 510.515(a)(7) that the cost of the items or services must not be shifted to another federal health care program.

We are also finalizing § 510.515(b) regarding the goals of the CJR model. We note that § 510.515(b)(2) is being finalized with modification to avoid redundancy. The provision will refer to beneficiary adherence to ''a care plan,'' rather than ''a follow-up care plan or care,'' since a care plan would include follow up and other care. In addition, we are finalizing the proposed documentation requirement for beneficiary incentives with certain changes; it will apply only to those items and services furnished as beneficiary incentives whose retail value exceeds $25, and it requires contemporaneous documentation to be retained for 10 years. As no commenters objected to the proposed limit of $1,000 in retail value for items and services involving technology provided to any one beneficiary in any one CJR episode, we are finalizing this requirement under § 510.515(d)(1). We are also finalizing in revised § 510.515(d)(2) the proposed condition that the items or services involving technology provided to a beneficiary must be the minimum necessary to advance a clinical goal for a CJR beneficiary. Moreover, we are modifying the requirement that items of technology furnished as beneficiary incentives remain the property of the participant hospital and be retrieved from the beneficiary at the end of the model to apply only to those items of technology that exceed $100 in retail value, and finalizing these requirements under § 510.515(d)(3) and paragraph (d)(3)(i). Under § 510.515(d)(3)(ii), documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement. Finally, we are adding new § 510.515(e) to establish the proposed documentation and record retention provision for beneficiary incentives furnished under the CJR model.

The final beneficiary incentive policies are set forth in § 510.515.

11. Waivers of Medicare Program Rules

a. Overview

In the proposed rule, we stated our belief that it may be necessary and appropriate to provide additional flexibilities to hospitals participating in CJR, as well as other providers that furnish services to beneficiaries in CJR episodes. The purpose of such flexibilities would be to increase LEJR episode quality and decrease episode

spending or provider and supplier internal costs, or both, and to provide better, more coordinated care for beneficiaries and improved financial efficiencies for Medicare, providers, and beneficiaries. These possible additional flexibilities could include use of our waiver authority under section 1115A of the Act, which provides authority for the Secretary to waive such requirements of title XVIII of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. This provision affords broad authority for the Secretary to waive statutory Medicare program requirements as necessary to carry out the provisions of section 1115A of the Act.

As we have stated elsewhere in sections I.A. and III.A.3 of this final rule, our previous and current efforts in testing episode payment models have led us to believe that models where entities bear financial responsibility for total Medicare spending for episodes of care hold the potential to incentivize the most substantial improvements in episode quality and efficiency. As discussed in section III.C. of this final rule, we proposed that hospitals participating in this model be eligible for reconciliation payments based on improved performance starting in performance year 1, and we would phase-in repayment responsibility for excess episode spending starting in performance year 2. In the proposed rule, we stated our belief that where participant hospitals bear repayment responsibility for excess episode spending that surpasses the target price while high quality care is valued, they will have an increased incentive to coordinate care furnished by the hospital and other providers and suppliers throughout the episode to improve the quality and efficiency of care. With these incentives present, there may be a reduced likelihood of over-utilization of services that could otherwise result from waivers of Medicare program rules. Given these circumstances, waivers of certain program rules for providers and suppliers furnishing services to CJR beneficiaries may be appropriate to offer more flexibility than under existing Medicare rules for such providers and suppliers, so that they may provide appropriate, efficient care for beneficiaries. An example of such a program rule that could be waived to potentially allow more efficient LEJR episode care would be the 3-day inpatient hospital stay requirement prior to a covered SNF stay for beneficiaries who could appropriately be discharged to a SNF after less than a 3-day inpatient hospital stay.

In addition, in the proposed rule we stated our belief that waivers of certain Medicare program rules are necessary to make reconciliation payments to or recoup payments from participant hospitals as a result of the NPRA for each performance year as discussed in section III.C.6.a. of this final rule, as well as to exclude beneficiary cost-sharing from these reconciliation payments or repayments.

We welcomed comments on possible waivers under section 1115A of the Act of certain Medicare program rules that surpass those specifically discussed in the proposed rule that might be necessary to test this model. In the proposed rule, we stated that we would consider the comments that are received during the public comment period and our early model implementation experience and may make future proposals regarding program rule waivers during the course of the model test. We noted that we were especially interested in comments explaining how such waivers could provide providers and suppliers with additional ways to increase quality of care and reduce unnecessary episode spending, but that could be appropriately used in the context of CJR where participant hospitals bear full responsibility for total episode spending by performance year 3. We were also interested in receiving comments regarding the timing and manner in which such waivers, were they to be offered, would be implemented. For example, would it be necessary and appropriate to offer program waivers early in the model to allow providers and suppliers adequate time to adjust their care coordination strategies to implement changes permitted by the waivers, despite there being no full repayment responsibility for excess episode spending until performance year 3? What program integrity and beneficiary protection risks could be introduced by waivers of the program rules described later in this section of this final rule and how could we mitigate those risks? What other issues should be considered when making use of waiver authority with respect to program rules? What operational issues do CMS and providers and suppliers furnishing services to beneficiaries in the model need to consider and what processes would need to be in place to implement these alternative program policies? What implications would there be for provider and supplier infrastructure, including IT and other systems and processes? What provider education would be needed? We noted that any waivers included in a final rule would be offered to participant hospitals, but depending on the specifics of each waiver, might be applied to services furnished by providers and suppliers other than the hospital. Where that is the case, we sought input on how we may best educate and disseminate information using methods effective in reaching providers and suppliers. Additionally, we sought comment on how we would appropriately and accurately track the use of waivers by providers and suppliers other than participant hospitals.

Specific program rules for which we proposed waivers under the CJR model to support provider and supplier efforts to increase quality and decrease episode spending and for which we invited comments are included in the sections that follow. We proposed that these waivers of program rules would apply to the care of beneficiaries who are in CJR episodes at the time a service is furnished to a beneficiary under a waiver, even if the episode is later canceled as described in section III.B.3.b of this final rule. If a service is found to have been billed and paid by Medicare under circumstances only allowed by a program rule waiver for a beneficiary not in the CJR model at the time a service under a waiver was furnished, CMS would recoup payment for that service from the provider or supplier who was paid, and require that provider or supplier to repay the beneficiary for any coinsurance previously collected.

The following is a summary of the comments received and our response.

Comment: Many commenters commended CMS for proposing that the waivers of Medicare program rules would apply to the care of beneficiaries who are in CJR episodes at the time a service is furnished to a beneficiary under a waiver, even if the episode is later canceled. The commenters believe that CMS addressed an important ambiguity that exists in the use of similar waivers under BPCI, given that both BPCI and the proposed CJR model are retrospective payment models where payment is made to Medicare providers and suppliers throughout the episode. Several commenters requested clarification of the proposal regarding its applicability to beneficiaries whose change in coverage at some point in the episode following provision of a service under a waiver leads to the beneficiary's care ultimately being excluded from the model. They provided examples such as a beneficiary who enrolled in a Medicare Advantage plan or whose Medicare eligibility changed to the ESRD benefit at some point during an

episode after a service permitted by a CJR model program rule waiver was furnished. These commenters argued that CMS should treat situations of changes in coverage that exclude beneficiaries' care from the CJR model the same as CMS proposed to treat episode cancellations. That is, the commenters recommended that the waivers should apply to the care of beneficiaries who are in CJR episodes at the time a service is furnished to a beneficiary under the waiver, even if the beneficiary's care is later excluded from the model due to a change in the beneficiary's coverage during the episode.

Response: We agree with the commenters that it would be appropriate to treat the applicability of program rule waivers to beneficiaries whose care is later excluded from the model due to changes in beneficiary coverage in the same way as we proposed to treat episode cancellations, because based on beneficiary coverage at the time services are furnished under the waiver, the beneficiary's care was included in the model. The ultimate exclusion of the beneficiary's care from the model would not be decided until a later point in the episode when a change in the beneficiary's coverage would result in cancellation of the episode. As discussed in the proposed rule in regard to episode cancellation, we believe it would be appropriate to cancel the episode when a beneficiary's status changes during the episode such that they no longer meet the criteria for inclusion. Therefore, if a beneficiary's coverage or circumstances change during the episode such that they no longer meet the criteria for inclusion, as would occur in the examples provided by the commenters, the episode would be canceled. Thus, under our proposal, waivers of Medicare program rules would apply to the care of beneficiaries who are in CJR episodes at the time a service is furnished to a beneficiary under a waiver even if the episode is later canceled, which includes circumstances where the beneficiary's care is ultimately excluded from the CJR model due to a change in the beneficiary's coverage during the episode. We believe it is important to structure the CJR Medicare program rule waivers in this way so that later episode cancellations that could not be known or anticipated by providers or beneficiaries at the time services are furnished under a waiver, would not result in unexpected provider or beneficiary financial liability.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal, without modification, that waivers of Medicare program rules would apply to the care of beneficiaries who are in CJR model episodes at the time the service is furnished to the beneficiary under the waiver, even if the episode is later canceled. This policy would include circumstances where a beneficiary's care is ultimately excluded from the CJR model due to a change in the beneficiary's coverage during the episode. As discussed in the proposed rule, if a service is found to have been billed and paid by Medicare under circumstances only allowed by a program rule waiver for a beneficiary not in the CJR model at the time a service under a waiver was furnished, CMS will recoup payment for that service from the provider or supplier who was paid. However, for this situation we are not finalizing our proposal to require that providers or suppliers repay the beneficiary for any coinsurance previously collected. We may consider other approaches to handling these types of issues in the future.

In the proposed rule, we also generally sought comment on any additional Medicare program rules that it may be necessary to waive using our authority under section 1115A of the Act in order to effectively test the CJR model that we could consider in the context of our early model implementation experience to inform any future proposals we may make.

The following is a summary of the comments received and our response.

Comment: Many commenters requested that CMS consider additional program rule waivers for the CJR model that surpass those specifically proposed for the model. The commenters provided information about how those waivers could be used to enhance the efficiency and quality of care for CJR model beneficiaries, allowing the widest variety of interested and well-prepared providers and suppliers to partner with hospitals in care redesign for LEJR episodes. Some suggested waivers were specific to payment, such as providing ''per diem'' payment for IRFs, changing payment under the IPPS PAC transfer policy, and eliminating the Part B therapy caps. Several commenters recommended that CMS waive the Part B copayments for CJR model beneficiaries. Requests for waivers specific to the rules governing certain types of providers and suppliers included waivers of the IRF 60-percent rule and 3-hour therapy rule that specifies the particular models of therapy permitted, waiver of the physician supervision rules for certified registered nurse anesthetists, and waiver of the requirement for physicians to certify home health services to allow NPPs to perform this task. Waivers of CMS review policies for CJR collaborators were requested by some commenters, including waivers of manual medical review policies and prepayment and postpayment reviews. Many commenters requested waivers of the hospital discharge planning requirements in order to allow hospitals to share lists of only those PAC providers collaborating on the model with the participant hospital, as well as waivers to allow home health providers to furnish pre-surgical counseling and visits and to assist with discharge planning and care transitions for beneficiaries. Finally, several commenters suggested that CMS provide very general waivers that would waive all policies that may impact a PAC provider's ability to admit a CJR beneficiary or be paid for services furnished to them or, even more broadly, waivers of all the relevant regulations that impede the ability of hospitals to effectively coordinate and manage a patient's care.

Response: We appreciate the information provided by the commenters and, as discussed in the proposed rule, we will consider the comments we received during the public comment period and our early model implementation experience and may make future proposals regarding program rule waivers during the course of the model test.

We refer readers to section III.F.2. of this final rule for a discussion of the discharge planning requirements under the CJR model.

Final Decision: We address the Medicare programmatic waivers we proposed in the proposed rule in the following sections. We decline at this time to waive any additional Medicare programmatic requirements. We will review the information provided by the commenters and our early model experience and may consider waiving additional requirements during the course of the model test.

b. Post-Discharge Home Visits

In the proposed rule, we stated our expectation that the broadly defined LEJR episodes with duration of 90 days following hospital discharge as we proposed in section III.B. of this final rule would result in participant hospitals redesigning care by increasing care coordination and management of beneficiaries following surgery. This would require participant hospitals to pay close attention to any underlying medical conditions that could be affected by the anchor hospitalization

and improving coordination of care across care settings and providers. Beneficiaries may have substantial mobility limitations during LEJR episodes following discharge to their home or place of residence that may interfere with their ability to travel easily to physicians' offices or other health care settings. Adopting new strategies to increase beneficiary adherence to and engagement with recommended treatment and follow-up care following discharge from the hospital or PAC setting would also be important to high quality episode care. Scientific evidence exists [48] to support the use of home nursing visits among Medicare beneficiaries in improving care coordination following hospital discharge. In addition, in the proposed rule, we stated our belief that the financial incentives in this episode payment model would encourage hospitals to closely examine the most appropriate PAC settings for beneficiaries so that the clinically appropriate setting of the lowest acuity is recommended following discharge from the anchor hospitalization. We discussed our expectation that all these considerations would lead to greater interest on the part of hospitals and other providers and suppliers caring for CJR beneficiaries in furnishing services to beneficiaries in their home or place of residence. Such services could include visits by licensed clinicians other than physicians and nonphysician practitioners.

In order for Medicare to pay for home health services, a beneficiary must be determined to be ''home-bound''. Specifically, sections 1835(a) and 1814(a) of the Act require that a physician certify (and recertify) that in the case of home health services under the Medicare home health benefit, such services are or were required because the individual is or was ''confined to the home'' and needs or needed skilled nursing care on an intermittent basis, or physical or speech therapy or has or had a continuing need for occupational therapy. A beneficiary is considered to be confined to the home if the beneficiary has a condition, due to an illness or injury, that restricts his or her ability to leave home except with the assistance of another individual or the aid of a supportive device (that is, crutches, a cane, a wheelchair or a walker) or if the beneficiary has a condition such that leaving his or her home is medically contraindicated. While a beneficiary does not have to be bedridden to be considered confined to the home, the condition of the beneficiary must be such that there exists a normal inability to leave home and leaving home requires a considerable and taxing effort by the beneficiary. Absent this condition, it would be expected that the beneficiary could typically get the same services in an outpatient or other setting. Thus, the homebound requirement provides a way to help differentiate between patients that require medical care at home versus patients who could more appropriately receive care in a less costly outpatient setting. Additional information regarding the homebound requirement is available in the Medicare Benefit Manual (Pub 100–02); Chapter 7, ''Home Health Services'' Section 30.1.1, ''Patient Confined to the Home''.

We considered whether a waiver of the homebound requirement would be appropriate under the CJR model, particularly beginning in performance year 2, where hospitals begin to bear repayment responsibility for excess episode spending. Waiving the homebound requirement would allow additional beneficiaries to receive home health care services in their home or place of residence. As previously discussed, physician certification that a beneficiary meets the homebound requirement is a prerequisite for Medicare coverage of home health services, and waiving the homebound requirement could result in lower episode spending in some instances. For example, if a beneficiary is allowed to have home health care visits, even if the beneficiary is not considered homebound, the beneficiary may avoid a hospital readmission. All other requirements for the Medicare home health benefit would remain unchanged. Thus, under such a waiver, only beneficiaries who otherwise meet all program requirements to receive home health services would be eligible for coverage of home health services without being homebound.

However, we did not propose to waive the homebound requirement under CJR for several reasons. Based on the typical clinical course of beneficiaries after LEJR procedures, we stated our belief that many beneficiaries would meet the homebound requirement for home health services immediately following discharge from the anchor hospitalization or following discharge to their home or place of residence from a SNF that furnished PAC services immediately following the hospital discharge, so they could receive medically necessary home health services under existing program rules. Home health episodes are 60 days in duration, and payment adjustments are made for beneficiaries who require only a few visits during the home health episode or who are discharged during the home health episode. For those CJR beneficiaries who could benefit from home visits by a licensed clinician for purposes of assessment and monitoring of their clinical condition, care coordination, and improving adherence with treatment but who are not homebound, we did not believe that paying for these visits as home health services under Medicare is necessary or appropriate, especially given that Medicare payments for home health services are set based on the clinical care furnished to beneficiaries who are truly homebound. Finally, in other CMS episode payment models, such as BPCI, we have not waived the homebound requirement for home health services.

The following is a summary of the comments received and our response.

Comment: Several commenters requested that CMS waive the homebound requirement for the entire 90-day period of time included in the LEJR episode following discharge from the anchor hospitalization. They recommended that such a waiver would allow home health services to be furnished whenever medically necessary throughout the entire length of the CJR model episode, leading to improvements in continuity and care coordination and serving as a natural extension of home health care furnished by a HHA that many beneficiaries would likely receive when homebound at an earlier time in the episode.

Response: While we appreciate the commenters' requests that we waive the homebound requirement for home health services, we disagree that waiving the homebound requirement is necessary for the test of the CJR model. As discussed in the proposed rule, we proposed to waive the ''incident to'' direct physician supervision requirement for post-discharge home visits in order to allow clinical staff to furnish post-discharge home visits to CJR model beneficiaries who do not meet the requirements for home health services. We believe that this would allow the home visits for non-homebound CJR model beneficiaries that we believe are necessary for testing the model. As we discussed in the proposed rule, we believe many CJR beneficiaries should qualify for home health services under the existing program rules, especially immediately after discharge from the hospital or discharge from an institutional setting such as a SNF to their residence.

[48] Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, Schwartz JS. Comprehensive discharge planning and home follow up of hospitalized elders: A randomized clinical trial. JAMA. 1999: 281(7): 613 620. doi:10/1001/jama.281.7.6136.

Furthermore, as a retrospective payment model, all providers and suppliers are paid for services furnished to model beneficiaries at their usual rates, and program payments for home health services are set based on the needs of Medicare beneficiaries who are truly homebound. The resources required to care for homebound beneficiaries in the home are likely greater than those required for CJR beneficiaries who are not homebound. Therefore, waiving the homebound requirement would lead to inappropriate payment for post-discharge home visits to CJR model beneficiaries and could result in increased CJR episode actual spending, which is counter to the goals of the CJR model.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal, without modification, to maintain the existing Medicare requirements for home health services, including the requirement that the beneficiary be homebound, when home health services are furnished to CJR model beneficiaries.

In the proposed rule, we noted that in BPCI, we have provided a waiver of the ''incident to'' direct physician supervision requirement in order to allow a physician or NPP participating in care redesign under a participating BPCI provider to bill for services furnished to a beneficiary who does not qualify for Medicare coverage of home health services as set forth under § 409.42 where the services are furnished in the beneficiary's home during the episode after the beneficiary's discharge from an acute care hospital. The ''incident to'' direct physician supervision requirement is set forth at § 410.26(b)(5), in which services and supplies furnished ''incident to'' the service of a physician or other practitioner must be provided under the direct supervision (as defined at § 410.32(b)(3)(ii)) of a physician or other practitioner.

In BPCI, the waiver is available only for services that are furnished by licensed clinical staff under the general supervision (as defined at § 410.32(b)(3)(i)) of a physician (or other practitioner), as long as the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner), or of the same entity that employs or contracts with the physician (or other practitioner), and while the services may be furnished by licensed clinical staff they must be billed by the physician (or other practitioner) in accordance with CMS instructions using a HCPCS G-code created by CMS specifically for the BPCI initiative. As discussed in section III.B. of this final rule, participants in the BPCI initiative are permitted to select the duration of an episode as 30 days, 60 days or 90 days. In the case of the ''incident to'' direct physician supervision waiver under BPCI, the waiver allows physicians and NPPs to furnish the services not more than once in a 30-day episode, not more than twice in a 60-day episode, and not more than three times in a 90-day episode. All other Medicare coverage and payment criteria must be met.

For the CJR model, we proposed to waive the ''incident to'' direct physician supervision requirement set forth at § 410.26(b)(5), to allow a CJR beneficiary who does not qualify for home health services to receive post-discharge visits in his or her home or place of residence any time during the episode. The waiver would not apply for beneficiaries who would qualify for home health services under the Medicare program, as set forth under § 409.42. Therefore these visits could not be billed for such beneficiaries. We proposed to allow licensed clinicians, such as nurses, either employed by a hospital or not, to furnish the service under the general supervision of a physician, who may be either an employee or a contractor of the hospital. We proposed to allow services furnished under such a waiver to be billed under the MPFS by the physician or NPP or by the hospital to which the supervising physician has reassigned his or her benefits. In the latter scenario, we noted that the post-discharge home visit services would not be ''hospital services,'' even when furnished by clinical staff of the hospital. While we used the term ''licensed clinicians'' in the proposed rule to describe the personnel furnishing a post-discharge home visit to CJR model beneficiaries, for purposes of consistency with correct coding guidelines, hereinafter we will instead use the term ''clinical staff'' as it is defined in the CPT coding guidelines. Specifically, in the ''CPT Coding Guidelines, Introduction, Instructions for Use of the CPT Codebook'' it says, a ''clinical staff member is a person who works under the supervision of a physician or other qualified health care professional, and who is allowed by law, regulation and facility policy to perform or assist in the performance of a specific professional service, but does not individually report that professional service.''

We proposed that up to 9 post-discharge home visits could be billed and paid during each 90-day post-anchor hospitalization CJR episode. Given the average PAC length of stay of approximately 45 days for these episodes and the incentives under CJR to improve efficiency, which may shorten PAC stays, 9 visits would represent a home visit on average of once per week for two-thirds of the 90-day episode duration, the period of time when the typical beneficiary may have concluded PAC in an efficient episode. In the proposed rule, we stated our belief that a home visit of once a week to a non-homebound beneficiary who has concluded PAC and who could also receive services in the physician's office or hospital outpatient department as needed, along with telehealth visits in the home from a physician or NPP as proposed, should be sufficient to allow comprehensive assessment and management of the beneficiary throughout the LEJR episode. We proposed that the service be billed with HCPCS code GXXXX (CJR model, home visit for patient assessment performed by a qualified health care professional for an individual not considered homebound, including, but not necessarily limited to patient assessment of clinical status, safety/fall prevention, functional status/ambulation, medication reconciliation/management, compliance with orders/plan of care, performance of activities of daily living, and making beneficiary connections to community and other services; (for use only in the Medicare approved CJR model); may not be billed for a 30 day period covered by a transitional care management code) and paid at approximately $50 under the MPFS. We proposed that the standard MPFS ratesetting methodologies would establish relative value units (RVUs) based on the resources required to furnish the typical service. We stated that final RVUs under the CY 2016 MPFS for the proposed new HCPCS code for CJR home visits would be included in the CJR final rule. In addition, we proposed to update the values each year to correspond to final values established under the MPFS.

The waiver would not apply with respect to a CJR beneficiary who has qualified, or would qualify, for home health services when the visit was furnished. We discussed our expectation that the visits by clinical staff could include patient assessment, monitoring, assessment of functional status and fall risk, review of medications, assessment of adherence with treatment recommendations, patient education, communication and coordination with other treating clinicians, care management to improve beneficiary connections to community and other services, etc. These post-discharge home visits would remove barriers to follow-up care outside of the

home with providers and suppliers and allow the beneficiary to be treated in his or her home environment or place of residence, where potential safety concerns, such as tripping hazards, could quickly be identified and remediated. Given these occasions for further patient assessment and intervention, we stated out belief that where such post-discharge home visits are furnished, there are opportunities to increase patient-centered care coordination and decrease episode spending, potentially resulting in higher quality care for beneficiaries and increased episode efficiency which may benefit the beneficiaries, the Medicare Trust Fund, and participant hospitals.

We also proposed to waive current Medicare billing rules in order to allow the separate reporting of these post-discharge home visits during surgical global periods. The MPFS payment for the surgical procedure includes 90 days of post-operative care furnished by the surgeon. Post-operative follow-up care is not separately billable by the surgeon. We note that in the proposed rule we had incorrectly stated that Medicare limits the separate billing of post-operative care when there is a transfer of care to another practitioner. The current construction of the global packages included in MPFS payments reflects a more narrow view of surgical follow-up care that does not encompass broader, more comprehensive models of post-operative care, such as an episode model like CJR. As we have noted in the past, it is also difficult to determine the appropriate valuation of the various components of the current global packages (2015 Physician Fee Schedule 79 FR 67584). We did not believe that the CJR post-discharge home visits, which can include nursing assessments for chronic conditions for which care may be affected by the surgery, would replace or substantially duplicate the kind of post-operative visits involved in furnishing post-operative follow-up care for the global surgery procedure under the MPFS. Instead, we anticipated that the work of these post-discharge visits would be similar to the work furnished by the physician coordinating the patient's overall episode care. Therefore, we proposed to waive the global surgery billing rules to allow the surgeon or other practitioners to furnish and bill for the post-discharge home visits during surgical global periods.

In the proposed rule, we noted that we planned to monitor utilization patterns of post-discharge home visits under CJR to monitor for overutilization and significant reductions in medical home health services. We sought comments on the proposed waiver of the ''incident to'' direct physician supervision requirement to pay for a maximum number of post-discharge home visits to beneficiaries who do not qualify for home health services by clinical staff under the general supervision of a physician.

The following is a summary of the comments received and our responses.

Comment: Many commenters commended CMS for the proposal to waive the ''incident to'' direct physician supervision requirement to allow a CJR beneficiary who does not qualify for home health services to receive post-discharge visits in his or her home or place of residence any time during the episode. The commenters believe these home visits will provide participant hospitals with a useful tool for care coordination and management that will ultimately improve the quality and reduce the cost of an LEJR episode extending 90 days following hospital discharge. The commenters asserted that the flexibility afforded by these post-discharge home visits and the latitude for testing different configurations of visits will be very valuable to the development of new care pathways for LEJR patients, to CJR model beneficiaries' health, and to overall participant hospital episode quality and payment performance. In addition, several commenters specifically commended CMS for proposing to waive current Medicare billing rules in order to allow the separate reporting of these post-discharge home visits during surgical global periods. These commenters explained that this proposal would allow the clinical staff of orthopedic surgeons engaged in care management throughout the CJR beneficiary's episode to furnish post-discharge home visits to address beneficiary health concerns, where the resources required for the surgeon to coordinate the beneficiary's overall episode of care during the global surgical period are not accounted for in the typical case used under the MPFS to price the global period for the surgical procedure.

Response: We agree that allowing post-discharge home visits to be furnished to non-homebound CJR model beneficiaries may contribute to improved care coordination and management and stronger patient engagement, ultimately resulting in better health outcomes and reduced episode spending. We also believe it is appropriate for these visits to be paid separately in addition to payment for the surgical procedure, if they are furnished during the global surgical period ''incident to'' the services of the physician who performed the surgical procedure.

Comment: Several commenters recommended that CMS permit home visits under the ''incident to'' direct physician supervision waiver, regardless of whether or not the beneficiary qualified for home health services. These commenters believe that participant hospitals should have the full flexibility to determine the most efficient and appropriate way to furnish home nursing visits to beneficiaries who would qualify for home health services, including those who are homebound.

Response: While we appreciate the commenters' suggestions that we provide maximal flexibility to participant hospitals to deliver the configuration of services the hospital believes to be most appropriate to manage a beneficiary's care, we continue to believe that home visits furnished under the ''incident to'' direct physician supervision waiver should be limited to CJR model beneficiaries who otherwise would not qualify for home health services. We note that while home health episodes are 60 days in duration, payment adjustments are made for beneficiaries who require only a few visits during the episode or who are discharged during the home health episode. Therefore, CJR model beneficiaries who qualify for home health services could receive home health services that would be appropriately paid even if they qualified for such services for less than 60 days. Those beneficiaries who qualify for home health services for any duration of time during the CJR model episode would not need to receive post-discharge home visits under the ''incident to'' direct physician supervisions waiver. Furthermore, we expect that homebound CJR model beneficiaries may typically need other types of services provided under the home health benefit than just post-discharge home visits by clinical staff, including skilled nursing services, therapy services, medical supplies, and medical social services. We would not expect that post-discharge home visits provided under the ''incident to'' direct physician supervision waiver would adequately substitute for home health services under the more comprehensive Medicare home health benefit. For those beneficiaries receiving home health care, paying additionally for post-discharge home visits under the ''incident to'' direct physician supervision waiver would be duplicative of services that should be furnished under the home health episode and could lead to ineffective care coordination and management due

to the involvement of multiple clinical staff working for different organizations or physician practices.

Comment: Many commenters expressed support for CMS's proposal to pay for up to 9 post-discharge home visits under the proposed ''incident to'' direct physician supervision waiver for CJR model beneficiaries during episodes of care. These commenters asserted that 9 post-discharge home visits should be sufficient to address the care coordination and management needs of beneficiaries throughout the episode during the time when those beneficiaries are not homebound. Other commenters recommended that CMS should not limit the number to 9 visits because such a limit inappropriately prescribes patterns of care. In the context of bundled payment that provides a target price for the episode, these commenters believe that providers should be able to furnish any number of home visits they believe is appropriate based on the beneficiary's clinical condition and that there is no risk of overutilization due to the pre-established target price. Other commenters arguing in favor of the proposal for up to 9 post-discharge home visits further recommended that CMS revisit the maximum number of visits over the course of the model and increase the maximum number permitted based on the early experience of model participants if a higher number of post-discharge visits seems warranted.

Response: While we understand that some commenters would prefer no limit or a higher limit on the number of post-discharge home visits, as discussed previously these visits are restricted to CJR model beneficiaries who do not quality for home health services. The commenters did not offer specific clinical rationale for setting a higher maximum number of post-discharge home visits. Moreover, we continue to believe it is appropriate to limit the number of post-discharge home visits that can be paid under the CJR model to mitigate the risk of overutilization, especially in the early years of the model where participant hospitals have no, or limited, repayment responsibility for excess actual episode spending above the target price. Thus, we continue to believe that it is most appropriate to allow up to 9 post-discharge home visits during a CJR model episode, which should be sufficient for the episode period when CJR model beneficiaries would not qualify for home health services. As we discussed in the proposed rule, 9 visits would represent a home visit on average of once per week for two-thirds of the 90-day episode duration, the period of time when the typical beneficiary may have concluded PAC in an efficient episode. We are not prescribing the periodicity, pattern, or number of these visits for model beneficiaries. We will monitor utilization of these visits and may revisit the maximum number of visits over the course of the model based on the implementation experience of participant hospitals.

Comment: Several commenters requested that CMS permit HHAs to bill and be paid for the post-discharge home visits under the proposed ''incident to'' direct physician supervision waiver. They asserted that such a policy would allow HHA expertise and experience to contribute to LEJR episode efficiency and quality because HHAs routinely furnish effective home nursing visits to homebound beneficiaries. A commenter pointed out that beneficiaries receiving home health care have especially low hospital readmission rates compared to beneficiaries receiving PAC from other types of providers. A number of commenters asserted that allowing HHAs to furnish home visits outside of home health episodes of care would contribute to continuity of care for CJR model beneficiaries, as nurses from the HHA with established relationships with the beneficiary and his or her family could continue to furnish home visits when the beneficiary was no longer homebound and, therefore, not eligible for home health services.

Some commenters suggested that HHAs furnishing post-discharge home visits could be paid under the MPFS at the same rate as physicians, while other commenters suggested that HHAs should be paid at the HHPPS discipline-specific LUPA rates for the post-discharge home visits. Commenters pointed out that HHAs regularly carry out assessment home visits paid by commercial insurers, and asserted that allowing HHAs to furnish home visits to CJR model beneficiaries who are not in a home health episode would provide opportunities for physician groups to partner with HHAs on needed interventions.

Some commenters recommended that other organizations be allowed to furnish and be paid for home visits to CJR model beneficiaries, including community-based organizations and hospitals. A few commenters asserted that hospitals should be able to send nurses to a CJR beneficiary's home and bill directly for the services, rather than a hospital-based physician billing for those services. Finally, a commenter suggested that nurse practitioners be allowed to bill for the home visits.

Response: We appreciate the commenters' suggestions that we permit HHAs and other organizations and providers to furnish post-discharge home visits to CJR model beneficiaries. We note that nurse practitioners may currently furnish and bill for home care visits that are paid by Medicare under the usual MPFS rules. Under our proposal, post-discharge home visits would be furnished ''incident to'' a physician's professional services while under the general supervision of a physician. In some cases, this may be the orthopedic surgeon who performed the surgical procedure during the anchor hospitalization, and in other cases it may be a physician identified by the participant hospital to assume care coordination and management responsibility following the beneficiary's discharge from the initial hospital stay. The regulations at § 410.26 outline specific limitations on ''incident to'' services. We require that services and supplies furnished ''incident to'' a physician's professional service must be—

- Furnished in a noninstitutional setting to a non-institutional patient.
- An integral, though incidental, part of the services of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.
- Commonly furnished without charge or included in the bill of a physician (or other practitioner).
- Of a type that are commonly furnished in the office or clinic of a physician (or other practitioner)
- Furnished under direct supervision of the physician or practitioner.
- Furnished by the physician, practitioner with an ''incident to'' benefit, or auxiliary personnel.
- A physician (or other practitioner) may be an employee or independent contractor.

Although we proposed to waive the direct physician supervision requirement in § 410.26(b)(5) as previously discussed, clinical staff providing post-discharge home visits as ''incident to'' services would still need to be considered ''auxiliary personnel'' (employed, contracted, or leased employee of the physician or same employing organization as physician) as required by § 410.26(a)(1) and § 410.26(b)(6). Therefore, it would not be permissible for HHAs, community-based organizations, hospitals, or others to provide post-discharge home visits under the proposed ''incident to'' direct physician supervision waiver as these entities would not meet the definition of ''auxiliary personnel'' as outlined in regulation. At this time, we are declining to waive any additional

requirements of the ''incident to'' rules that would be necessary for these other entities to furnish CJR post-discharge home visits because we continue to believe that the post-discharge home visits should always be ''incident to'' a physician's professional services, including that they are an integral, although incidental, part of the physician's professional services in the course of the diagnosis or treatment of an illness of injury, and that they are furnished by auxiliary personnel (if not by the physician or practitioner with an ''incident to'' benefit), who by definition are linked to the physician (or employing organization of the physician) by employment, contract, or lease. We believe the ''incident to'' relationship of post-discharge home visits to a physician's professional services is critical due to the importance of robust care coordination and close care management to episode cost and quality performance, given the lengthy, broadly defined CJR episodes. We note that in the case where a post-discharge home visit is furnished by clinical staff employed by the hospital, the hospital could bill under the MPFS if the supervising physician who is an employee or a contractor of the hospital has reassigned his or her benefits to the hospital.

As a result, we are not providing additional waivers for post-discharge home visits to beneficiaries in the CJR model who otherwise do not qualify for Medicare home health services, other than under our proposal to allow for 9 post-discharge home visits under the ''incident to'' direct physician supervision waiver. We further note that under BPCI, post-discharge home visits consistent with the goals of episode payment for LEJR procedures are furnished under a similar ''incident to'' direct physician supervision waiver, and BPCI participants have not expressed concerns that the waiver limits their ability to efficiently provide the necessary visits. This leads us to believe that the limited waiver of only the direct physician supervision requirement for ''incident to'' post-discharge home visits that we are providing under the CJR model will be sufficient.

Comment: Several commenters recommended that CMS require physician claims for post-discharge home visits to identify and document the specialties of clinical staff providing the visit. They recommended that billing for services provides no information about the process of care coordination, which would be important to understand success under the model test. The commenters expressed concern that the waiver of the ''incident to'' direct physician supervision requirement could allow a non-qualified clinician to provide follow up care to CJR beneficiaries, supervised only by a hospital contractor. Several commenters requested that CMS further specify the clinical staff who can furnish post-discharge home visits to CJR model beneficiaries. Finally, another commenter inquired whether a nurse, physical therapist, or occupational therapist could furnish the visit under the order of a physician.

Response: We appreciate the interest of the commenters in understanding the roles of various clinical staff in care coordination under the CJR model. However, we do not plan to collect specific information about the clinical staff who furnish post-discharge home visits under this waiver of the ''incident to'' direct physician supervision requirement because this would be administratively burdensome to the physicians involved who are not themselves participants in the CJR model and, we believe, unnecessary to ensure the delivery of safe, medically necessary services. We proposed to waive only the direct physician supervision requirement for ''incident to'' services in order to permit general physician supervision for these home visits. All other Medicare rules for coverage and payment of services ''incident to'' a physician's service continue to apply, including that the personnel meet the definition of ''auxiliary personnel'' (requiring a relationship with the billing professional); that the services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness; and that the services and supplies must be of a type that are commonly furnished in the office or clinic of a physician (or other practitioner) and must be in compliance with state law. Thus, we do not believe it is necessary to apply a different standard or other requirements to post-discharge home visits permitted under the CJR model. We also will not further define the clinical staff that can furnish the post-discharge home visit but would refer readers to the description of clinical staff in the CPT coding guidelines that we provided earlier in this section. We further note that the HCPCS G-code descriptor for the post-discharge home visits includes various activities that must be in the clinical staff's scope of practice, as would be true for any service furnished ''incident to'' a physician's service. Finally, the evaluation approach to the model as described in section IV. of this final rule will yield information about care redesign approaches and their association with quality and cost performance under the CJR model.

Comment: Several commenters expressed support for the proposed level of payment for the post-discharge home visits, agreeing that this should provide adequate payment for the service. A few commenters recommended that $50 would not cover the cost of a home visit by any licensed provider and recommended that CMS substantially increase the payment amount for the visits to reflect the fair market value of the services.

Response: In response to commenters recommending a higher payment for the post-discharge home visits, we note that we have experience with home visits being furnished to model beneficiaries under BPCI, and BPCI participants have not expressed concern about the MPFS payment for post-discharge home visits under that model that are priced in the same way as our proposal for payment of such visits under the CJR model. We proposed to use the standard MPFS ratesetting methodologies to establish the MPFS RVUs based on the resources required to furnish the typical CJR model post-discharge home visit service. We did not receive any specific information from commenters about the resources required to furnish these CJR model post-discharge home visits that would lead us to adjust our proposed rule estimate of the resources required to furnish the typical CJR model post-discharge home visit service, which is similar to the BPCI post-discharge home visit service. Therefore, we are not changing our methodology for determining the payment for the CJR model post-discharge home visit under the MPFS. We have crosswalked the RVUs for the CJR model post-discharge home visit directly from those used for the similar service under BPCI, because we estimate that the typical resources to furnish these services under the two models are the same. We provide specific information on the final HCPCS post-discharge home visit G-code and CY 2016 pricing in the following Table 26.

Comment: Several commenters recommended that CMS waive the ''incident to'' direct physician supervision requirement for services other than just post-discharge home visits. The commenters recommended that CMS pay for those services using existing CPT codes and their RVUs under the MPFS in order to ensure appropriate payment for the resources

required. Infusion therapy was identified as a service for which the waiver should be provided, in order to allow CJR model beneficiaries who experience post-surgical infections to receive infusion therapy at home, a practice that commenters believe would improve the efficiency of the episode and increase beneficiary satisfaction with care.

Response: We appreciate the requests that CMS waive the ''incident to'' direct physician supervision requirement for services other than post-discharge home visits. However, we do not agree with the commenters that such a waiver is necessary for the CJR model because we believe existing Medicare program policies and other proposed waivers of program rules for this model, such as the proposed telehealth waiver, will provide sufficient flexibility to meet the episode care management and care coordination needs for CJR model beneficiaries in a variety of facility, office, and home settings after discharge from the anchor hospitalization.

In the specific clinical scenario cited by the commenters, we note that there are already several circumstances in which CMS may cover and pay for home infusions under existing Medicare program rules should a beneficiary develop a post-surgical infection that is not preventable following LEJR surgery and that requires treatment with intravenous antibiotics. For example, many post-surgical beneficiaries will be homebound for a period of time, and skilled nursing visits for infusion would be covered under the home health benefit if the beneficiary is homebound and has no willing and able caregiver that could administer such a service. In addition, aDME for an infusion pump would be covered under the DME benefit if the drug being infused is included on the national coverage determination (NCD) for infusion pumps (*https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=223&ncdver=2&DocID=280.14&SearchType=Advanced&bc=IAAAABAAAAAA&*). If an infusion pump is covered under DME, Prosthetics, Orthotics, and Supplies (DMEPOS), the DME supplier is required to set up the equipment and provide the training necessary to teach the patient how to infuse themselves at home. Infusion therapy may also be furnished in SNFs, physicians' offices, and hospital outpatient departments. Thus, because coverage is readily available to beneficiaries, we do not believe it is necessary to waive the ''incident to'' direct physician supervision requirement for other services, including infusion therapy, in order to allow them to be furnished in the beneficiary's home under the general supervision of a physician.

Final Decision: After consideration of the public comments we received, we are finalizing the proposal, without modification, to waive the ''incident to'' direct physician supervision requirement set forth at § 410.26(b)(5), to allow a CJR beneficiary who does not qualify for home health services to receive up to 9 post-discharge visits in his or her home or place of residence any time during the episode following discharge from an anchor hospitalization. We will allow clinical staff, such as nurses, considered ''auxiliary personnel'' as defined in § 410.26(a)(1), to furnish the service under the general, rather than direct, supervision of a physician. In some situations the clinical staff providing these services may be employees of the participant hospital and, as long as these clinical staff are supervised by a physician and the appropriate relationship exists between the physician and the clinical staff, payment under the MPFS can be made. Services furnished under the waiver will be billed under the MPFS by the physician or NPP or by the entity, including a hospital, to which the supervising physician or NPP has reassigned his or her benefits. We are also waiving current Medicare billing rules in order to allow the separate reporting by the physician who performed the LEJR procedure of these post-discharge home visits during surgical global periods when he or she is providing the general supervision of the post-discharge home visit.

The post-discharge home visit will be billed with the HCPCS code displayed in Table 26. This code will be payable for CJR model beneficiaries beginning April 1, 2016, the start date of the first CJR model performance year as discussed in section III.C.2.a. of this final rule. Rather than finalizing the specific RVUs for this new HCPCS code in this final rule, we are finalizing them through reference to the RVUs for another HCPCS G-code paid under the MPFS, which will be released in proximity to this rule. Specifically, the RVUs for this new code will be based upon the same inputs used to determine the CY 2016 payment rate for HCPCS code G9187 (BPCI initiative home visit for patient assessment performed by a qualified health care professional for individuals not considered homebound including, but not limited to, assessment of safety, falls, clinical status, fluid status, medication reconciliation/management, patient compliance with orders/plan of care, performance of activities of daily living, appropriateness of care setting; (for use only in the Medicare-approved BPCI initiative); may not be billed for a 30-day period covered by a transitional care management code), the specific HCPCS G-code currently used to report post-discharge home visits under BPCI. We are crosswalking the RVUs for new HCPCS code G9490 to the RVUs for the existing post-discharge home visit HCPCS G-code for the BPCI model because, given our view of the similarities between these two services in the two different models and the similar HCPCS G-code descriptors, we expect the resources required to be the same so the two codes are assigned the same inputs under the standard MPFS ratesetting methodologies. In summary, we are finalizing the policy in this CJR final rule that the new HCPCS code G9490 for CJR model post-discharge home visits will have the same RVUs as HCPCS code G9187 for BPCI model post-discharge home visits, and we will finalize the RVUs for HCPCS code G9187 in the CY 2016 MPFS final rule.

The final CY 2016 RVUs, geographic practice cost indices and conversion factor that determine the MPFS payment for HCPCS code G9187 will be included in the CY 2016 MPFS final rule. We will annually update the RVUs for HCPCS code G9490 for post-discharge home visits for CJR model beneficiaries by crosswalking the RVUs for HCPCS code G9490 to HCPCS code G9187as part of the annual MPFS update, and information on the update will be included in the MPFS final rule each year.

TABLE 26—HCPCS CODE FOR POST-DISCHARGE HOME VISITS FOR CJR MODEL BENEFICIARIES

HCPCS code No.	Long descriptor	Short descriptor	RVUs equal to those of this HCPCS code for same calendar year under the MPFS
G9490	CJR model, home visit for patient assessment performed by clinical staff for an individual not considered homebound, including, but not necessarily limited to patient assessment of clinical status, safety/fall prevention, functional status/ambulation, medication reconciliation/management, compliance with orders/plan of care, performance of activities of daily living, and ensuring beneficiary connections to community and other services. (for use only in the Medicare-approved CJR model); may not be billed for a 30 day period covered by a transitional care management code.	Joint replac mod home visit	G9187.

Beneficiaries will be able to receive post-discharge home visits furnished under the ''incident to'' direct physician supervision waiver only during the CJR LEJR episode. All other Medicare rules for coverage and payment of services ''incident'' to a physician's service continue to apply.

The final post-discharge home visit policies are set forth at § 510.600, which has been revised to use the term clinical staff instead of licensed clinician, as well as to eliminate references to licensed clinician and supervising physician employment relationships that are unnecessary because all other ''incident to'' coverage and payment policies continue to apply. The waiver of certain post-operative billing restrictions under the MPFS global surgery rules is set forth at § 510.615.

We note that we plan to monitor utilization patterns of post-discharge home visits under CJR to monitor for overutilization or significant reductions in home health services. c. Billing and Payment for Telehealth Services

As discussed in the previous section, in the proposed rule, we described our expectation that the CJR model design features would lead to greater interest on the part of hospitals and other providers and suppliers caring for CJR beneficiaries in furnishing services to beneficiaries in their home or place of residence, including physicians' professional services. While physicians and NPPs may furnish and be paid by Medicare for home visits under the MPFS, few visits are actually furnished to Medicare beneficiaries because of the significant physician and NPP resources required for such visits and the general structure of most physician and non-physician practitioner office-based practices. For example, in 2014 only 2.6 million physician or NPP home E/M visits were furnished to Medicare beneficiaries in contrast to almost 250 million office or other outpatient evaluation and management visits furnished by physicians or NPPs. CJR would create new incentives for comprehensive episode care management for beneficiaries, including early identification and intervention regarding changes in health status following discharge from the anchor hospitalization. We discussed our understanding that participant hospitals may want to engage health care professionals in furnishing timely visits to homebound or non-homebound CJR beneficiaries in their homes or places of residence to address concerning symptoms or observations raised by beneficiaries themselves, by clinicians furnishing home health services, or by clinical staff furnishing post-discharge home visits, but physicians and NPPs committed to LEJR care redesign may not be able to revise their practice patterns to meet this home visit need for CJR beneficiaries.

Under section 1834(m) of the Act, Medicare pays for telehealth services furnished by a physician or practitioner under certain conditions even though the physician or practitioner is not in the same location as the beneficiary. The telehealth services must be furnished to a beneficiary located in one of the eight types of originating sites specified in section 1834(m)(4)(C)(ii) of the Act, and the site must satisfy at least one of the requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act. These sites include the following:

- Offices of physicians or practitioners.
- Hospitals.
- CAHs.
- RHCs
- Federally Qualified Health Centers.
- Hospital-based or CAH-based Renal Dialysis Centers (including satellites).
- SNFs.
- CMHCs.

Generally, for Medicare payment to be made for telehealth services under the MPFS, several conditions must be met, as set forth under § 410.78(b). Specifically, the service must be on the Medicare list of telehealth services and meet all of the following other requirements for payment:

- The service must be furnished via an interactive telecommunications system.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the services must be in an eligible originating site.

When all of these conditions are met, Medicare pays a facility fee to the originating site and provides separate payment to the distant site practitioner for the service. Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include professional consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system. For the list of approved Medicare telehealth services, see the CMS Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.html.* Under section 1834(m)(4)(F)(ii) of the Act, we have an annual process to consider additions to and deletions from the list of telehealth services. We do not include any services as telehealth services when Medicare does not otherwise make a separate payment for them.

Some literature suggests that technologies that enable health care providers to deliver care to patients in locations remote from providers are being increasingly used to complement face-to-face patient-provider encounters in both urban and rural areas.[49] In these

[49] Telehealth in an Evolving Health Care Environment: Workshop Summary (2012).

cases, the use of remote access technologies may improve the accessibility and timeliness of needed care, increase communication between providers and patients, enhance care coordination, and improve the efficiency of care. We noted that certain professional services that are commonly furnished remotely using telecommunications technology are paid under the same conditions as in-person physicians' services, and thus do not require a waiver to be considered as telehealth services. Such services that do not require the patient to be present in person with the practitioner when they are furnished are covered and paid in the same way as services delivered without the use of telecommunications technology when the practitioner is in person at the medical facility furnishing care to the patient.

In other CMS episode payment models, such as BPCI Models 2 and 3, we determined it was necessary to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act. This waiver allows telehealth services to be furnished to eligible telehealth individuals when they are located at one of the eight originating sites at the time the service is furnished via a telecommunications system but without regard to the site meeting one of the geographic site requirements. For CJR, we proposed a waiver of this same provision as well as waiver of the requirement that the eligible telehealth individual be in an originating site when the otherwise eligible individual is receiving telehealth services in his or her home or place of residence. This waiver would allow providers and suppliers furnishing services to CJR beneficiaries to utilize telemedicine for beneficiaries that are not classified as rural and to allow the greatest degree of efficiency and communication between providers and suppliers and beneficiaries by allowing beneficiaries to receive telehealth services at their home or place of residence. In the proposed rule, we stated our belief that these waivers are essential to maximize the opportunity to improve the quality of care and efficiency for LEJR episodes under CJR.

Specifically, like the telehealth waiver for BPCI, we proposed to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000. Waiver of this requirement would allow beneficiaries located in any region to receive services related to the episode furnished via telehealth, as long as all other Medicare requirements for telehealth services are met. Any service on the list of Medicare approved telehealth services and reported on a claim with an ICD–10–CM principal diagnosis code that was not excluded from the CJR episode definition (see section III.B.2. of this final rule) could be furnished to a CJR beneficiary, regardless of the beneficiary's geographic location. Under CJR, this waiver would support care coordination and increasing timely access to high quality care for all CJR beneficiaries, regardless of geography. Additionally, we proposed to waive, only for the purpose of testing the CJR model, the originating site requirements of section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system. Specifically, we proposed to waive the requirement only when telehealth services are being furnished in the CJR beneficiary's home or place of residence during the episode. Any service on the list of Medicare approved telehealth services and reported on a claim with an ICD–10–CM principal diagnosis code that was not excluded from the CJR episode definition (see section III.B.2. of the final rule) could be furnished to a CJR beneficiary in his or her home or place of residence, unless the service's HCPCS code descriptor precludes delivering the service in the home or place of residence. For example, subsequent hospital care services could not be furnished to beneficiaries in their home since those beneficiaries would not be inpatients of the hospital.

The following is a summary of the comments received and our responses.

Comment: Many commenters expressed support for CMS's proposal to waive the geographic site requirements for telehealth services to allow beneficiaries in any community to receive telehealth services. The commenters believe that this proposal would allow CJR participant hospitals the flexibility and opportunity to deliver needed professional services via telehealth throughout LEJR episodes in order to improve care coordination and management and respond timely to beneficiary health changes over the course of the episode. They urged CMS to finalize this proposal.

Response: Many commenters supported our proposal to waive the geographic site requirements for telehealth services. We agree with the commenters that this waiver may benefit CJR beneficiaries by allowing them to receive clinically appropriate telehealth services regardless of their geographic region, especially given the national breadth of the final selected MSAs for the model.

Comment: Many commenters expressed support for CMS's proposal to waive the originating site requirements of the Act that specify the facility or office site at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system when telehealth services are being furnished in the CJR beneficiary's home or place of residence during the episode. The commenters believe that home telehealth services would allow timely access to needed care for CJR model beneficiaries, improve communication among health care professionals caring for the beneficiary, enhance care coordination, and contribute to improved beneficiary adherence to recommended treatments. Several commenters suggested that home telehealth services could be especially valuable for specialist physicians treating beneficiaries for surgical complications, such as infectious disease specialists providing consultation on post-surgical infections. Commenters urged CMS to finalize this proposal.

Additionally, several commenters recommended that CMS modify the proposed waiver to waive the originating site requirements of the Act to allow telehealth services to be delivered to a model beneficiary when the beneficiary is not in a facility, office, or home. A commenter provided the example of a beneficiary experiencing an acute event while in a car who could pull the car off the road and access needed medical services via telehealth for treatment of his or her condition if CMS applied the proposed waiver to sites other than the home.

Response: Commenters supported our proposal to allow telehealth services to be covered when furnished in the CJR beneficiary's home or place of residence. We agree that home telehealth services may play an important role in ensuring efficient, high quality episode care for beneficiaries recovering at home following a major lower extremity surgical procedure furnished during an anchor hospitalization.

We do not agree with commenters who suggested we apply this waiver

Available at: *http://www.ic4n.org/wpcontent/uploads/2014/06/IoM%20Telehealth%202012%20Workshop%20Summary.pdf.* Accessed on June 7, 2015.

beyond the beneficiary's home or place of residence. Given the breadth of originating sites under section 1834(m)(4)(C)(ii) of the Act, which include the office of a physician or practitioner, a CAH, a rural health clinic, a federally qualified health center, a hospital, a hospital-based or CAH-based renal dialysis center (including satellites), a SNF, and a community mental health center (CMHC), and our waiver to allow telehealth services in the model beneficiary's home or place of residence, we do not believe it is necessary to include additional locations for beneficiaries to receive telehealth services during a CJR model episode. For urgent needs while traveling or otherwise not at home, we expect beneficiaries would seek care as they currently would for such circumstances to ensure timely services. For non-urgent needs, consistent with coordinated episode care that is a goal of the CJR model, we expect that beneficiaries would seek care from treating physicians and NPPs that could be delivered in one of the sites permitted under the statute and our limited waiver of the originating site requirements.

Comment: Several commenters recommended that CMS provide additional waivers that would allow payment for telehealth services other than those on the list of Medicare-approved telehealth services. Some commenters suggested that CMS should allow payment of any services delivered by telehealth, while other commenters requested that CMS permit certain additional services to be furnished by telehealth. Requested services include telemental health, teleconsultations, telenursing, and home monitoring services, including those services that are currently bundled and not separately paid by Medicare. Given that CJR beneficiaries are in LEJR episodes and would commonly require substantial rehabilitation services during their post-operative recovery period, many commenters recommended that CMS allow telerehabilitation services to be furnished by telehealth, including physical therapy, occupational therapy, and speech language pathology services.

Response: We appreciate the interest of the commenters in furnishing additional services to CJR model beneficiaries via telehealth. However, do not agree that we should waive additional requirements to increase the list of services that surpass those currently on the Medicare-approved telehealth list. We note that some of the requested services, including individual psychotherapy and certain other mental health services, are already on the Medicare-approved list of telehealth services and could, therefore, be furnished to a CJR beneficiary during an episode in the beneficiary's home or place of residence or at any geographic location under our proposed waiver. Certain consultation services, such as initial inpatient or emergency department consultations or follow-up inpatient hospital or SNF consultations, are also already on the Medicare-approved telehealth list and could be furnished via telehealth regardless of a CJR beneficiary's geographic location under our proposed waiver. We do not believe it would be appropriate to pay separately for currently bundled services, as this could lead to duplicate payment. Furthermore, we do not believe it would be appropriate to add rehabilitation services to the telehealth list as we expect that in-person therapy services already will be available to many CJR model beneficiaries in the home, such as during home health care episodes or furnished by therapists in private practice. We note that the CJR episode payment model is testing episode payment to improve care coordination and management to achieve higher quality care at a lower cost and, therefore, it is not a telehealth model testing the quality and cost outcomes due to different services furnished by telehealth. Thus, we plan to continue to rely on the list of Medicare-approved telehealth services to specify those services that may be furnished via telehealth to CJR beneficiaries. That list is updated annually and is posted on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.html*.

Comment: Several commenters recommended that CMS waive the existing requirements that define the interactive telecommunications system that is required for telehealth services to mean multimedia communication equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Some commenters specifically recommended that CMS permit store and forward technologies to be used, while other commenters suggested that CMS let providers determine the manner in which the specific telehealth service could be furnished, such as store and forward, passive remote monitoring, or audio only, assuming all other requirements for billing the services are met. These commenters recommended that such changes would expand access to telehealth services for CJR model beneficiaries who would benefit from enhanced monitoring and care management.

Response: We appreciate the information from commenters on alternative approaches to providing care to patients that are not in-person. We note that the CJR model is not testing a telehealth model and, therefore, we do not intend to fundamentally change the scope of telehealth requirements for payment under Medicare. Rather, we proposed to waive certain existing telehealth requirements to provide participant hospitals with additional tools to improve episode quality and efficiency given the constraints on physician time for in-person visits at distant locations or in the beneficiary's home. The proposed waivers would allow greater physician engagement via telehealth in CJR beneficiary care coordination and management following surgery, regardless of the beneficiary's geographic location or home location. We believe that under the CJR model it is important for beneficiaries to receive telehealth services in a way that permits them to interact with treating health care professionals in real-time, including being able to both see and interact with those providers, and the treating health care professionals being able to see and listen to the beneficiaries. Beneficiaries recovering at home following major joint replacement surgery benefit from meaningful engagement in care that is patient-centered in order to improve their understanding and adherence to treatment regimens. Therefore, we do not believe it would be appropriate to allow telehealth services to be furnished to CJR model beneficiaries that do not meet the existing Medicare telehealth requirements for communications technology.

Final Decision: After consideration of the public comments received, we are finalizing our proposal, without modification, to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000. Any service on the list of Medicare-approved telehealth services and reported on a claim with an ICD–10–CM principal diagnosis code that is not excluded from the CJR episode definition (see section III.B.2. of this final rule) can be furnished to a CJR beneficiary, regardless of the beneficiary's geographic location. We

also are finalizing our proposal to waive the originating site requirements of section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system only when telehealth services are being furnished in the CJR beneficiary's home or place of residence during the episode. Any service on the list of Medicare approved telehealth services and reported on a claim with an ICD–10–CM principal diagnosis code that is not excluded from the CJR episode definition (see section III.B.2. of this final rule) can be furnished to a CJR beneficiary in his or her home or place of residence, unless the service's HCPCS code descriptor precludes delivering the service in the home or place of residence. We will continue to require that telehealth services furnished under the CJR model telehealth waiver be furnished using an interactive telecommunications system, consistent with the current requirement for payment of telehealth services under the MPFS.

The existing set of codes used to report evaluation and management (E/M) visits are extensively categorized and defined by the setting of the service, and the codes describe the services furnished when both the patient and the practitioner are located in that setting. Section 1834(m) of the Act provides for particular conditions under which Medicare can make payments for office visits when a patient is located in a health care setting (the originating sites authorized by statute) and the eligible practitioner is located elsewhere. However, in the proposed rule, we stated that we did not believe that the kinds of E/M services furnished to patients outside of health care settings via real-time, interactive communication technology are accurately described by any existing E/M codes. This would include circumstances when the patient is located in his or her home and the location of the practitioner is at another location. Therefore, in order to create a mechanism to report E/M services accurately under the CJR model, we proposed to create a specific set of HCPCS G-codes to describe the E/M services furnished to CJR beneficiaries in their homes via telehealth when the physician or practitioner is in another location.

Among the existing E/M visit services, we stated that we envision these services would be most similar to those described by the office and other outpatient E/M codes. Therefore, we proposed to structure the new codes similarly to the office/outpatient E/M codes but adjusted to reflect the location as the beneficiary's residence and the virtual presence of the practitioner. Specifically, we proposed to create a parallel structure and set of descriptors currently used to report office or other outpatient E/M services, (CPT codes 99201 through 99205 for new patient visits and CPT codes 99212 through 99215 for established patient visits). For example, in the proposed rule we discussed a HCPCS G-code for a level 3 E/M visit for an established patient would be a telehealth visit for the evaluation and management of an established patient in the patient's home, which requires at least 2 of the following 3 key components:

- An expanded problem focused history.
- An expanded problem focused examination.
- Medical decision making of low complexity.

Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the patient's or family's needs or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent with the patient or family or both via real-time, audio and video intercommunications technology. The preceding text would be included in the code descriptor for the proposed level 3 established patient telehealth E/M visit HCPCS G-code, just as this information is currently included in the code descriptor for the corresponding level 3 established patient office/outpatient E/M CPT code.

In the proposed rule, we noted that we were not proposing a HCPCS G-code to parallel the level 1 office/outpatient visit for an established patient, since that service does not require the presence of the physician or other practitioner. We stated our belief that this would duplicate the home visits for non-homebound beneficiaries previously discussed in this section.

We proposed to develop payment rates for these new telehealth G-codes for E/M services in the patient's home that are similar to the payment rates for the office/outpatient E/M services, since the codes will describe the work involved in furnishing similar services. Therefore, we proposed to include the resource costs typically incurred when services are furnished via telehealth. In terms of the relative resource costs involved in furnishing these services, in the proposed rule we stated our belief that the efficiencies of virtual presentation generally limit resource costs other than those related to the professional time, intensity, and MP risk to marginal levels. Therefore, we proposed to adopt work and MP RVUs associated with the corresponding level of office/outpatient codes as the typical service because the practitioner's time and intensity and MP liabilities when conducting a visit via telehealth are comparable to the office visit. We stated that final RVUs under the CY 2016 MPFS would be included in the CJR final rule. Additionally, we proposed to update these values each year to correspond to final values established under the MPFS.

We considered whether each level of visit typically would warrant support by auxiliary licensed clinical staff within the context of the CJR model. The cost of such staff and any associated supplies, for example, would be incorporated in the practice expense (PE) RVUs under the MPFS. For the lower level visits, levels 1 through 3 for new visits and 2 and 3 for established visits, we did not believe that the visit would necessarily require auxiliary clinical staff to be available in the patient's home. We anticipated these lower level visits would be the most commonly furnished and would serve as a mechanism for the patient to consult quickly with a practitioner for concerns that can be easily described and explained by the patient. We did not propose to include PE RVUs for these services, since we did not believe that virtual visits envisioned for this model typically incur the kinds of costs included in the PE RVUs under the MPFS. For higher level visits, we typically would anticipate some amount of support from auxiliary clinical staff. For example, wound examination and minor wound debridement would be considered included in an E/M visit and would require licensed clinical staff to be present in the beneficiary's home during the telehealth visit in order for the complete service to be furnished. We stated our belief that it would be rare for a practitioner to conduct as complex and detailed a service as a level 4 or 5 E/M home visit via telehealth for CJR beneficiaries in LEJR episodes without licensed clinical staff support in the home.

However, we also noted that the proposed model already includes several avenues for licensed clinical staff to be in the patient's home, either through a separately paid home visit as proposed for the model or through home health services as discussed earlier in this final rule. Therefore, although we considered support by auxiliary clinical staff to be typical for level 4 or 5 E/M visits furnished to CJR beneficiaries in

the home via telehealth, we did not propose to incorporate these costs through PE RVUs. Given the anticipated complexity of these visits, we noted that we would expect to observe level 4 and 5 E/M visits to be reported on the same claim with the same date of service as a home visit or during a period of authorized home health care. If neither of these occurs, we proposed to require the physician to document in the medical record that auxiliary licensed clinical staff were available on site in the patient's home during the visit and if they were not, to document the reason that such a high-level visit would not require such personnel.

We noted that because the services described by the HCPCS G-codes for the proposed model, by definition, are furnished remotely using telecommunications technology, they therefore are paid under the same conditions as in-person physicians' services and they do not require a waiver to the requirements of section 1834(m) of the Act. We also noted that because these home telehealth services would be E/M services, all other coverage and payment rules regarding E/M services would continue to apply.

We additionally noted that under the CJR model, this proposal to waive the originating site requirements and create new home visit telehealth HCPCS codes would support the greatest efficiency and timely communication between providers and beneficiaries by allowing beneficiaries to receive telehealth services at their places of residence.

The following is a summary of the comments received and our response.

Comment: Several commenters expressed support for CMS's proposal to establish specific HCPCS G-codes for reporting telehealth visits furnished in the beneficiary's home or place of residence. They believe these codes would facilitate tracking these services and improve understanding of the role of these visits in episode care. Several commenters suggested that the resources required to deliver these visits would be similar to the existing CPT office and other outpatient care E/M visit codes paid under the MPFS, consistent with CMS's proposal. A commenter suggested that as the CPT Editorial Panel develops CPT codes to report telehealth services, CMS should consider their use in the future for the CJR model.

Response: We agree that currently specific HCPCS G-codes are the most appropriate way for telehealth visits furnished in the CJR beneficiary's home or place of residence to be reported and paid. We have established that the work and MP RVUs for these new HCPCS G-codes will be the same as those for the comparable office and other outpatient E/M visit codes under the CY 2016 MPFS. The HCPCS G-codes, their descriptors, and the CPT codes upon which their RVUs are based are displayed in Table 27. As noted in the proposed rule, we will not be including PE RVUs in the payment rate for these unique CJR model services as we believe any practice expenses incurred to furnish these services are marginal or are paid for through other MPFS services. Accordingly, we are waiving section 1834(m)(4)(2)(B) to allow this deviation from the payment of office/outpatient visits for purposes of the CJR model telehealth in-home visit services. Finally, we will consider new CPT codes as they are released according to our usual processes, and will specifically evaluate whether they may be used in the future to report home telehealth visits for CJR model beneficiaries.

Final Decision: After considering the public comments we received, we are finalizing our proposal, without modification, to create 9 HCPCS G-codes to report home telehealth E/M visits furnished under the CJR waiver as displayed in Table 27. These codes will be payable for CJR model beneficiaries beginning April 1, 2016, the start date of the first CJR model performance year as discussed in section III.C.2.a. of this final rule. Rather than finalizing the RVUs for the new HCPCS codes in this final rule, we are finalizing them through reference to the RVUs for other CPT codes paid under the MPFS as equal to the work and MP RVUs that will be established for the comparable office/outpatient visits in the CY 2016 MPFS final rule.

The final CY 2016 RVUs, geographic practice cost indices and conversion factor that determine the payment rates for the CPT codes will be included in the CY 2016 MPFS final rule.

We will update the RVUs for the CJR model HCPCS telehealth G-codes annually by crosswalking them to the corresponding CPT codes as part of the annual MPFS update, and information on the updates will be included in the MPFS final rule each year.

TABLE 27—HCPCS CODES FOR TELEHEALTH VISITS FOR CJR MODEL BENEFICIARIES IN HOME OR PLACE OF RESIDENCE

HCPCS Code No.	Long descriptor	Short descriptor	Work and MP RVUs Equal to Those of the Corresponding Office/ Outpatient E/M Visit CPT Code for Same Calendar Year under the MPFS
G9481	Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved CJR model, which requires these 3 key components: • A problem focused history; • A problem focused examination; and • Straightforward medical decision making, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.	Remote E/M new pt 10mins.	99201

TABLE 27—HCPCS CODES FOR TELEHEALTH VISITS FOR CJR MODEL BENEFICIARIES IN HOME OR PLACE OF RESIDENCE—Continued

HCPCS Code No.	Long descriptor	Short descriptor	Work and MP RVUs Equal to Those of the Corresponding Office/ Outpatient E/M Visit CPT Code for Same Calendar Year under the MPFS
G9482	Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved CJR model, which requires these 3 key components: • An expanded problem focused history; • An expanded problem focused examination; • Straightforward medical decision making, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Remote E/M new pt 20mins.	99202
G9483	Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved CJR model, which requires these 3 key components: • A detailed history; • A detailed examination; • Medical decision making of low complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.	Remote E/M new pt 30mins.	99203
G9484	Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved CJR model, which requires these 3 key components: • A comprehensive history; • A comprehensive examination; • Medical decision making of moderate complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.	Remote E/M new pt 45mins.	99204
G9485	Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved CJR model, which requires these 3 key components: • A comprehensive history; • A comprehensive examination; • Medical decision making of high complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate to high severity. Typically, 60 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.	Remote E/M new pt 60mins.	99205
G9486	Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved CJR model, which requires at least 2 of the following 3 key components: • A problem focused history; • A problem focused examination; • Straightforward medical decision making, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.	Remote E/M est. pt 10mins.	99212

TABLE 27—HCPCS CODES FOR TELEHEALTH VISITS FOR CJR MODEL BENEFICIARIES IN HOME OR PLACE OF RESIDENCE—Continued

HCPCS Code No.	Long descriptor	Short descriptor	Work and MP RVUs Equal to Those of the Corresponding Office/ Outpatient E/M Visit CPT Code for Same Calendar Year under the MPFS
G9487	Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved CJR model, which requires at least 2 of the following 3 key components: • An expanded problem focused history; • An expanded problem focused examination; • Medical decision making of low complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.	Remote E/M est. pt 15mins.	99213
G9488	Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved CJR model, which requires at least 2 of the following 3 key components: • A detailed history; • A detailed examination; • Medical decision making of moderate complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Remote E/M est. pt 25mins.	99214
G9489	Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved CJR model, which requires at least 2 of the following 3 key components: • A comprehensive history; • A comprehensive examination; • Medical decision making of high complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.	Remote E/M est. pt 40mins.	99215

With respect to home health services paid under the HH PPS, in the proposed rule we emphasized that telehealth visits under this model cannot substitute for in-person home health visits per section 1895(e)(1)(A) of the Act. Furthermore, telehealth services by social workers could not be furnished for CJR beneficiaries who are in a home health episode of care because medical social services are included as home health services per section 1861(m) of the Act and paid for under the Medicare HH PPS. However, telehealth services permitted under section 1834 of the Act and furnished by physicians or other practitioners, specifically physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, nurse anesthetists, psychologists, and dieticians, could be furnished for CJR beneficiaries who are in a home health episode of care. Finally, sections 1835(a) and 1814(a) of the Act require that the patient has a face-to-face encounter with the certifying physician or an allowed NPP working in collaboration with or under the supervision of the certifying physician before the certifying physician certifies that the patient is eligible for home health services. Under § 424.22(a)(1)(v), the face-to-face encounter can be performed up to 90 days prior to the start of home health care or within 30 days after the start of home health care. Section 424.22(a)(1)(v)(A) also allows a physician, with privileges, who cared for the patient in an acute or PAC setting (from which the patient was directly admitted to home health) or an allowed NPP working in collaboration with or under the supervision of the acute or PAC physician to conduct the face-to-face encounter.

Although sections 1835(a) and 1814(a) of the Act allow the face-to-face encounter to be performed via telehealth, we did not propose that the waiver of the telehealth geographic site requirement for telehealth services and the originating site requirement for telehealth services furnished in the CJR beneficiary's home or place of residence would apply to the face-to-face encounter required as part of the home health certification when that encounter is furnished via telehealth. In other words, when a face-to-face encounter furnished via telehealth was used to meet the requirement for home health certification, the usual Medicare

telehealth rules would apply with respect to geography and eligibility of the originating site. We discussed our expectation that this policy would not limit CJR beneficiaries' access to medically necessary home health services because beneficiaries receiving home health services during a CJR episode would have had a face-to-face encounter with either the physician or an allowed NPP during their anchor hospitalization or a physician or allowed NPP during a PAC facility stay prior to discharge directly to home health services.

The following is a summary of the comments received and our responses.

Comment: Some commenters recommended that CMS waive additional telehealth requirements to allow HHAs, physical therapists, occupational therapists, and speech language pathologists to furnish telehealth services to CJR model beneficiaries.

Response: Commenters expressed interest in increasing the types of providers and suppliers eligible to deliver telehealth services to CJR model beneficiaries; however, we believe it is most appropriate to continue to limit the health care professionals who can furnish telehealth services under the CJR model to those currently authorized to provide telehealth services under the statute, specifically, physicians, nurse practitioners, physician assistants, nurse-midwives, clinical nurse specialists, certified registered nurse anesthetists, clinical psychologists, clinical social workers, and registered dieticians or nutrition professionals. Given the services on the Medicare-approved telehealth list and CMS's experience with telehealth services furnished by currently eligible physicians and practitioners, we do not believe it is necessary to increase the types of practitioners eligible to provide telehealth services under the CJR model. As discussed earlier in this section, we are not adding additional types of services to the telehealth list and, therefore, we do not see a need to add other types of health care professionals to the list of those currently authorized to furnish telehealth services. We note that the model is not a test of telehealth services and that the proposed telehealth waivers under the CJR model are designed to increase the opportunities for care management and coordination for this test of episode payment. Finally, we expect that CJR model beneficiaries in home health episodes of care will commonly receive in-home health nursing visits and therapy services by HHAs on a regular basis. We note that while we expect the proposed telehealth waivers to increase access to services in the home where otherwise beneficiaries would not have access to such services, this would not hold true for HHAs who typically currently provide services in the home to Medicare beneficiaries under existing program rules.

Comment: Several commenters recommended that CMS permit the certification for home health services to occur via telehealth, regardless of the geographic location of the beneficiary, as well as at the beneficiary's home or place of residence.

Response: Commenters expressed interest in broadening the circumstances in which home health certification may occur via telehealth, as discussed previously we do not believe that the limitations under current law will lead to access problems for CJR model beneficiaries. During a CJR episode most beneficiaries would have had a face-to-face encounter with either the physician or an allowed NPP during their anchor hospitalization or a physician or allowed NPP during a PAC facility stay prior to discharge directly to home health services. Therefore, the usual Medicare telehealth rules would apply to these CJR beneficiaries with respect to geography and eligibility of the originating site.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal, without modification, to allow telehealth services furnished under the CJR model waiver of telehealth requirements to be furnished only by physicians and practitioners currently eligible to furnish Medicare-approved telehealth services under the MPFS. In addition, the usual Medicare rules regarding geography and originating site will continue to apply to the face-to-face encounter required for home health certification.

As we further discussed in the proposed rule, under the proposed waiver of the geographic site requirement and originating site requirement, all telehealth services would be required to be furnished in accordance with all Medicare coverage and payment criteria, and no additional payment would be made to cover set-up costs, technology purchases, training and education, or other related costs. The facility fee paid by Medicare to an originating site for a telehealth service would be waived if there is no facility as an originating site (that is, the service was originated in the beneficiary's home). Finally, providers and suppliers furnishing a telehealth service to a CJR beneficiary in his or her home or place of residence during the episode would not be permitted to bill for telehealth services that were not fully furnished when an inability to provide the intended telehealth service is due to technical issues with telecommunications equipment required for that service. Beneficiaries would be able to receive services furnished in accordance with the telehealth waivers only during the CJR LEJR episode.

The following is a summary of the comments received and our response.

Comment: Several commenters recommended that CMS pay a technology fee for telehealth services originating in a model beneficiary's home, comparable to the facility originating site fee. The commenters recommended that such a fee was necessary to pay the costs of technology required in the home for a beneficiary to receive a telehealth visit furnished via a real-time interactive telecommunications system.

Response: We appreciate the commenters' perspective on the beneficiary's technology needs for telehealth visits. However, we do not plan to provide a fee because we believe that in most circumstances, the technology can be available to the beneficiary in the home if necessary for a telehealth visit without requiring additional resources. Many beneficiaries may already have such technology in their home, such as a computer with the needed capacity. In addition, we expect that clinical staff furnishing visits paid under a home health episode of care or providing post-discharge home visits will commonly carry such technology that could be used if the timing of the telehealth visit is coordinated with the presence of such clinical staff in a beneficiary's home. We expect that in some cases, efficient and effective care management during an episode may result in closer collaboration among treating providers and clinical staff caring for CJR beneficiaries such that such coordinated visits may occur. As discussed earlier in this section, we believe that it would be rare for a practitioner to conduct as complex and detailed a service as a level 4 or 5 E/M home visit via telehealth for CJR beneficiaries in LEJR episodes without licensed clinical staff support in the home. Finally, we note that as discussed in section III.C.10.a.(2) of this final rule, participant hospitals are permitted to furnish certain beneficiary incentives to CJR beneficiaries, including items of technology that could be used for a beneficiary telehealth visit.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal, without

modification, to waive the facility fee for telehealth services furnished in a beneficiary's home or place of residence under the CJR model.

Summary of Final Decisions: For CJR model beneficiaries, with the exception of the existing geographic site requirement for a face-to-face encounter for home health certification, we are finalizing our proposal, without modification, to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000. Any service on the list of Medicare-approved telehealth services and reported on a claim with an ICD–10–CM principal diagnosis code that is not excluded from the CJR episode definition (see section III.B.2. of this final rule) can be furnished to a CJR beneficiary, regardless of the beneficiary's geographic location. For CJR model beneficiaries, with the exception of the existing originating site requirement for a face-to-face encounter for home health certification, we are also finalizing our proposal, without modification, to waive the originating site requirements of section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system only when telehealth services are being furnished in the CJR beneficiary's home or place of residence during the episode. Any service on the list of Medicare-approved telehealth services and reported on a claim with an ICD–10–CM principal diagnosis code that is not excluded from the CJR episode definition (see section III.B.2. of this final rule) can be furnished to a CJR beneficiary in his or her home or place of residence, unless the service's HCPCS code descriptor precludes delivering the service in the home or place of residence.

We are also finalizing our proposal, without modification, to create 9 HCPCS G-codes to report home telehealth E/M visits furnished under the CJR waiver of telehealth requirements as displayed in Table 27. These codes will be payable for CJR model beneficiaries beginning April 1, 2016. We are also waiving the requirement that the same payment made for comparable office/outpatient visits be made to eligible distant site practitioners for services reported with the new HCPCS G-codes that we are creating for the CJR model to reflect that these CJR model telehealth home visit services do not require significant practice expenses. In addition, we are finalizing our proposal, without modification, that if a level 4 or 5 home telehealth visit is furnished and a post-discharge home visit is not billed on the same claim with the same date of service or the beneficiary is not in a period of authorized home health care, we will require that the physician or NPP furnishing the home telehealth visit document the presence of auxiliary licensed clinical staff in the home or include an explanation in the medical record as to the specific circumstances precluding the need for auxiliary staff for the specific telehealth visit. Finally, providers and suppliers furnishing a telehealth service to a CJR beneficiary in his or her home or place of residence during the episode will not be permitted to bill for telehealth services that were not fully furnished when an inability to provide the intended telehealth service is due to technical issues with telecommunications equipment required for that service.

Under the waiver of the geographic site requirement and originating site requirement for the CJR model, we are finalizing our proposal, without modification, that no additional payment will be made to cover set-up costs, technology purchases, training and education, or other related costs. The facility fee paid by Medicare to an originating site for a telehealth service will be waived if there is no facility as an originating site (that is, the service is originated in the beneficiary's home).

All other requirements for Medicare coverage and payment of telehealth services not otherwise waived in this final rule will continue to apply, including the list of services approved to be furnished by telehealth and the eligible distant site practitioners. Beneficiaries can receive services furnished under the telehealth waivers only during the CJR LEJR episode.

The final telehealth policies are set forth at § 510.605. We have revised § 510.605(a) and (b) to clarify that the telehealth waivers do not apply to the requirements for a face-to-face encounter for home health certification. We have revised § 510.605(c) to specify the two waivers of selected payment provisions, moving the waiver of the facility fee if the telehealth service is provided in the beneficiary's home from proposed § 510.605(b)(2) to § 510.605(c)(1) and adding § 510.605(c)(2) for the waiver of the payment requirements under section 1834(m)(2)(B) for the in-home telehealth visit HCPCS G-codes created for the CJR model. We have renumbered proposed § 510.605(c) to new (d).

We note that we plan to monitor patterns of utilization of telehealth services under CJR to monitor for overutilization or reductions in medically necessary care, and significant reductions in face-to-face visits with physicians and NPPs. We will specifically monitor the distribution of new telehealth home visits, as we anticipate greater use of lower level telehealth visits than higher level telehealth visits for CJR model beneficiaries. Given our concern that auxiliary clinical staff be present for level 4 and 5 visits furnished remotely, we will also monitor whether these visits are billed on the same claim with the same date of service as a post-discharge home visit or during a period of authorized home health care, and, if neither of the prior two conditions are met, whether our final requirement that the physician or NPP document the presence of auxiliary licensed clinical staff in the home or include an explanation in the medical record as to the specific circumstances precluding the need for auxiliary staff for the specific visit is met.

d. SNF 3-Day Rule

In the proposed rule, we discussed our expectation that the CJR model would encourage participant hospitals and their provider and supplier partners to redesign care for LEJR episodes across the continuum of care extending to 90 days post-discharge from the anchor hospitalization. We stated our belief that hospitals would seek to develop and refine the most efficient care pathways so beneficiaries receive the lowest intensity, clinically appropriate care at each point in time throughout the episode. We understand that in some cases, particularly younger beneficiaries undergoing total knee replacement, certain beneficiaries receiving LEJR procedures may be appropriately discharged from the acute care hospital to a SNF in less than the 3 days required under the Medicare program for coverage of the SNF stay. While total knee arthroplasty (TKA) remains payable by Medicare to the hospital only when furnished to hospital inpatients, we have heard from some stakeholders that these procedures may be safely furnished to hospital outpatients with a hospital outpatient department stay of only 24 hours. Finally, we noted that the current geometric mean hospital length of stay for LEJR procedures for beneficiaries without major complications or comorbidities (MS–DRG 470) is only 3 days and that for MS–DRG 469 for beneficiaries with such complications or comorbidities is 6 days. Thus, in the

proposed rule we stated our belief that it is possible that hospitals working to increase episode efficiency may identify some CJR beneficiaries who could be appropriately discharged from the hospital to a SNF in less than 3 days, but that early discharge would eliminate Medicare coverage for the SNF stay unless a waiver of Medicare requirements were provided under CJR.

The Medicare SNF benefit is for beneficiaries who require a short-term intensive stay in a SNF, requiring skilled nursing or skilled rehabilitation care or both. In accordance with section 1861(i) of the Act, beneficiaries must have a prior inpatient hospital stay of no fewer than 3-consecutive days in order to be eligible for Medicare coverage of inpatient SNF care. We refer to this as the SNF 3-day rule. We note that the SNF 3-day rule has been waived or is not a requirement for Medicare SNF coverage under other CMS models or programs, including BPCI Model 2. BPCI Model 2 awardees that request and are approved for the waiver can discharge Model 2 beneficiaries in less than 3 days from an anchor hospital stay to a SNF, where services are covered under Medicare Part A as long as all other coverage requirements for such services are satisfied.

Currently, FFS Medicare beneficiary discharge patterns to a SNF immediately following hospitalization for an LEJR procedure vary regionally across the country, from a low of approximately 10 percent of Medicare beneficiaries to a high of approximately 85 percent.[50] Additionally, a study of Medicare beneficiaries has shown that over the period of time between 1991 and 2008, as the inpatient hospital length-of-stay for total hip arthroplasty (THA) decreased from an average of 9.1 days to an average of 3.7 days, the average percentage of primary THA patients discharged directly to home declined from 68 percent to 48 percent while the proportion discharged directly to skilled care (primarily SNFs) increased from 17.8 percent to 34.3 percent,[51] reflecting that nationally there has been increasing SNF utilization over almost two decades for beneficiaries following discharge from a hospitalization for primary THA. Similar to the proposed CJR payment policies that we discuss in section III.C. of this final rule, which would require participating CJR hospitals to repay Medicare for excess episode spending beginning in performance year 2, participants in BPCI Model 2 assume financial responsibility for episode spending for beneficiaries included in a Model 2 episode. Episode payment models like BPCI and CJR have the potential to mitigate the existing incentives under the Medicare program to overuse SNF benefits for beneficiaries, as well as to furnish many fragmented services that do not reflect significant coordinated attention to and management of complications following hospital discharge. The removal of these incentives in an episode payment model lays the groundwork for offering participant hospitals greater flexibility around the parameters that determine SNF stay coverage. BPCI participants considering the early discharge of a beneficiary in accordance with the waiver during a Model 2 episode must evaluate whether early discharge to a SNF is clinically appropriate and SNF services are medically necessary. Next, they must balance that determination and the potential benefits to the hospital in the form of internal cost savings due to greater financial efficiency with the understanding that a subsequent hospital readmission, attributable to premature discharge or low quality SNF care, could substantially increase episode spending while also resulting in poorer quality of care for the beneficiary. Furthermore, early hospital discharge for a beneficiary who would otherwise not require a SNF stay (that is, the beneficiary has no identified skilled nursing or rehabilitation need that cannot be provided on an outpatient basis) following a hospital stay of typical length does not improve episode efficiency under an episode payment model such as BPCI or CJR.

Because of the potential benefits we see for participating CJR hospitals, their provider partners, and beneficiaries, we proposed to waive in certain instances the SNF 3-day rule for coverage of a SNF stay following the anchor hospitalization under CJR beginning in performance year 2 of the model, when we proposed that repayment responsibility for actual episode spending that exceeds the target price would begin. We proposed to use our authority under section 1115A of the Act with respect to certain SNFs that furnish Medicare Part A post-hospital extended care services to beneficiaries included in an episode in the CJR model. We stated our belief that this waiver is necessary to the model test so that participant hospitals can redesign care throughout the episode continuum of care extending to 90 days post-discharge from the anchor hospitalization in order to maximize quality and hospital financial efficiency, as well as reduce episode spending under Medicare. However, we did not propose to waive this requirement in performance year 1, when we did not propose that participating hospitals would be responsible for excess actual episode spending. In the proposed rule, we stated our belief that there is some potential for early hospital discharge followed by a SNF stay to increase actual episode spending over historical patterns unless participant hospitals are particularly mindful of this potential unintended consequence. Without participant hospital repayment responsibility in performance year 1, we were concerned that Medicare would be at full risk under the model for increased episode spending because, without a financial incentive to closely manage care, hospitals might be more likely to discharge beneficiaries to SNFs early, leading to increased episode spending for which the hospital would bear no responsibility. Beginning in performance year 2 and continuing through performance year 5, we proposed to waive the SNF 3-day rule because we proposed that participant hospitals would bear responsibility (capped at the proposed stop-loss limit described in section III.C.8. of this final rule) for excess episode actual spending, thereby providing a strong incentive in those years for participant hospitals to redesign care with both quality and efficiency outcomes as priorities. All other Medicare rules for coverage and payment of Part A-covered SNF services would continue to apply to CJR beneficiaries in all performance years of the model.

In addition, because the average length of stay for Medicare beneficiaries hospitalized for LEJR procedures without major complications or comorbidities is already relatively short at 3 days, and in view of our concerns over protecting immediate CJR beneficiary safety and optimizing health outcomes, we proposed to require that participant hospitals may only discharge a CJR beneficiary under this proposed waiver of the SNF 3-day rule to a SNF with an overall rating of three stars or better by CMS based on information publicly available at the time of hospital discharge. Problem areas due to early hospital discharge may not be discovered through model monitoring and evaluation activities until well after the episode has concluded, and the potential for later negative findings alone may not afford sufficient beneficiary protections. CMS

[50] ''Analysis of Medicare claims with admission dates from July 1, 2013 through June 30, 2014 accessed through the Chronic Conditions Warehouse.''

[51] Cram P, Lu X, Kaboli PJ, et al. Clinical Characteristics and Outcomes of Medicare Patients Undergoing Total Hip Arthroplasty, 1991–2008. JAMA. 2011;305(15):1560–1567.

created a Five-Star Quality Rating System for SNFs to allow SNFs to be compared more easily and to help identify areas of concerning SNF performance. The Nursing Home Compare Web site (*www.medicare.gov/NursingHomeCompare/*) gives each SNF an overall rating of between 1 and 5 stars. SNFs with 5 stars are considered to have much above average quality, and SNFs with one star are considered to have quality much below average, while SNFs with three stars are considered to have average quality. Published SNF ratings include distinct ratings of health inspection, staffing, and quality measures, with ratings for each of the three sources combined to calculate an overall rating. These areas of assessment are all relevant to the quality of SNF care following discharge from the anchor hospitalization initiating a CJR episode, especially if that discharge occurs after less than three days in the hospital. A study of the clinical factors that kept patients in a Danish hospital unit dedicated to discharge in three days or fewer following total hip and knee arthroscopy procedures found that that pain, dizziness, and general weakness were the main clinical reasons for longer hospitalization, as well as problems with personal care and walking 70 meters with crutches.[52] Medicare beneficiaries discharged from the hospital to a SNF in less than three days may be at higher risk of these uncomfortable symptoms and disabling functional problems not being fully resolved at hospital discharge, although we expected that under the CJR episode payment model participant hospitals would have a strong interest in ensuring appropriate discharge timing so that hospital readmissions and complications would be minimized. Therefore, because of the potential greater risks following early inpatient hospital discharge, in the proposed rule we stated our belief that it would be appropriate for all CJR beneficiaries discharged from the participant hospital to a SNF in less than 3 days be admitted to a SNF that has demonstrated that it is capable of providing quality care to patients with significant unresolved post-surgical symptoms and problems. We believed such a SNF would need to provide care of at least average overall quality, which would be restated by an overall rating of three-stars or better.

We proposed that the waiver be available for the CJR beneficiary's care. The SNF would insert a Treatment Authorization Code on the claim for a beneficiary in the model where the SNF seeks to the use the waiver. This process would promote coordination between the SNF and the participant hospital, as the SNF would need to be in close communication with the participant hospital to ensure that the beneficiary is in the model at the time the waiver is used. We proposed that where the beneficiary would be eligible for inclusion in a CJR episode of care at the time of hospital discharge, use of the waiver would be permitted where it is medically necessary and appropriate to discharge the beneficiary to a SNF prior to a 3-day inpatient stay.

Beneficiaries would be eligible to receive services furnished under the 3-day rule waiver only during the CJR episode. In the proposed rule, we described our plan to monitor patterns of SNF utilization under CJR, particularly with respect to hospital discharge in less than 3 days to a SNF, to ensure that beneficiaries are not being discharged prematurely to SNFs and that they are able to exercise their freedom of choice without patient steering. We sought comment on our proposal to waive the SNF 3-day stay rule for stays in SNFs rated overall as three stars or better following discharge from the anchor hospitalization in CJR episodes.

The following is a summary of the comments received and our responses.

Comment: Most commenters expressed strong support for CMS's proposal to waive the SNF 3-day rule to allow CJR model beneficiaries to be discharged to a SNF after less than a 3-day inpatient hospital stay where such a discharge is clinically appropriate and medical necessary. These commenters stated that this flexibility would be very important to participant hospitals developing partnerships with PAC providers to redesign care for LEJR episodes for CJR model beneficiaries. The commenters agreed with CMS that participant hospitals would be incentivized to use this waiver judiciously because they will be actively managing care with their eye on the approach of downside risk. A commenter estimated that approximately 20 percent of elective joint replacement patients would need to be discharged to a SNF and would be able to do so safely after fewer than 3 inpatient hospital days. A small number of commenters opposed the waiver altogether because of concerns that, without sufficient protections to ensure beneficiaries' readiness for early hospital discharge, bundled payment could encourage premature hospital discharge so hospitals could reduce their internal costs for the anchor hospitalization.

Given the importance of this waiver to care redesign for LEJR episodes, many commenters recommended that CMS implement the waiver in the first performance year of the model, even though CMS proposed that hospitals would have no repayment responsibility in that year. The commenters asserted that participant hospitals would be focused in the first year of the model on creating and implementing episode care processes and procedures in order to achieve successful quality and episode spending performance. These activities would include establishing or reviewing discharge planning protocols and clinical pathways. The commenters stated that if the waiver were unavailable until performance year 2, hospitals would have to undertake many of these activities again in the second performance year, creating inefficiency and unnecessary administrative burden.

Response: Commenters supported our proposal of the SNF 3-day rule waiver to allow CJR model beneficiaries to be discharged to a SNF with an overall rating of three stars or better after less than a 3-day inpatient hospital stay. As we discussed in the proposed rule, an episode payment model like CJR has the potential to mitigate the existing incentives under the Medicare program to overuse SNF benefits for beneficiaries, as well as to furnish many fragmented services that do not reflect significant coordinated attention to and management of complications following hospital discharge. The reduction of these incentives in an episode payment model lays the groundwork for offering participant hospitals greater flexibility around the parameters that determine SNF stay coverage. We understand from many current BPCI Model 2 participants engaged in LEJR episodes that this waiver plays an important role in their care redesign efforts to streamline and improve the quality of care, as they work closely with their SNF partners. While we appreciate the concerns of those commenters identifying the need for sufficient protections for beneficiaries, we believe that our proposal to limit use of the SNF 3-day stay rule waiver to discharges of beneficiaries to SNFs with an overall rating of three stars or better, as discussed later in this section, provides sufficient protection against premature hospital discharge, especially in the context of the financial and quality incentives under the model itself.

Regarding the commenters' request to make the SNF 3-day stay rule waiver available to participant hospitals in the

[52] Husted H, Lunn TH, Troelsen A, Gaarm-Larsen L, Kristensen BB, Kehlet H. Why still in hospital after fast-track hip and knee arthroplasty? Acta Orthopaedica. 2011; 82(6)679–684.

first year of the model, we remain concerned that without participant hospital repayment responsibility in performance year 1, hospitals may be more likely to discharge beneficiaries to SNFs early leading to increased episode spending for which the hospital would bear no responsibility. Given that we are delaying the start date of the model to April 1, 2016 as discussed in section III.C.2. of this final rule, we believe hospitals will be engaged in care redesign through most of the 9 months of the shortened performance year 1 and, knowing the waiver will be available in performance year 2, can plan care processes with the appropriate use of the waiver in mind so no duplication of hospital effort will be necessary. Most commenters requesting a delayed start date for the model provided extensive information about the necessary and lengthy preparatory activities required for success under the CJR model, such as obtaining and analyzing CMS data to identify areas for performance improvement, establishing systems to track patients across the continuum of care, and forming the necessary financial arrangements. Many commenters estimated that this work would take 6 to 12 months or more. These commenters suggested that under our proposed start date of January 1, 2016, the participant hospitals moving into performance year 2 would likely have been able to complete only limited work toward restructuring care. Thus, based on our final timeline for the model performance years, the lack of hospital repayment responsibility in performance year 1, and our understanding of the work that will need to be done by participant hospitals to redesign care over the first performance year, we do not believe it is necessary or appropriate to make the SNF 3-day stay rule waiver available in performance year 1 in order to test the CJR model.

Comment: Many commenters requested that CMS make the SNF 3-day stay rule available for all medically appropriate CJR beneficiary discharges in less than 3 days from the anchor hospitalization, regardless of the star rating of the admitting SNF. The commenters asserted that such a limitation on the SNFs where a beneficiary could be discharged would limit beneficiary freedom of choice, despite CMS's assertions elsewhere in the rule that beneficiaries would retain freedom of choice about all providers and suppliers. Several commenters questioned what would happen if a beneficiary chose a SNF rated two stars or lower and was discharged in less than 3 days.

The commenters opposing the proposal to allow the waiver to be used only for CJR model beneficiaries' discharges to SNFs with an overall rating of three stars or better recommended that this proposal would create two tiers of separate and unequal care because the percentage of SNFs that meet this requirement in the selected MSAs was so variable. The commenters asserted that participant hospitals located in those MSAs with an adequate supply of three star or greater SNFs, such as where half or more of the SNFs meet the quality requirement, would be able to establish flexible, patient-centered care pathways, where participant hospitals located in those MSAs with an inadequate supply of three star or better SNFs, such as where less than half of the SNFs meet the quality requirement, would need to create more restrictive care pathways driven by CMS's SNF overall star rating requirements. Some commenters estimated that the variation in the percentage of qualifying SNFs in the selected MSAs was 20 percent to 80 percent, and recommended that this variation created an unlevel playing field for hospitals required to participate in the CJR model.

A number of commenters acknowledged the quality rationale for CMS's proposal but stated arguments about why the SNF overall star rating was not appropriate for use as the quality requirement for waiver use. These commenters asserted that the overall star rating provides little information about the quality of care for short stay residents, the category that CJR model beneficiaries would fall into, because few of the assessment questions would apply to them. Some commenters pointed out that the current star rating does not incorporate important measures of quality of care for LEJR episode beneficiaries, such as function, the ability to ambulate, hospital readmissions, and emergency department utilization. Other commenters believe that periodic recalibration activities by CMS that alter SNF scores could lead high quality SNFs working in close partnership with CJR participant hospitals to suddenly become ineligible to treat model beneficiaries under the waiver. These commenters described significant month-to-month fluctuations in SNF overall star ratings for individual SNFs that could be highly disruptive to stable care redesign under the CJR model. Several commenters suggested that SNFs with embedded specialty expertise, such as behavioral health, might be unable to admit CJR model beneficiaries who required that specialized SNF expertise.

Some commenters recommended that CMS provide accommodation for those MSAs with low percentages of qualifying SNFs, but did not specify the parameters that should accompany such accommodation. Other commenters recommended that CMS deem all hospital-owned SNFs eligible for the waiver, regardless of their star rating, or beneficiaries may need to leave their home geographic area. A commenter pointed out that swing beds in CAHs that may function as PAC providers do not have star ratings and, under CMS's proposal, would therefore be ineligible for payment under the SNF 3-day rule waiver for CJR model beneficiaries. The commenter suggested that CMS waive the proposed three star or better requirement when the PAC provider is a CAH swing bed, because these PAC providers can be an excellent choice for rural beneficiaries following an LEJR procedure due to the available resources in the CAH and the proximity of the facility to beneficiary's home.

A number of commenters recommended that CMS modify its proposal to base SNF eligibility on the overall star rating to instead base SNF eligibility on a rating of three stars or better on two of the three criteria used in the overall rating, specifically quality measures and staffing. These commenters recommended that these two criteria are meaningful for LEJR episode patients, while including the state survey criterion (the third criterion in the overall star rating) would lead to large facilities being disadvantaged because state surveyors would be more likely to find deficiencies based on larger numbers of residents. The commenters asserted that different states and different surveyors could lead to unpredictable results on the health inspections criterion for various SNFs that would unfairly affect the overall star rating and, therefore, the ability of SNFs to accept CJR model beneficiaries under the waiver. However, several other commenters pointed out that two of the three criteria used in the SNF overall star rating are self-reported by SNFs without verification, observing that only the annual inspection is derived from assessment by an independent observer.

Several commenters observed that the BPCI SNF quality requirement for use of the waiver is less stringent. BPCI Model 2 Awardees are approved to use the waiver for all of the Awardee's BPCI Model 2 beneficiaries based on their submission of partner SNFs each quarter, where the majority of those

SNFs had a three star or better overall rating for 7 of the 12 months based on the most recent SNF star data. Once approved, however, there is no requirement that a BPCI beneficiary discharged under the waiver actually go to one of the SNFs on the partner list, thereby ensuring beneficiary freedom of choice. The commenters recommended that CMS adopt a similar policy for the CJR model if CMS believes quality criteria must be applied.

Response: Commenters expressed concern about our proposal to limit the use of the waiver for CJR model beneficiaries to SNFs with an overall star rating of three stars or better. We reiterate that this proposal applies only to circumstances where the beneficiary is medically appropriate for discharge and requires a SNF stay after less than a 3-day inpatient hospital stay. Medicare will continue to cover SNF stays for CJR model beneficiaries who require SNF care and remain in the hospital 3 days or longer under all existing rules for Medicare coverage and payment of Part A-covered SNF services, and these rules do not include a star rating requirement. In this way, the CJR model waiver of the SNF 3-day stay rule is an extension of existing coverage for a Part A-covered SNF stay, and is not a limit on it.

As we stated in the proposed rule, we continue to believe that because of the potential risk of premature hospital discharge before a beneficiary is medically stable and of care stinting that may result from the financial incentives under the CJR model to reduce actual episode spending and generate hospital internal cost savings, we need to ensure that when a CJR beneficiary is discharged to a SNF before having stayed in the hospital for a qualifying 3-day or longer stay, discharges are to SNFs that provide care of at least average overall quality. Balancing beneficiary protection with the potential for participant hospitals to create patient-centered care pathways that improve quality and episode efficiency, we believe it is most appropriate for all CJR beneficiaries discharged from the participant hospital to a SNF in less than 3 days be admitted to a SNF that has demonstrated that it is capable of providing quality care to patients with significant unresolved post-surgical symptoms and problems. Thus, we believe that establishing a quality performance requirement for SNFs accepting each CJR beneficiary under the waiver is important, especially given the geographic distribution and variety of hospitals included in the CJR model, as well as the estimate from a commenter of the significant number of model beneficiaries (20 percent of elective THA and TKA model beneficiaries) that could be eligible for early hospital discharge to a SNF.

We do not believe that adopting the BPCI Model 2 SNF 3-day stay waiver policy in totality is appropriate. Under BPCI Model 2, so long as the participant identifies sufficient partnerships with SNFs with an overall rating of three stars or better, then the 3-day stay requirement is waived for that participant's discharges of BPCI model beneficiaries, even if beneficiaries are admitted to SNFs with an overall star rating of fewer than three stars. In other words, the 3-day stay rule waiver applies at the level of the financially responsible entity. Moreover, BPCI is a voluntary model where participants sign participation agreements with CMS after having assessed the opportunities under the model and chosen to participate, and can select among 48 different clinical episodes. These design features of BPCI reduce the potential risks of decreased access to care and care stinting. In contrast, under the CJR model which requires participation of substantially all IPPS hospitals in the selected MSAs, where the participant hospitals have varying levels of readiness to develop the care pathways and partnerships necessary for high quality and cost performance under an episode payment model, we believe it is necessary and appropriate to apply the waiver at the SNF level. That is, we believe that in the CJR model, it is necessary to ensure that every CJR beneficiary discharged to a covered SNF stay after less than a 3-day anchor hospitalization is discharged to a SNF that provides care of at least average quality.

In terms of establishing the quality requirement for SNFs accepting CJR model beneficiaries under the waiver, while we appreciate the variation in qualifying SNFs under our proposal across the participating MSAs, we need to balance the goal of improved efficiency under an episode payment model through additional access to a covered SNF stay after an anchor hospitalization of less than 3 days with protecting beneficiaries from the risks of care stinting and premature discharge from the hospital that may result from the financial incentives of episode payment. We estimate that although the national average percentage of SNFs rated three stars or better is greater than 60 percent, the percentage of qualifying SNFs in the MSAs selected for this model range from 22 percent to over 80 percent. However, we note that every MSA does have at least one SNF that would qualify for the waiver under our proposal and, therefore, all CJR model beneficiaries would have access to at least one SNF in the MSA of the participant hospital that meets the SNF overall star rating requirement for the waiver.

We believe it is appropriate to restrict access to the waiver for beneficiaries who are eligible for discharge to a medically necessary SNF stay after less than a 3-day anchor hospitalization to discharge to a SNF with an overall star rating of three stars or better in order to ensure SNF quality and, therefore, protect the beneficiary from potential harm that could arise from the financial incentives of the CJR episode payment model. We believe we need to balance the importance of beneficiary access to the waiver with our concerns about sufficient beneficiary protections under this innovative episode payment model that otherwise alters the rules under which Medicare pays hospitals and allows different financial arrangements among providers and suppliers. Problem areas due to early hospital discharge may not be discovered through model monitoring and evaluation activities until well after the episode has concluded, and we do not believe the potential for later negative findings alone provides sufficient beneficiary protections. Thus, we believe it is appropriate to establish a quality requirement for SNFs accepting patients for Part A-covered stays under the waiver, and believe that participant hospitals will need to convey all relevant information to CJR model beneficiaries who require SNF stays and are candidates for discharge from the anchor hospitalization in less than 3 days. If a CJR beneficiary is discharged to a SNF with an overall rating of two stars or less without a preceding 3-day anchor inpatient hospital stay, the SNF stay will not be covered under Medicare Part A, consistent with existing Medicare rules. However, we note that imposing conditions upon a waiver that, in effect, provides for additional coverage of certain SNF stays is not the same as restricting access to certain SNFs. We are not restricting beneficiary choice of SNFs. We believe it is important for beneficiaries to have unrestricted choice of providers under this model as well as access to SNFs with appropriate specialty expertise or located in their immediate community. We refer readers to section III.F.2. of this final rule for further discussion of the beneficiary choice and notification issues under this model, including their applicability to model beneficiaries who may be discharged in less than 3 days to a SNF.

Finally, for the reasons previously discussed regarding our need to balance access to the waiver with beneficiary protections, we are not making any exceptions to the overall star rating requirement for PAC providers without a star rating or hospital-owned SNFs. We note that all existing Medicare program rules will continue to apply to these providers regarding Part A-covered SNF stays, and CJR model beneficiaries will continue to be able to be discharged to these PAC providers for a Medicare-covered stay as long as the preceding inpatient hospital stay extends at least 3 days.

We appreciate the suggestions of commenters regarding alternatives to using the SNF overall star rating to determine the eligibility of a SNF to be paid for CJR model beneficiaries under the waiver based on the quality of SNF care. However, we continue to believe that SNF overall star ratings reflect important differences in quality among SNFs that are applicable to care for CJR model beneficiaries recovering after LEJR surgery. CMS rates nursing homes on three categories: Results from onsite inspections by trained surveyors, performance on certain quality measures, and levels of staffing. We use these three categories to create an overall star rating, which balances facility-reported information with independent observation. While consumers can see and focus on any of the three individual categories, we believe for purposes of this model that the overall star rating that incorporates all three categories of SNF quality performance in an overall rating is the most appropriate choice to determine SNF eligibility for use of the waiver under the CJR model, based on the SNF's record of average or better care as reflected in the most comprehensive SNF quality rating that takes into account all categories of information about SNF quality.

We acknowledge the disruption to partnerships among hospital participants and SNFs that may occur due to the potential for month-to-month changes in a SNF's quality rating and periodic CMS recalibration. We understand the substantial effort necessary for provider collaboration in care redesign and do not want the SNF 3-day stay waiver policies of the CJR model to unnecessarily disrupt or hamper these partnerships. We proposed to require that participant hospitals may only discharge a CJR beneficiary under the proposed waiver of the SNF 3-day rule to a qualified SNF with an overall rating of three stars or better by CMS based on information publicly available at the time of hospital discharge. However, in order to create more stability in our determination of SNF eligibility based on a pattern of quality performance, and in response to comments, we are modifying our proposal. Under our final policy, we will determine a SNF's qualification for payment under the CJR model waiver based on an overall star rating of three stars or better for at least 7 of the 12 preceding months according to the most recent star rating data available for the quarter in which the CJR beneficiary's admission to the SNF occurs. Specifically, we will prepare and make publicly available a list of qualified SNFs for each calendar quarter of the CJR model performance years, based on our examination of the most recent rolling 12-month period of SNF overall star ratings, and the waiver will apply for admissions to SNFs on our list during the relevant calendar quarter, assuming all other requirements for the waiver are met as discussed in this final rule. The use of such a list to determine qualified SNFs who are eligible for payment under the waiver will facilitate the ease of administration of the policy through CMS's shared systems, as well as ensure a common understanding among participant hospitals, SNFs, CJR model beneficiaries and other providers and suppliers about the specific SNFs who are qualified for Medicare Part A payment under the waiver at any given time in the model performance period.

While we will be using the pattern of SNF quality performance reflected over a rolling 12-month period to qualify SNFs for the 3-day stay waiver under the CJR model, similar to our examination of 12 months of SNF overall star ratings for BPCI partner SNFs, in contrast to BPCI Model 2, the CJR model waiver will only permit a Part A-covered SNF stay if the CJR beneficiary receives care at a qualified SNF, defined as a SNF that meets our quality requirements as determined by its inclusion on the applicable quarterly list of qualified SNFs at the time of the CJR beneficiary's admission to that SNF. In this regard, our standard under the CJR model is more stringent than under BPCI Model 2, in order to provide additional beneficiary protections under this model that includes substantially all IPPS hospitals in 67 MSAs, rather than Awardees participating in a voluntary model such as BPCI. As discussed earlier in this section, we believe that stronger beneficiary protections under the CJR model are necessary due to the required, rather than voluntary, hospital participation in the model, which will include hospitals at varying stages of readiness for engagement in the care redesign and partnerships necessary for high quality and cost performance under episode payment.

We expect that the most recent SNF quality data will lag the admission to the SNF under the CJR by several months, at a minimum. As under BPCI Model 2, we will update our determination of SNFs that qualify for the CJR model waiver every quarter, to ensure that we regularly incorporate updated SNF star ratings reflective of the most recent SNF quality performance into our determinations of SNF eligibility to admit CJR model beneficiaries under the waiver. To minimize any confusion about SNF qualification for participant hospitals and SNFs, we will post to the CMS Web site prior to the beginning of each quarter the list of qualified SNFs who may use the waiver for admissions of CJR model beneficiaries with less than a 3-day anchor hospitalization. We believe the use of a rolling 12-month period to assess SNF qualification based on the pattern of overall star ratings appropriately balances our interest in ensuring SNF quality for a beneficiary during a timeframe that is reasonably close to the CJR beneficiary's admission to the SNF, with our interest in encouraging stable, effective arrangements between SNFs that furnish high quality care and participant hospitals in the CJR model.

Comment: Several commenters requested clarification about whether the waiver of the SNF 3-day stay rule would only apply to those CJR model beneficiaries discharged in less than 3 days directly from the anchor hospitalization to a SNF or whether a beneficiary who was discharged to home in less than 3 days but later in the episode developed complications could be admitted to a SNF under the waiver.

Response: We note that the waiver under this model would make Part A post-hospital extended stay coverage available, in the context of all other current Medicare rules for coverage and payment of Part A-covered SNF services, to CJR model beneficiaries who are discharged in less than 3 days from the anchor hospitalization. Thus, in regard to the scenario stated by the commenters, if a CJR beneficiary is discharged to home after less than a 3-day inpatient hospital stay and requires SNF services within the first 30 days after discharge from the anchor hospitalization, the CJR beneficiary could be admitted to a SNF for a Part A-covered stay, assuming all other requirements for coverage and payment of Part-A covered SNF services are met and the SNF meets the quality

requirements for use of the waiver by its inclusion on the list of qualified SNFs for the calendar quarter in which the SNF admission occurs.

Comment: Several commenters posed a variety of operational questions to CMS about how the proposed waiver would be implemented, such as from whom would a SNF get a treatment authorization code and how could the waiver be used because at the time of SNF billing services could already have been rendered.

Response: Commenters expressed interest in a better understanding of the operational plans for implementing the SNF 3-day stay rule waiver. We note that since the waiver will not be available until performance year 2, CMS will publicly release various provider education materials, such as MLN Matters articles, prior to performance year 2 to educate providers regarding the use of the treatment authorization code and other billing instructions. For an example of a MLN Matters article intended for SNFs submitting claims to MACs for BPCI Model 2 beneficiaries that conveys information regarding the waiver use in that model, we refer readers to the CMS Web site at: *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8792.pdf*. We note that this is an example only, and providers caring for CJR model beneficiaries should await information specific to the CJR model before making changes to their systems.

We expect that SNFs using this waiver to bill for a Part A-covered SNF stay for a CJR beneficiary discharged from a participant hospital after an inpatient stay of less than 3-days will need to work closely with the participant hospital to determine the applicability of the waiver prior to admitting the beneficiary to the SNF because billing will not occur until after the SNF services are rendered. Specifically all of the following requirements will need to be met for the stay to be covered under the waiver:

- The hospitalization does not meet the prerequisite hospital stay of at least 3 consecutive days for Part A coverage of ''extended care'' services in a SNF. If the hospital stay would lead to covered PAC SNF treatment in the absence of the waiver, then the waiver is not necessary for the stay.
- The discharge is from a participant hospital in the CJR model. Participant hospitals can be confirmed by a posted file on the CMS Web site.
- The beneficiary's discharge is from MS–DRG 469 or MS–DRG 470.
- The beneficiary must have been discharged from the CJR model participant hospital for one of the two specified MS–DRGs within 30 days prior to the initiation of SNF services.
- The beneficiary meets the criteria for inclusion in the CJR model at the time of SNF admission: That is, he or she is enrolled in Part A and Part B, eligibility is not on the basis of ESRD, is not enrolled in any managed care plan, is not covered under a United Mine Workers of American health plan, and Medicare is the primary payer.
- The SNF is qualified to admit CJR model beneficiaries under the waiver on the date of SNF admission based on its overall star rating, which can be confirmed for the applicable date of SNF admission by a posted file on the CMS Web site that identifies qualified SNFs based on their overall star rating of three stars or better for at least 7 of the preceding 12 months. The file will be updated quarterly, reflecting a rolling 12-month period of SNF overall star ratings.

We will provide additional information on the use of this waiver to providers through MLN Matters articles and other methods prior to the beginning of performance year 2. Medicare will not cover and pay under Part A for SNF services under the CJR model SNF 3-day stay rule waiver unless all of the previously stated criteria are met. SNFs who report the treatment authorization code under circumstances where one or more of these criterion are not met will not be paid by Medicare under the waiver.

Final Decision: After consideration of the public comments we received, we are finalizing the proposal to waive the SNF 3-day rule for episodes being tested in the CJR model in performance years 2 through 5, with modification of the SNF quality requirements. We will waive the SNF 3-day rule for a CJR beneficiary following the anchor hospitalization only if the SNF is qualified at the time of the CJR beneficiary's SNF admission. We define a qualified SNF as one that has an overall rating of three stars or better in the Five-Star Quality Rating System for SNFs on the Nursing Home Compare Web site for at least 7 of the 12 preceding months, as determined by CMS based on the most recent rolling 12 months of SNF star rating data available for the calendar quarter that includes the date of the beneficiary's admission to the SNF. We will post the list of qualified SNFs quarterly to the CMS Web site. If a SNF is on this list, the other requirements for the waiver as listed previously are met, and other existing Medicare coverage requirements are met, the SNF stay for the CJR beneficiary will be covered under Part A under the CJR model SNF 3-day rule waiver.

Beneficiaries will be able to receive a Part A-covered SNF stay furnished in accordance with the SNF 3-day stay rule waiver only during the CJR episode. All other Medicare rules for coverage and payment of Part A-covered SNF services continue to apply.

The final SNF 3-day stay rule policies are set forth at § 510.610, where § 510.610(a) has been revised to clarify that the waiver applies to SNFs on the calendar quarter list of qualified SNFs and subparagraphs (1) and (2) added to reflect CMS's quarterly determination of qualified SNFs based on their overall rating of three stars or better for at least 7 of the 12 months of rolling data and subsequent posting to the CMS Web site of the list of qualified SNFs for the calendar quarter.

e. Waivers of Medicare Program Rules To Allow Reconciliation Payment or Repayment Actions Resulting From the Net Payment Reconciliation Amount (NPRA)

In order to make reconciliation payment to or carry out repayment from a participant hospital that results from the NPRA calculation for each performance year as discussed in section III.C.6.a. of this final rule, in the proposed rule we stated our belief that we would need to waive certain Medicare program rules. Therefore, in accordance with the authority granted to the Secretary in section 1115A(d)(1) of the Act, we proposed to waive requirements of the Act for all Medicare Part A and Part B payment systems only to the extent necessary to make reconciliation payments or receive repayments based on the NPRA that reflect the episode payment methodology under the proposed payment model for CJR participant hospitals selected in accordance with CMS's proposed selection methodology. In addition, we did not propose that reconciliation payments or repayments change beneficiary cost-sharing from the regular Medicare program cost-sharing for the related Part A and Part B services that were paid for CJR beneficiaries and aggregated to determine actual episode spending in the calculation of the NPRA. We therefore proposed to waive the requirements of sections 1813 and 1833(a) of the Act to the extent that they would otherwise apply to reconciliation payments or repayments from a participant hospital under the CJR model. We sought comment on our proposed waivers related to repayment and repayment actions as a result of the NRPA calculated.

Final Decision: We received no public comments on the proposed waivers of the requirements of sections 1813 and 1833(a) of the Act to the extent that they would otherwise apply to reconciliation payments or repayments from a participant hospital under the CJR model. Therefore, we are finalizing our proposal, without modification, to waive requirements of the Act for all Medicare Part A and Part B payment systems only to the extent necessary to make reconciliation payments or receive repayments based on the NPRA that reflect the episode payment methodology under the final payment model for CJR participant hospitals selected in accordance with CMS's final selection methodology. Reconciliation payments or repayments will not change beneficiary cost-sharing from the regular Medicare program cost-sharing for the related Part A and Part B services that were paid for CJR beneficiaries and aggregated to determine actual episode spending in the calculation of the NPRA.

This waiver is set forth at new § 510.620.

12. Enforcement Mechanisms

CMS must have certain mechanisms to enforce compliance with the requirements of the model, either by the participant hospital, or by an entity or individual included in the CJR model by furnishing a service to a beneficiary during a CJR episode. The following discussion details the enforcement mechanisms we proposed to make available to CMS for the CJR model.

We proposed an enforcement structure that would be consistent with other CMMI models. We believed that Model 2 of the BPCI initiative is an appropriate model for comparison, given that Model 2 and CJR share many of the same policy characteristics, particularly with respect to episode definition. For example, the participation agreement between CMS and a participant (called an Awardee) in BPCI Model 2 provides that CMS may immediately or with advance notice terminate the awardee's participation in the model or require the Awardee to terminate its agreement (''participant agreement'') with a participating provider or supplier that is not in compliance with BPCI requirements. In such circumstances, CMS may direct the Awardee to terminate its participant agreement with a participating provider or supplier because the Awardee has a participation agreement with CMS, whereas the participating provider or supplier does not. CMS may require termination of the Awardee or a participating provider or supplier if—

- CMS determines that it no longer has the funds to support the BPCI model;
- CMS terminates the model pursuant to section 1115A(b)(3)(B) of the Act; or
- The BPCI awardee or an individual or entity participating in BPCI under the awardee does any of the following:

++ Takes any action that threatens the health or safety of patients; avoids at-risk Medicare beneficiaries, as this term is defined in § 425.20; or avoids patients on the basis of payer status.

++ Is subject to sanctions or final actions of an accrediting organization or federal, state or local government agency that could lead to the inability to comply with the requirements and provisions of the BPCI agreement.

++ Takes or fails to take any action that CMS determines for program integrity reasons is not in the best interests of the BPCI initiative.

++ Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions.

Under the terms of the BPCI agreement, upon CMS's termination of the agreement for any of the reasons previously listed in this section, CMS may immediately cease the distribution of positive reconciliation payments to the awardee and the awardee must immediately cease the distribution of any gainsharing payments.

Many CMMI models also allow for CMS to impose remedial actions to address noncompliance by either a participant that has a direct relationship (participation agreement) with CMS, or by any individual or entity participating in the CMMI model pursuant to an agreement with the participant hospital. For example, with respect to the BPCI Model 2, where CMS determines that there may be noncompliance, CMS may take any or all of the following actions:

- Notify the BPCI awardee of the specific performance problem.
- Require the awardee to provide additional data to CMS or its designees.
- Require the awardee to stop distributing funds to a particular individual or entity.
- Require the awardee to forgo the receipt of any positive reconciliation payments from CMS.
- Request a corrective action plan from the awardee.

++ If CMS requests a corrective action plan, then the following requirements apply to awardees in the BPCI initiative:

—The awardee must submit a corrective action plan for CMS approval by the deadline established by CMS.

—The corrective action plan must address what actions the awardee will take within a specified time period to ensure that all deficiencies are corrected and that it remains in compliance with the BPCI agreement.

Under the CJR model, we proposed that CMS would have the enforcement mechanisms detailed in this section available for use against participant hospitals and any entity or individual furnishing a service to a beneficiary during a CJR episode, where the participant hospital or such entity or individual: (1) Does not comply with the CJR model requirements; or (2) is identified as noncompliant via CMS' monitoring of the model or engage in behavior related to any of the reasons previously described that apply to the BPCI initiative. These mechanisms will support the goals of CJR to maintain or improve quality of care. Given that participant hospitals may receive reconciliation payments, and choose to distribute or share those payments with other providers or suppliers (''CJR collaborators'') we believed that enhanced scrutiny and monitoring of participant hospitals and CJR collaborators under the model is necessary and appropriate. Participant hospitals and CJR collaborators will also be subject to all existing requirements and conditions for Medicare participation not otherwise waived under section 1115A(d)(1) of the Act.

We proposed that CMS would have the option to use any one or more of the following enforcement mechanisms for participant hospitals in CJR. We further proposed that these enforcement mechanisms could be instituted and applied in any order, as is consistent with other CMMI models:

- Warning letter—We proposed to give CMS the authority to issue a warning letter to participant hospitals to put them on notice of behavior that may warrant additional action by CMS. This letter would inform participant hospitals of the issue or issues identified by CMS leading to the issuance of the warning letter.
- Corrective Action Plan—We proposed to give CMS the authority to request a corrective action plan from participant hospitals. We proposed the following requirements for corrective action plans:

++ The participant hospital would be required to submit a corrective action plan for CMS approval by the deadline established by CMS.

++ The corrective action plan would be required to address what actions the

participant hospital will take within a specified time period to correct the issues identified by CMS.

++ The corrective action plan could include provisions requiring that the participant hospital terminate collaborator agreements with CJR collaborators that are determined by HHS to be engaging in activities involving noncompliance with the provisions of this final rule, engaged in fraud or abuse, providing substandard care, or experiencing other integrity problems.

++ The participant hospital's failure to comply with the corrective action plan within the specified time period could result in additional enforcement action, including: (1) Termination; (2) automatic forfeiture of all or a portion of any reconciliation payments as that term is defined in section III.C. of the proposed rule; (3) CMS's discretionary reduction or elimination of all or a portion of the hospital's reconciliation payment; or (4) a combination of such actions.

• Reduction or elimination of reconciliation amount—We proposed to give CMS the authority to reduce or eliminate a participant hospital's reconciliation amount based on noncompliance with the model's requirements, negative results found through CMS' monitoring activities, or the participant hospital's noncompliance associated with a corrective action plan. For example, where CMS requires a participant hospital to submit a corrective action plan, the result of the participant hospital's failure to timely comply with that requirement could be a 50 percent reduction in the reconciliation amount due to the participant hospital at the end a performance year, where the participant hospital's reconciliation report reflects a positive reconciliation amount. We solicit comments on whether negative monitoring results and noncompliance with program requirements or corrective action plans should result in automatic forfeiture of all or a portion of positive NPRA, the amount that could be forfeited or reduced, the number of performance periods over which NPRA may be forfeited or reduced per instance or episode of noncompliance, whether the amount should be a fixed percentage of NPRA or a variable amount depending on the nature and severity of the noncompliance, and the criteria CMS should use in deciding the severity of noncompliance.

Where the participant hospital's reconciliation report reflects a repayment amount, forfeiture of a reconciliation amount would not be an option for that performance year. In such a case, we considered whether CMS would require the participant hospital to forfeit a certain percentage of a reconciliation amount in the reconciliation report for a future performance year. However, in the case of a failure to comply with the model's requirements, presence of negative results found through CMS's monitoring activities, or noncompliance associated with a corrective action plan, we believed a policy that would increase the amount of repayment amount on the reconciliation report for the performance year in which the noncompliance occurred by the participant hospital is more likely to result in compliance from the hospital. Therefore, we proposed to add 25 percent to a repayment amount on a reconciliation report, where the participant hospital fails to timely comply with a corrective action plan or is noncompliant with the model's requirements. We sought comments on this forfeiture policy, including the percentage to be added to a repayment amount on a reconciliation report; the number of performance periods over which a reconciliation amount may be forfeited or reduced per instance or episode of noncompliance; whether the amount should be a fixed percentage of a reconciliation amount or repayment amount, as applicable, or a variable amount depending on the nature and severity of the noncompliance; and the criteria CMS should use in deciding the severity of noncompliance.

• Termination from the model—Given the provisions we proposed outlining the participation of hospitals in the model, we believed that, in contrast to other CMS models, termination from the CJR model would contradict the model's design. As a result, in some circumstances termination from the model may be unlikely to be a sufficient mechanism to deter noncompliance by participant hospitals. While we believed termination is a remedy unlikely to be frequently used by CMS in this model, we nonetheless leave open the possibility that in extremely serious circumstances termination might be appropriate, and for that reason, we proposed to include it as an available enforcement option. Where a participant hospital is terminated from the CJR model, we proposed that the hospital would remain liable for all negative NPRA generated from episodes of care that occurred prior to termination. We proposed that CMS may terminate the participation in CJR of a participant hospital when the participant hospital, or a CJR collaborator that has a collaborator agreement with a participant hospital and performs functions or services related to CJR activities, fails to comply with any of the requirements of the CJR model. We further proposed that CMS could terminate the participant hospital's participation in the model, or require a participant hospital to terminate a collaborator agreement with a CJR collaborator for reasons including, but not limited to the following:

• CMS determines that it no longer has the funds to support the CJR model.

• CMS terminates the model pursuant to section 1115A(b)(3)(B) of the Act.

• The CJR participant hospital, or an individual or entity participating in CJR under the participant hospital does any of the following:

++ Takes any action that threatens the health or safety of patients; avoids at-risk Medicare beneficiaries, as this term is defined in § 425.20; or avoids patients on the basis of payer status.

++ Is subject to sanctions or final actions of an accrediting organization or federal, state or local government agency that could lead to the inability to comply with the requirements and provisions of this final rule.

++ Takes or fails to take any action that CMS determines for program integrity reasons is not in the best interests of the CJR model.

++ Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions.

++ Is subject to action involving violations of the physician self-referral law, civil monetary penalties law, federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to the CJR model.

• Other Enforcement Mechanisms—We seek to incorporate policies regarding enforcement mechanisms that are necessary and appropriate to test the CJR model. Thus, we sought public comment on additional enforcement mechanisms that would contribute to the following goals:

++ Allow CMS to better operate or monitor the model.

++ Appropriately engage and encourage all entities and individuals furnishing a service to a beneficiary during a CJR episode to comply with the requirements and provisions of the CJR model.

++ Preserve the rights of Medicare beneficiaries to receive medically necessary care, to not be endangered by providers and suppliers engaging in noncompliant activities, and to be able to choose from whom they want to receive care.

We sought public comment on these proposals and invited commenters to propose additional safeguards we should consider in the final rule.

The following is a summary of the comments received and our responses.

Comment: Several comments focused on our proposal regarding termination of participant hospitals from the model. Most of these comments recommended that we add requirements such as the provision of substandard care and patient steering to the list of circumstances meriting termination. Another related line of comments suggested that a participant hospital should be appropriately penalized if it is found to have provided substandard care, delayed or withheld medically necessary care, or engaged in patient steering.

Response: Issues associated with care stinting, provision of substandard care, or denial of medically necessary care are serious matters. In no way does this final rule permit providers and suppliers furnishing services to beneficiaries in a CJR episode to engage in these sorts of behaviors. Thus, we appreciate the comments on this matter and the opportunity to clarify how we have included protections for beneficiaries by including language at § 510.410(b) that allows CMS to take action against any participant hospital that takes any action that threatens the health or safety of patients. Providers and suppliers furnishing services to CJR beneficiaries must comply with applicable Medicare CoPs and similar requirements. Nothing in this final rule alters the CoPs and similar requirements for providers and suppliers that furnish services to CJR beneficiaries. If a participant hospital or its CJR collaborator is found to have taken any action that threatens the health or safety of patients, including but not limited to withholding or delaying medically necessary care, providing substandard health care, or steering beneficiaries to certain providers or suppliers, this final rule allows CMS to take action against the participant hospital that is noncompliant or has a collaborator agreement with the noncompliant entity. These actions include the institution of corrective action plans, reduction or elimination of reconciliation payments, increased repayment amounts, and termination from the model. Furthermore, existing laws, rules, and regulations governing these matters also continue to apply to providers and suppliers furnishing services to CJR beneficiaries. Where HHS (including CMS and OIG) discovers noncompliance with existing laws, rules, and regulations, participation in the CJR model would not provide protection for participant hospitals or CJR collaborators engaging in actions that implicate care stinting, provision of substandard care, denial of medically necessary care, or any other scheme or action that is illegal or causes beneficiary harm.

Comment: Other commenters stated that CMS should strengthen the accountability of participant hospitals by implementing a separate financial penalty for hospitals found to have deliberately withheld medically necessary care or steered a patient toward a health care provider known to be delivering substandard care. Commenters suggested that such a penalty should be sizable enough to act as a disincentive for hospitals and other providers that might consider stinting as potentially profitable.

Response: As we described in our previous response, given the enforcement mechanisms delineated in this final rule, as well as the prevalence of existing laws, rules, and regulations prohibiting care stinting, provision or substandard care, or denial of medically necessary care, we believe that it unnecessary to implement processes for a separate financial penalty specifically for this model outside of the enforcement mechanisms we have already proposed. Where a participant hospital engages in these behaviors, CMS could consider reducing or eliminating that participant hospital's reconciliation payment, as well as notifying our Federal program integrity colleagues and, where appropriate, law enforcement, of such behavior, particularly in instances in which HHS (including CMS and OIG) discovered knowing violations or patterns of violations of requirements that directly impacted the safety and health of patients.

Comment: Some commenters suggested that CMS specify the amount by which it would reduce a reconciliation payment in instances of noncompliance. By contrast, other commenters recommended that CMS should have the discretion to assess penalties based on the severity of the violation or noncompliance; the degree of negligence, recklessness, or willful behavior of the parties; and evidence of patterns or practice of noncompliance or violations by participant hospitals. These commenters suggested that CMS should not be locked into a set penalty percentage, but rather should take into account all the facts and circumstances of each confirmed noncompliance or violation and set a penalty that is appropriate to address the problem and encourage improvement by the parties.

Response: We appreciate comments on this issue and agree with the latter group of commenters. We intend to exercise our authority to reduce or eliminate a participant hospital's reconciliation payment based on the severity of the noncompliance. We believe that this is a prudent approach, particularly given that, as some commenters noted, these instances are often complex and fact-specific. However, we are finalizing our proposal to add 25 percent to a repayment amount on the participant hospital's reconciliation report in the following circumstances: (1) CMS has required a corrective action plan from a participant hospital; (2) the participant hospital is not due a positive reconciliation payment but instead owes a repayment amount to CMS; and (3) the participant hospital fails to timely comply with a corrective action plan or is noncompliant with the model's requirements. This provision is added as new § 510.410(b)(3).

We leave open the possibility for future rulemaking on the issue of enforcement mechanisms for this model. We believe that providing, at a minimum, a non-exhaustive list of the types of behaviors against which CMS would use each of these enforcement mechanisms could offer useful clarification for participant hospitals and CJR collaborators.

Final Decision: After consideration of the public comments we received, we are finalizing the proposal with a modification to apply these enforcement mechanisms only to participant hospitals. We also have included a non-exhaustive list of examples of behaviors that may lead to application of these enforcement mechanisms. These policies are set forth in regulation at § 510.410.

We had proposed that CMS would have the enforcement mechanisms detailed in this section available for use against participant hospitals and any entity or individual furnishing a service to a beneficiary during a CJR episode, where the participant hospital or such entity or individual: (1) Does not comply with the CJR model requirements; or (2) is identified as noncompliant via CMS' monitoring of the model, or (3) engage in behavior related to any of the reasons previously described that apply to the BPCI initiative.

We are finalizing this proposal with a modification to clarify that CMS will enforce the model's requirements against participant hospitals. Given that participant hospitals may receive reconciliation payments, and choose to distribute or share those payments with other providers or suppliers (''CJR collaborators'') we believe that enhanced scrutiny and monitoring of participant hospitals is necessary and appropriate. We also believe that by making the participant hospital responsible for compliance with the CJR model, CMS will be indirectly ensuring CJR collaborators compliance, in addition to any direct monitoring by HHS (including CMS and OIG) of providers and suppliers that are CJR collaborators. However, because entities and individuals that are not participant hospitals are not actually participants in the CJR model, we will hold the participant hospital responsible for their own and their CJR collaborators' compliance with applicable model requirements. Thus, where CMS, HHS, or its designees discovers an instance of noncompliance by a CJR collaborator with the requirements of the CJR model, CMS, HHS, or its designees may take remedial action against the participant hospital, which may include requiring the participant hospital to terminate a collaborator agreement with a CJR collaborator and prohibit further engagement in the CJR model by that CJR collaborator. Participant hospitals and CJR collaborators remain subject to all existing requirements and conditions for Medicare participation not otherwise waived for this model under section 1115A(d)(1) of the Act.

We are finalizing our proposal to give CMS the option to use any one or more of the following enforcement mechanisms for participant hospitals in CJR. These enforcement mechanisms may be instituted and applied in any order, as is consistent with other CMS models:

- Warning letter—We are finalizing our proposal to give CMS the authority to issue a warning letter to participant hospitals to put them on notice of behavior that may warrant additional action by CMS. This letter will inform participant hospitals of the issue or issues identified by CMS leading to the issuance of the warning letter.
- Corrective Action Plan—We are finalizing our proposal to give CMS the authority to request a corrective action plan from participant hospitals. We are finalizing our proposal the following requirements for corrective action plans:

++ The participant hospital will be required to submit a corrective action plan for CMS approval by the deadline established by CMS.

++ The corrective action plan will address what actions the participant hospital must take within a specified time period to correct the issues identified by CMS.

++ The corrective action plan may include provisions requiring that the participant hospital terminate collaborator agreements with CJR collaborators that are determined by CMS, HHS, or its designees to be engaging in activities involving noncompliance with the provisions of this final rule, engaged in fraud or abuse, providing substandard care, or experiencing other integrity problems.

++ The participant hospital's failure to comply with the corrective action plan within the specified time period could result in additional enforcement action, including: (1) Termination; (2) automatic forfeiture of all or a portion, at CMS' discretion, of any reconciliation payments as that term is defined in section III.C. of the proposed rule; or (3) a combination of such actions.

- Reduction or elimination of reconciliation amount—We are finalizing our proposal to give CMS the authority to reduce or eliminate a participant hospital's reconciliation payment based on noncompliance with the model's requirements, negative results found through CMS' monitoring activities, or the participant hospital's noncompliance associated with a corrective action plan (as noted previously). For example, where CMS requires a participant hospital to submit a corrective action plan, the result of the participant hospital's failure to timely comply with that requirement could be a 50 percent reduction in the reconciliation payment due to the participant hospital at the end a performance year, where the participant hospital's reconciliation report reflects a reconciliation payment.

Where the participant hospital's reconciliation report reflects a repayment amount, forfeiture of a reconciliation payment would not be an option for that performance year. Therefore, we are finalizing our proposal to add 25 percent to a repayment amount on a reconciliation report, where the participant hospital fails to timely comply with a corrective action plan or is otherwise noncompliant with the model's requirements. This provision includes noncompliance by CJR collaborators with the model's requirements.

- Termination from the model—Given this model's provisions outlining the participation of hospitals in the model, we believe that, in contrast to other CMS models, termination from the CJR model would contradict the model's design. Nonetheless, we believe it is important for CMS to have this enforcement mechanism as an available option, and thus we are finalizing our proposal that CMS may terminate a participant hospital from the CJR model if the participant hospital, or its CJR collaborator that has a collaborator agreement with a participant hospital and performs functions or services related to CJR activities, fails to comply with any of the requirements of the CJR model or is noncompliant in other respects, which are discussed in detail later in this section. These areas of noncompliance are set forth in regulation at § 510.410(b)(1).

The effect of termination from the model is that the hospital would no longer be a participant hospital in the CJR model. We note, however, that any information collected by CMS in relation to termination of a hospital from the model would be shared with our program integrity colleagues at HHS, the Department of Justice, and their designees. Should a participant hospital, or one of its CJR collaborators, be noncompliant with the requirements of the CJR model or engage in unlawful behavior related to participation in the CJR model, we note that such information could be used in proceedings unrelated to the enforcement mechanisms in this section.

Where a participant hospital is terminated from the CJR model, we are finalizing our proposal that the hospital would remain liable for all repayment amounts from episodes of care that occurred prior to termination. CMS may terminate a participant hospital from the CJR model when the participant hospital, or its CJR collaborator performs functions or services related to CJR activities, fails to comply with any of the requirements of the CJR model. CMS may terminate a participant hospital's participation in the model, or require a participant hospital to terminate a collaborator agreement with a CJR collaborator for reasons including, but not limited to the following:

- The CJR participant hospital, a CJR collaborator that has a collaborator agreement with the participant hospital, or an individual or entity participating in the CJR model under the participant hospital does any of the following:

++ Takes any action that threatens the health or safety of patients; avoids at-risk Medicare beneficiaries, as this term is defined in § 425.20; or avoids patients on the basis of payer status.

++ Is subject to sanctions or final actions of an accrediting organization or

federal, state or local government agency that could lead to the inability to comply with the requirements and provisions of this final rule.

++ Takes any action that CMS determines for program integrity reasons is not in the best interests of the CJR model, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the CJR model.

++ Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions.

++ Is subject to action involving violations of the physician self-referral prohibition, civil monetary penalties law, federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to the CJR model.

Finally, we are clarifying our proposal that CMS may terminate the CJR model for reasons including but not limited to the following:

- CMS determines that it no longer has the funds to support the CJR model.
- CMS terminates the model pursuant to section 1115A(b)(3)(B) of the Act. As provided by section 1115A(d)(2) of the Act, termination of the model is not subject to administrative or judicial review. This provision is set forth in regulation at new § 510.900

D. Quality Measures and Display of Quality Metrics Used in the CJR Model

1. Background

a. Purpose of Quality Measures in the CJR Model

In section III.D.1.a. of the proposed rule, we stated that the priorities of the National Quality Strategy [53] include making care safer and more affordable, promoting effective communication and coordination as well as engaging patients and families in their care. We also stated our belief that quality measures that encourage providers to focus on the National Quality Strategy priorities will ultimately improve quality of care and cost efficiencies. In section III.C.5. of the proposed rule, we proposed that in order for a hospital in the model to receive a reconciliation payment for the applicable performance year, the participant hospital's measure results must meet or exceed certain thresholds compared to the national hospital measure results calculated for all HIQR-participant hospitals for all three measures for each performance period. More specifically, for performance years 1 through 3, a participant hospital's measure results must be at or above the 30th percentile of the national hospital measure results calculated for all hospitals under the HIQR Program for each of the three measures for each performance period (for a detailed discussion see section III.C.5.b. of the proposed rule). For performance years 4 and 5, a participant hospital's measure results must be at or above the 40th percentile of the national hospital measure results (for a detailed discussion see section III.C.5.b. of the proposed rule). In section III.D. of the proposed rule we proposed and described quality measures that will be used for public reporting and to determine whether a participant hospital is eligible for the reconciliation payment under the model. We proposed a Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) complications measure and readmissions measure, as well as a patient experience survey measure for the model. We stated that these measures assess the priorities of safer care, transitions of care and effective communication, and engagement of patients in their care, respectively. Specifically, we proposed the following three CMS outcome measures:

- The Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) (as referred to as THA/TKA Complications measure (NQF #1550)).
- The Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) (as referred to as THA/TKA Readmissions measure (NQF #1551)).
- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure (NQF #0166).

We indicated in the proposed rule that these measures are fully developed for the inpatient hospital settings, are endorsed by the National Quality Forum (NQF), and recommended by the NQF Measure Application Partnership (MAP) with subsequent implementation in the HIQR Program, HVBP Program, and the HRRP (see FY 2015 IPPS/LTCH final rule 79 FR 50031, 50062, 50208 through 50209, and 50259). These measures are also publicly reported on the *Hospital Compare* Web site.

We previously stated that an important purpose of the proposed quality measures for the model is to provide transparent information on hospital performance for the care of patients undergoing eligible elective joint replacement surgery, and to ensure that care quality is either maintained or improved. The proposed measures assess the following key outcomes for patients undergoing elective joint replacement surgery:

- Serious medical and surgical complications.
- Unplanned readmissions.
- Patient experience.

In the proposed rule we discussed the impact of THA/TKA procedures on complications and unplanned readmissions. We noted that THA/TKA procedure complications and readmissions result in excess inpatient and PAC spending, and reductions in these undesirable events will improve patient outcomes while simultaneously lowering healthcare spending. To this end, we also stated that the THA/TKA Complications measure (NQF #1550) will inform quality improvement efforts targeted towards minimizing medical and surgical complications during surgery and the postoperative period, and that the THA/TKA Readmissions measure (NQF #1551) captures the additional priorities of care provided in the transition to outpatient settings and communication between patients and providers, during and immediately following inpatient admission. We stated our belief that improved quality of care, specifically achieved through coordination and communication among providers, and with their patients and their caregivers, can favorably influence performance on these measures. We continue to believe improvement in measure performance will also mean improved quality of care and reduced cost.

We also stated in the proposed rule our continued focus on patient experience during hospitalizations, and our belief that the HCAHPS Survey measure (NQF #0166) provides not only the opportunity for patients to share their LEJR hospital experience, but also for hospitals to improve quality of care based on patient experience. For example, the HCAHPS Survey measure (NQF #0166) ''categories of patient experience'' specifically provides areas (for example, communication with doctors and nurses, responsiveness of hospital staff, pain management) in which a hospital could improve transition of care and increase patient safety (80 FR 41282). We also

[53] National Quality Strategy. Working for Quality: About the National Quality Strategy. Available at: *http://www.ahrq.gov/workingforquality/about.htm#develnqs*. Accessed on April 15, 2015.

summarized that the HCAHPS survey includes measures related to nurse and physician communication, pain management, timeliness of assistance, explanation of medications, discharge planning and cleanliness of the hospitals to provide specific areas for hospitals to improve on,[54] and indicated in the proposed rule the some of the specific questions on provider communication included the following:

- How often the patient believed providers listened carefully to his or her questions?
- Whether the purpose of medications and associated adverse events were explained?
- Whether discussions on post-discharge instructions and plans occurred so that the patient had a clear understanding of how to take medications and an understanding of his or her responsibilities in managing his or her health post-discharge?

In the proposed rule we addressed how these areas of patient experience would be invaluable to improving hospital quality of care. We noted that Manary, *et al.*[2] suggested that by focusing on patient outcomes, hospitals could improve patient experience and highlighted that timeliness of measuring patient experience is important due to the potential for recall inaccuracies. We noted that administration of the HCAHPS Survey measure (NQF #0166) must begin between 2 and 42 days after discharge from a hospital.

We also briefly addressed the concern regarding the question of whether there is a relationship between patient satisfaction and quality of surgical care. We addressed this question by noting the work of Tsai, *et al.*[55] We noted that Tsai *et al.* recently assessed patient satisfaction using the HCAHPS survey results and correlated quality performance using nationally implemented structural, process and outcome surgical measures (that is, structural, process and outcome surgical measures in the HVBP program and the HRRP). The study found a positive relationship between patient experience of care and surgical quality of care, among the 2,953 hospitals that perform six high cost and high frequency surgical procedures that are also associated with morbidity and mortality in Medicare beneficiaries. The study also included hip replacement procedures, and specifically noted that those hospitals with high patient satisfaction also had high performance on nationally implemented surgical quality measures (such as the Surgical Care Improvement Project measures and 30-day risk-adjusted readmission and perioperative mortality outcome measures). We noted that although the HCAHPS Survey measure (NQF #0166) is not specific to joint replacements, the survey provides all patients the opportunity to comment on their hospital experience, including patients who have received LEJRs, having all patients responding to the survey helps to inform hospitals on areas for improvement. We also indicated that while HCAHPS scores are aggregated at the hospital level, the surgical service line is one of three service lines encompassed by the survey.[56]

Finally we shared our goal to strive to align as many measures and programs as is feasibly possible, and stated our belief that proposing fully developed measures that are used in other CMS hospital quality programs will minimize the burden on participant hospitals for having to become familiar with new measures, while still allowing us to appropriately capture quality data for the model.

The following is a summary of the many comments received and our responses.

Comment: We note multiple stakeholders supported the proposed three measures and the THA/TKA voluntary data submission in the CJR model. Others specifically supported the mandatory nature of the measures because it encourages hospitals to improve quality of care for THA/TKA patients.

Response: We appreciate support by multiple stakeholders for the measures and the THA/TKA voluntary data submission in the CJR model.

Comment: A few commenters indicated concerns over beneficiary protections and potential for stinting of care as it relates to the financial incentives of the CJR model, and there were concerns about the three proposed measures being insufficient metrics to assess CJR beneficiary health care outcomes, such as a return to activities of daily life. Other beneficiary protection concerns included the potential unintended consequences of encouraging: (1) Inappropriate care shifting by providers within the 90-day post-operative day window for the THA/TKA Readmissions measure (NQF #1551); (2) readmissions related to infection, hematoma, pulmonary embolus following THA or TKA replacement which may not be controllable despite adherence to best practices should not be included in the episode of care; and (3) providers may decrease or deny access to care for patients with comorbidities, in order to improve rates on the THA/TKA Readmissions measure (NQF #1551) and THA/TKA Complications measure (NQF #1550).

Response: We appreciate the commenters' concerns about potential unintended consequences for beneficiaries resulting from implementation of the three proposed measures. We note that the CJR model does address beneficiary protections, access to care, quality of care, and delayed care, as discussed in section III.F. of this final rule.

Regarding the concern about the proposed measures being inadequate to determine whether the care provided to the patient was sufficient to promote an adequate recovery and return to activities of daily life, we acknowledge that the proposed measures do not specifically address activities of daily living, but we note that the THA/TKA PRO data collection does include survey instruments (that is, PROMIS and VR–12 surveys) that assess activities of daily life information and pain management. Through this voluntary initiative, we believe we will begin to address this gap in the current measure set for the CJR model.

Regarding the concern about the potential unintended consequences of care shifting by providers to prevent poor performance on the THA/TKA Readmissions measure (NQF #1551), we note from the beneficiary protection perspective that the model allows beneficiaries to choose their providers and suppliers, and has processes where CMS will be monitoring claims data from participant hospitals—for example, to compare a hospital's case mix relative to a pre-model historical baseline, to determine whether complex patients are being systematically excluded. We will also be publishing this data as part of the model evaluation to promote transparency and an understanding of the model's effects. We note from a quality measurement perspective that the readmission measure assesses unplanned readmissions in the 30 days following discharge from an eligible hospitalization. As previously discussed in the context of the HIQR Program (77 FR 53521), the measure uses a 30-day timeframe because it is a clinically meaningful and sufficient time period for hospitals to show the result of their

[54] Manary MP, Boulding W, Staelin R, Glickman SW. The Patient Experience and Health Outcomes. New England Journal of Medicine. Jan 2013; 368(3):201–203.

[55] Tsai TC, Orav EJ, Jha AK. Patient Satisfaction and quality of surgical care in US hospitals. Annals of Surgery. 2015; 261:2–8.

[56] Giordano LA, Elliott MN, Goldstein E, Lehrman WG, Spencer PA. Development, Implementation, and Public Reporting of the HCAHPS Survey. Medical Care Research and Review. 2010;67(1):27–37.

efforts to reduce readmissions. However, we believe that hospitals should be monitored for shifts in patient care. In the context of the Hospital Readmission Reduction Program (77 FR 53376), we acknowledged stakeholders' concerns for unintended consequences of inappropriate shifting of care, increased morbidity and mortality and other negative unintended consequences for patients. We stated our commitment to monitor the outcome measures and assess unintended consequences over time. In addition to internal monitoring of hospital performance and potential unintended consequences, we specifically publish online each year the Medicare Hospital Quality Chartbook (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/OutcomeMeasures.html*). This annual Chartbook provides new information about recent trends and variation in condition specific and surgical procedure outcomes by location, hospital characteristics, and patient disparities. In the FY2016 IPPS/LTCH final rule (80 FR 49674 through 49690), we finalized reporting of two new excess days in acute care measures that will complement the existing readmission measures by providing addition information and insight about patients that return to the hospital for emergency department visits, observation stays or inpatient readmissions after hospitalization for acute myocardial infarction and heart failure.

Regarding the concern that readmissions related to infection, hematoma, and pulmonary embolus following THA or TKA replacement may not be controlled despite adherence to best practices, we acknowledge that we do not expect hospitals to achieve a hospital-level THA/TKA RSRR of zero, but instead expect hospitals to seek and implement processes to improve their annual THA/TKA RSRR. We base this belief on the need to improve THA/TKA RSRRs, based on Medicare FFS administrative claims data from July 1, 2011 to June 30, 2014, which revealed a median RSRR of 4.8 percent with a range of 2.6 percent to 8.5 percent. A range of 2.6 percent to 8.5 percent suggests room for improvement. Further, we note that we measure all-cause readmission, including readmission for conditions such as infection, hematoma, and pulmonary embolus, rather than a narrowly defined set of conditions, to assess performance for several reasons. First, from the patient perspective, readmission for any reason is likely to be an undesirable outcome of care after an acute hospitalization. Secondly, readmissions not directly related to hip/knee replacement may still be a result of the care received during hospitalization for the procedure. For example, a patient who underwent a THA/TKA procedure who develops a hospital-acquired infection may ultimately be readmitted for sepsis. It would be inappropriate to treat this readmission as unrelated to the care the patient received during the index hospitalization. Furthermore, the range of potentially avoidable readmissions also includes those not directly related to the initial hospitalization, such as those resulting from poor communication at discharge or inadequate follow-up. In addition, readmissions for rare reasons completely unrelated to hospital care, such as car accidents involving the patient as a passenger, are likely to be distributed randomly across hospitals and are not expected to introduce bias into the measure results.

We appreciate the concern expressed by the commenter that surgeons may choose not to operate on patients who have comorbid conditions in order to improve the hospital's performance on the readmission measure. We had similar concerns about this potential unintended consequence, and for this reason the THA/TKA Readmissions measure (NQF #1551) risk adjusts for patients' risk factors, thereby taking into account case mix differences across providers. Adjusting for case mix is an important aspect for measuring a RSRR that accurately reflects factors that can confound an outcome rate when not adequately adjusted.

Finally, we do not believe that the proposed measures are insufficient metrics to assess CJR model patients. We note that hospitals are the unit of analysis for this model and that the proposed measures are hospital-level measures. We believe that these hospital-level measures do assess how hospitals provide care for THA/TKA patients since the measures assess complications, which are costly, and assess patients' perspectives on their hospital experience, which also includes patient feedback on communication with doctors, communication with nurses, responsiveness of hospital staff, pain management, communication about medicines, discharge information, cleanliness of the hospital environment, quietness of the hospital environment, and transition to post-hospital care. While we acknowledge that the proposed measures do not include reported functional outcomes, we have proposed the THA/TKA voluntary data submission initiative to begin to assess post-operative functional outcomes. To our knowledge a hospital-level risk-adjusted patient-reported functional outcome measure using a non-proprietary instrument to assess the measure outcome does not exist nor did we receive any suggestions from the public for measures that fit this description. We anticipate including hospital-level risk-adjusted patient-reported functional outcome measure in years 4 and 5 of this model.

Comment: Some commenters expressed concern that the current CJR model measure set does not adequately protect patients, since the measure set does not include what LEJR patients care most about, which is being able to walk following their joint replacement surgery and minimizing post-surgical pain. These commenters suggested that the CJR model require measures that address assessment of how well pain was managed, the patient's pain experience and the inclusion of a functional measure that meaningfully assesses the ability to walk after surgery.

Response: We note that the three proposed measures address inpatient care and that outpatient care will begin to be assessed by the by the voluntary data submission for the THA/TKA patient-reported outcome-based measure currently in development (80 FR 41284 through 41289). The HCAHPS Survey measure (NQF #0166) was created to capture many different aspects of care experienced by inpatients. The proposed HCAHPS Survey measure (NQF #0166) specifically assesses how well hospital staff help patients manage pain, how responsive hospital staff are to patients' needs and how well the patients are prepared for the transition to post-hospital care. Because the HCAHPS Survey measure (NQF #0166) begins to address areas of pain management and ambulation by assessing transition to post-hospital care, and because hospitals are very familiar with the HCAHPS Survey measure (NQF #0166), we believe that this measure is a good starting point to assess and quantify how well patients' pain was managed and whether patients' pain experience was assessed during a hospitalization. Furthermore, we believe that the THA/TKA voluntary PRO data submission portion of the CJR model does begin to address the concerns of patients, as this measure in development included patients as members of the Technical Expert Panel convened by the measure developer. The Technical Expert Panel, which included patient members, provided input into all aspects of the

development of this measure, including the proposed pre-operative and post-operative THA/TKA voluntary data elements (80 FR 41285 and 41286). We also note that patient participation was integral to the creation of the THA patients' Hip disability and Osteoarthritis Outcome Score (HOOS) and TKA patients' Knee injury and Osteoarthritis Outcome Score (KOOS) surveys. For these reasons, we believe the HCAHPS Survey measure (NQF #0166) and the HOOS and KOOS surveys in the voluntary submitted data for the THA/TKA patient-reported outcome based measure do address the perspective of patients regarding pain management, the quality of pain care and the functional assessment of walking post-primary elective THA and TKA. Finally, we emphasize we anticipate that a fully specified and tested THA/TKA patient-reported outcome-based performance measure will be included in years 4 and 5 of the CJR model.

Comment: Many commenters requested that CMS assess patient experience regarding pain experience, pain management and ambulation. In addition, they requested that measures be instituted that assess pain management frequently to counterbalance the economic interests of hospitals. Some shared that pain measures should be conducted every day and long-term measures be conducted quarterly during the first post-operative year.

Response: We appreciate the suggestions to expand the measure set for the CJR model to include inpatient and outpatient experience regarding pain management and ambulation. We note that the HCAHPS Survey measure (NQF #0166) does include inpatient pain management experience and that the THA/TKA voluntary data submission also addresses post-operative ambulation. To our knowledge, there are no other hospital-level risk-adjusted outcome measures for patient experience that assesses pain experience, pain management and ambulation. As the CJR model continues to refine its measure set we will consider the recommendation for pain management patient experience of care measures that are applied frequently to counterbalance hospital economic interests.

Comment: Commenters suggested placing a greater weight on measures that address assessment of how well pain was managed, the patient's pain experience and the inclusion of a functional measure that meaningfully assesses the ability to walk after surgery.

Response: As discussed in a prior related comment, we note that the HCAHPS Survey measure (NQF #0166) specifically assesses how well hospital staff help patients manage pain, how responsive hospital staff are to patients' needs and how well the patient was prepared for the transition to post-hospital care. We also note that section III.C.5.(c)(ii) of the proposed rule discussed an alternative link to quality and payment provided a weight of 30 percent to the HCAHPS Survey measure (NQF #0166). We refer reviewers to section III.C.5. of this final rule for responses to this comment from a payment perspective for a full discussion of the finalized policy for reconciliation payment based on measure performance. From an HCAHPS Survey measure (NQF #0166) perspective, we note that the HCAHPS survey captures the inpatient experience from the patient's perspective and the survey must be conducted within 48 hours and 6 weeks of discharge. We also note that the THA/TKA voluntary PRO data submission includes both pre-operative surveys covering 90 to 0 days of care, and post-operative surveys focus on days 270 to 365 post-surgery for the primary elective THA/TKA procedure.

Comment: Many commenters supported the proposed three measures, and specifically the mandatory nature of the measures and the proposed weights in the reconciliation payment composite quality score methodology (80 FR 41241 Table 8).

Response: We appreciate the support of the mandatory nature of the three proposed measures in the CJR model.

Comment: We received comments regarding how the CJR model links quality and payment. The comment was made based on the already low complication and readmission rates, with the suggestion to have incentive payments for sustained top performance.

Response: For a discussion of how the CJR model links quality and payment and incentive payments, we refer readers to section III.C.5. of this final rule.

Regarding that portion of the comment stating that the THA/TKA complications and readmissions rates are already low, we note that there is still room for improvement related to the complication and readmission rates for primary elective THA/TKA procedures. As previously noted in the preamble the median hospital-level primary elective THA/TKA RSCR's for April 1, 2011 through March 31, 2014 was 3.1 percent with a range from 1.4 percent to 6.9 percent. Similarly, the data on the THA/TKA RSRR for a 3-year period (July 1, 2011 to June 30, 2014) revealed a median RSRR of 4.8 percent with a range of 2.6 percent to 8.5 percent. We believe both sets of data with the median RSCR and RSRR and the associated ranges, rather than suggesting a low rate, suggest room for improvement in preventing complications. Finally, we believe, from a patient's perspective, that readmissions and complications are undesirable outcome of care, and therefore providers should strive to improve all aspects of health care that influence the occurrence of complications and readmissions so that the median RSCR, RSRR, and their ranges consistently improve over time.

Comment: A commenter while supporting the three proposed measures and the THA/TKA voluntary data submission, indicated that CMS needs to provide a stronger financial incentive and compensation for additional costs related to submission of THA/TKA voluntary PRO data.

Response: We appreciate the support of the three proposed measures and the THA/TKA voluntary PRO data submission. Regarding the comment indicating that CMS needs to provide a stronger financial incentive and compensation for additional costs related to submission of THA/TKA voluntary data, we refer readers to section III.C.5.b.(5)(c)(iii) of this final rule.

Comment: Many commenters suggested various ways to adjust the robustness of the current proposed measure set for the CJR model. Suggestions included that we (1) add more patient-reported functional measures that address ambulation and pain management, such as specific functional measures like Functional Change: Change in Motor Score (NQF #2287), CARE: Improvement in Mobility (NQF #2612) and CARE: Improvement in Self Care (NQF #2613); (2) add measures used in the BPCI model 2, including the all-cause mortality and the emergency department use without hospitalization; (3) have appropriateness measure (measuring appropriateness of care at the beginning of the episode) or a utilization measure (assessing utilization patterns and case mix as part of the evaluation); (4) have measures specific to assess care provided in a continuum consistent with the episode of care and inclusive of the PAC settings in general and specifically for home health agencies; (5) have a measure set that is similar to the Physician Quality Reporting System (PQRS) Total Knee Replacement Measures Group; and (6) incorporate Unique Device Identification (UDI) of

hip and knee replacements into administrative claims data since it would benefit the CJR model by providing better information to hospitals on device quality and costs, and could enhance data to CMS to ensure quality.

Response: We appreciate these suggestions for ways to increase the robust nature of the CJR model measure set.

We appreciate the suggestion for the Functional Change: Change in Motor Score (NQF #2287), as it helps us to be sure we have considered all possible measures. We note that the suggested measure of Functional Change: Change in Motor Score (NQF #2287) was developed for use in inpatient rehabilitation facilities (IRFs). Specifically, the Functional Change: Change in Motor Score (NQF #2287) measure is based upon the Functional Independence Measure (FIM), which is intended for use with nursing home residents and IRF patients and assesses functional status items relevant to that patient population, including Feeding, Grooming, Dressing Upper Body, Dressing Lower Body, Toileting, Bowel, Expression, Memory, Transfer to/from Bed/Chair/Wheelchair, Transfer to/from Toilet, Locomotion and Stairs. Since the unit of analysis is not acute care hospitals, this measure would not be appropriate for CJR model. We note that the TEP convened by the measure development contractor, which included clinical and technical experts as well as patients, believed the HOOS/KOOS, VR–12 and PROMIS-Global instruments assessed more meaningful pain and function outcomes at 270 to 365 days after elective primary THA/TKA patient population, which led to our proposal of the HOOS/KOOS, VR–12 and PROMIS-Global instruments. Additionally, we note that the suggested Functional Change: Change in Motor Score (NQF #2287) measure does not focus on acute care hospital care of THA/TKA patients, which is important since CJR hospitals are the unit of analysis for this model. We acknowledge the importance of assessing patient-reported functional changes, which is why we also proposed the THA/TKA voluntary data for patient-reported functional outcomes. We note that the voluntary submission of THA/TKA voluntary data for patient-reported functional outcomes using the proposed survey tools will begin to address functional outcomes of ambulation, thereby adding to the HCAHPS Survey measure (NQF #0166), which assesses inpatient pain management.

Regarding the suggestion to use BPCI model 2 measures that assessed all-cause mortality and the emergency department use without hospitalization. We note that these were not measures but instead interim analyses performed to assess these aspects of the model. Since the CJR model is specific to LEJR we chose to identify measures that were not only specific to these procedures but were risk-adjusted and developed for acute care hospitals. We also chose the proposed measures for the reasons outlined in Background sections of III.D.1.a., III.D.2.a., III.D.2.b. and III.D.2.c.

Regarding the suggestions for specific PAC measures (for example, CARE: Improvement in Mobility (NQF #2612) and CARE: Improvement in Self Care (NQF #2613)), and the general comment to add measures that: (1) Address care across the continuum of the CJR model episode of care; (2) are specific to the PAC setting; and (3) and/or are similar to the Total Knee Replacement (TKR) Measures Group found in the PQRS, we note that for this CJR model we restricted our choice of measures to hospital-level measures given that attribution of the model is at the hospital level, and specifically to risk-adjusted hospital-level outcome measures. In addition, although these suggested functional outcome measures assess functional change in the PAC setting and potentially across the continuum of the episode of care, they are not specific to the THA/TKA procedure patients in our 5-year CJR model.

Regarding the suggestion to include an appropriateness measure or a utilization measure, we are unaware of existing consensus guidelines as to what pre-operative level of pain or functional disability justifies elective primary THA or TKA procedures. Therefore, we believe it is premature to create an appropriateness measure without engaging with patients and providers to define appropriateness. Further, while we have developed a measure of Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA), this measure will not have been publicly reported until July 2016 and was therefore not considered for the CJR model at this time. We will consider changes to the quality measure components for the CJR during future rulemaking as appropriate.

Regarding the suggestion to consider device selection in measures, we understand this comment to be about post-marketing surveillance of medical devices used in THA/TKA procedures. We note that the addition of device selection and the ability to capture it through administrative claims codes will impact many other measures and CMS programs. We will evaluate this concern in the future as needed.

Comment: A single commenter requested that quality measurements between hospitals and physicians should be delinked when determining eligibility for savings, so that high-performing physicians are eligible for savings even when a hospital is underperforming.

Response: We note that section III.B. of the proposed rule provides a detailed summary of the episode definition (80 FR 41212) and a detailed discussion on why hospitals are the unit of analysis for the CJR model episode of care and the proposed quality measures. We refer reviewers to section III.C. of this final rule for a discussion on how physicians could influence their eligibility for savings under the CJR model. We note that the quality measures are all hospital-level since acute care hospitals are the unit of analysis for quality measures and that physicians will continue to be assessed through programs such as the Physician Quality Reporting System. As the CJR model undergoes refinement in the subsequent years, if it becomes reasonable and feasible to implement physician-level measures, we will consider implementing such changes to the CJR model through notice-and-comment rule making.

Comment: Some stakeholders recommended that CMS, over time, require information about patients' changes in function so that this data can be used as an outcome measure. They also agreed with the MedPAC's public comment that CMS consider collection of the same information on function that is required of PAC providers to comply with the requirements of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014.

Response: We note that CMS recently finalized an 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; endorsed on July 23, 2015) in multiple PAC settings for FY 2018 and subsequent years (for the IRF setting, see 80 FR 47100; for the LTCH setting, see 80 FR 49739). This is a process measure that requires the collection of admission and discharge functional status data using standardized clinical assessment items, or data elements that assess specific functional activities, that is, self-care and mobility activities across

PAC settings. In addition to proposing a process-based measure for the domain in the IMPACT Act of functional status, cognitive function, and changes in function and cognitive function, we also intend to develop outcomes-based quality measures, including functional status and other quality outcome measures, to further satisfy this domain. Although these measures will assess functional change for each care setting as well as across care settings, they will not be specific to the THA/TKA procedure patients in the 5-year performance period of the CJR model.

Notwithstanding the important changes instituted by the IMPACT Act, we note that current patient function data collected in various PAC PPSs gather patient function data from the provider's perspective, that is, these data are provider-reported, while the proposed THA/TKA voluntary data submission collects functional data from the patient's perspective (that is, patient-reported). We are committed to prioritizing patient-reported outcomes as these data are likely to focus attention on the most patient-centered care feasible. We also note that the PAC data are collected after the THA/TKA procedure and therefore cannot be used to assess the patient's response to this elective intervention. In addition, these data are collected at admission and discharge from PAC settings. Therefore, these data are not captured over a standard time period, and changes in these assessments may not reflect differences in quality of care across providers. Finally, these assessments are administered to patients during the acute recovery phase following these procedures, as they are intended to assess the quality of care provided during the immediate post-operative rehabilitation period. Patient function during this period is usually restricted by the responsible physician for a period of weeks to ensure prosthetic joint stability; patients' activities are then advanced as tolerated over time. Therefore, short-term functional assessments are inadequate for capturing the full patient outcomes after these procedures, and the Technical Expert Panel convened by our measure development contractor strongly urged post-operative data be collected at least 9 months after surgery. For all of these reasons, we believed the proposed voluntary PRO data collection specifications better reflect outcomes meaningful to patients undergoing elective joint replacement surgery and better assess hospital-level quality of care. We also note that depending on the quality measure used and the setting in which the measure is applied, the measure may not allow collection of identical patient function data across all settings, since an applicable patient-related functional data element in one setting may not necessarily be applicable in another setting. For example, if the intent of a patient functional measure is to assess the frequency of post-operative infections for hospitals, the same measure may not be applicable to an IRF or a HHA.

Finally, we note that we are committed to considering the implementation of quality measures that are standardized and interoperable across PAC and hospital settings using standardized patient assessment data.

Comment: Some commenters believed that linking quality measure performance to eligibility for reconciliation payment in order to ensure continued attention to quality of care throughout the duration of the program and promote collaboration among all parties involved in beneficiaries' care approach fails to reflect the quality of care to be delivered in the context of the model. These commenters believe that the currently proposed methodology to determine performance on quality measures and linkage to reconciliation payment eligibility uses arbitrary distinctions in performance among hospitals that are not borne out by the data or even by CMS's own method of rating performance on the *Hospital Compare* Web site. Further, these commenters recommend that we adopt a balanced approach by using a methodology similar to the confidence intervals used in *Hospital Compare* that distinguishes performance based on the three categories of comparison to the national average. They recommended using only the performance on THA/TKA Complications measures (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) to determine if a hospital is eligible for reconciliation payment. Specifically, they recommended that if performance on both of these two measures is both statistically worse than the national average, then a hospital should not be eligible for reconciliation payment. Additionally, other commenters agreed that use of measure result point estimates to determine percentiles may not be appropriate because—(1) The measures are a ratio comparing observed to expected, where expected is based on the national performance. An individual hospital's performance should be assessed within confidence intervals as the measure was originally specified, tested, and endorsed by the NQF; and (2) they believe that there may not be a distinguishable difference in the performance of hospitals at the 50th percentile and the 30th percentile. These commenters specifically recommended a solution that uses confidence intervals similar to how outcome measure results are presented in *Hospital Compare,* where hospitals are grouped into ''no different than the national rate,'' ''better than the national rate,'' or ''worse than the national rate.'' Hospitals that are ''no different than the national rate'' or ''better than the national rate'' should automatically be deemed eligible for any potential savings.

Response: We appreciate these comments and refer reviewers to section III.C.5.b.(5)(c)(iii) of this final rule for a detailed response to these concerns.

Comment: A single commenter sought guidance on how a hospital system will measure quality of care delivered by outside agencies.

Response: We understand the commenter to be referring to guidance on measuring the quality of care delivered by PAC providers. CMS has several PAC quality and payment programs with quality metrics. We encourage hospitals to review the—(1) IRF Program Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html*; (2) Long-Term Care Hospital Quality Reporting Program Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html?redirect=/LTCH-Quality-Reporting/*; and (3) Skilled Nursing Facility Quality initiative Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting.html.* At this time, these three PAC quality programs do not report quality measure results on a Compare Web site. For Home Health Agencies please see: *https://www.medicare.gov/homehealthcompare/*) and for Nursing Homes please see ''about the data'' tab at *https://www.medicare.gov/nursinghomecompare/* for an explanation of the measures used in these programs. We also refer the public to Data.Medicare.gov (see: *https://data.medicare.gov/*) for a list of measures in these two programs. Both the Home Health Compare and Nursing Home Compare Web sites explain their respective data sources and may be of help in guiding hospital systems that are interested in measuring quality of care delivered by home health agencies and nursing homes. For example, in the Home Health Compare Web site the section entitled ''About the Data''

indicates that data come from the following two sources: (1) CMS's health inspection database—Includes the nursing home characteristics and health deficiencies issued during the 3 most recent state inspections and recent complaint investigations. Data about staffing and penalties made against nursing homes also come from this database; and (2) National database known as the Minimum Data Set (MDS)—Data for quality measures come from the MDS Repository. The MDS is an assessment done by the nursing home at regular intervals on every resident in a Medicare- or Medicaid-certified nursing home. Information is collected about the resident's health, physical functioning, mental status, and general well-being. These data are used by the nursing home to assess each resident's needs and develop a plan of care. Understanding how CMS and states assess the care of home health agencies and becoming familiar with the guidelines that CMS sets for home health agencies can help to inform individual hospitals or hospital systems on how to assess quality of care by PAC agencies.

Comment: Some commenters had concerns regarding the proposed requirement that hospitals pass all three thresholds in order to realize and receive payment for savings. They expressed concern that such a requirement will have the effect of filtering out close to 60 percent of the participants, and believe that the proposed measures act as a triple filter and are biased against teaching hospitals and urban hospitals. They believe that the HCAHPS Survey measure (NQF #0166) is particularly biased against teaching and urban hospitals. They believe that CMS should establish a quality metric or a set of metrics that more accurately reflect care during the performance period, that are based on a set threshold, and that do not remove a certain percentage of the participants.

Response: In section III.C.5.b.(5)(c). of the proposed rule, we discussed how we would link performance on quality measures with the reconciliation payments, including the proposal to use a 30 percent threshold for the first 2 years of the model, followed by a 40 percent threshold for years 3–5 of the model. We refer reviewers to section III.C.5. of this final rule for a full discussion regarding this proposal and our final policy.

In section III.D. of the proposed rule (80 FR 41276), we discussed, in detail, the three proposed measures. From a measure perspective, we believe that the proposed measures (80 FR 41276 through 41290) of the THA/TKA Complications measure (NQF #1550), THA/TKA Readmissions (NQF #1551) and the HCAHPS Survey measure (NQF #0166) all accurately reflect the care provided by hospitals and their services as defined in the episode definition proposed in section III.B. of the proposed rule. Additionally, we believe that the proposed THA/TKA voluntary data submission initiative (80 FR 41284 through 41289) is also appropriate for the CJR model. We believe the proposed measures are appropriate because they are risk-adjusted outcome measures which assess important patient outcomes that are consistent with the National Quality Strategy (80 FR 41276), which acknowledges that complications and readmissions are disruptive to patients and caregivers, costly to the healthcare system, and puts patients at additional risk of hospital-acquired infections, and specifically recognizes that readmissions are also a major source of patient and family stress and may contribute substantially to loss of functional ability, particularly in older patients. We believe through the HCAHPS Survey measure (NQF #0166), CMS programs continue to highlight the importance of assessing patient experience of care. While we acknowledge that the current set of proposed measures do not include assessment of patient-reported functional outcomes in PAC settings, we note that the CJR model episode of care has acute care hospitals as the unit of analysis for this model. To our knowledge a hospital-level, risk-adjusted patient-reported outcome functional measure does not exist for ready use in the CJR model. We believe that the THA/TKA voluntary PRO data submission initiative begins to address this gap in available patient-reported outcome functional measures through this model. While the proposed outcome measures and the THA/TKA voluntary PRO data submission initiative are not all inclusive of all CJR model episode of care settings, these measures address the concerns of patients. Also, since this is a test model we believe the current measures begin to inform us of ways to improve future models. We also have indicated that we will be reviewing the quality measure landscape for measures that can provide further insight on hospital-level quality of care for THA/TKA procedures.

Comment: A commenter was concerned that some of the savings in the CJR model will occur after discharge and that the savings associated with the post-discharge care could impact quality of care. In order to assess this potential unintended consequence, the commenter suggested as a potential future research topic that CMS consider assessing in which setting the cost savings occur and compare that result to the quality data for the associated provider. The goal would be to answer the following questions: (1) Did any other quality measures decline as a result of the cost savings; and (2) if costs increased in a particular service area, what was the impact on the quality measures? The commenter believes that by answering these questions, we would potentially have data to help CMS better align quality measures and incentives in future models. Some commenters suggested that we assess the impact of quality measures in the CJR model and especially changes in performance amongst PAC settings relative to those participant hospitals that experienced cost savings.

Response: We will take these suggestions into consideration as CMS assesses ways in which to improve the CJR model. We are committed to ensuring that the CJR model continues to anticipate and identify unintended consequences that may adversely impact beneficiary care.

Comment: Some commenters, including consumers, strongly agreed with the quality measure thresholds of 30 percent and, later, 40 percent for earning savings. These commenters believe that retaining these standards is an essential component of the demonstration that is needed to mitigate risks of reduced care or quality for consumers.

Response: We appreciate the support of the proposed measures and the suggestion to retain the proposed quality measure thresholds of 30 percent and, in later years of the CJR model 40 percent, in order to mitigate the unintended consequence of reduced quality of care for consumers. We are also concerned about mitigating unintended consequences for consumers and refer readers to section III.C.5. of this final rule, where the policy for use of 30 percent threshold is fully discussed, and section III.F. of this final rule, where we have outlined our intent to monitor and ensure beneficiary protection against potential unintended consequences. We appreciate the importance of mitigating risks of reduced quality of care for CMS beneficiaries by finalizing thresholds that will encourage hospitals and other PAC settings to strive for improvement on measure performance. We note that in section III.C.5.b.(5)(c)(iii) of this final rule in the composite quality scoring methodology that a 30 percent threshold

was set in order to begin receiving points for performance on a measure.

Comment: A few commenters urged CMS to harmonize measures so that the goals of care will be consistent across the care continuum.

Response: While we acknowledge that the current proposed measures are hospital-level measures, we note that acute care hospitals are the unit of analysis for this model. As the CJR model continues, we will take into consideration ways in which to add measures to the model in order to have a more robust set of measures assessing all aspects of the CJR model episode.

Comment: Many commenters supported the use of all three proposed measures, while many others opposed the use of proposed measures since the measure cohorts are not completely aligned with the proposed CJR model cohorts, which are based on the MS–DRGs of 469 and 470. These MS–DRGs include all LEJR and non-elective THA/TKA procedures. Those opposed to the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) noted that the measure cohorts are limited to primary elective THA/TKA patients and that the HCAHPS Survey measure (NQF #0166) applies to all inpatients. The primary concern was that the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) fail to provide insight on quality for a significant portion of the patient population included in the CJR model. A few commenters indicated that they would not be opposed to these measures if the CJR model cohorts were completely aligned with the measure cohorts. Finally, a commenter requested clarification on the implication of using the THA/TKA Complications measure (NQF #1550), which assesses primary elective procedures and does not include patients undergoing PHA procedures.

Response: We appreciate the comments of those that supported the proposed measures. We also appreciate commenters' concerns regarding the lack of complete alignment between the CJR model cohorts and the proposed measure cohorts. We note, however, that the goal of the CJR model and the proposed episode definition are fully discussed in section III.B. of this final rule. The implication of not aligning with the MS–DRG 469 and 470 CJR model cohorts is that it will be difficult to assess the smaller percentage of non-elective THA and TKA patients. We note that elective THA and TKA cases make up the majority of MS–DRG 469 and 470 cases. We also note that the THA/TKA Complications measure (NQF #1550) was created to assess hospital performance on THA and TKA procedures that are not only primary procedures but also elective. In addition, the measure cohort was defined, with the input of clinical experts, a nationally convened Technical Expert Panel convened by our measure development contractor and public comment, to create a clinically coherent group of patients for whom appropriate risk prediction could be accomplished. As partial arthroplasty procedures are primarily done for hip fractures and are typically performed on patients who are older, frailer, and have more comorbid conditions, the clinical experts and other Technical Expert Panel members believed that these procedures represented a distinct clinical risk group and should therefore be excluded from the measure. As discussed in the proposed rule (80 FR 41278), THA and TKA elective procedures are commonly performed, and the associated complication rates are rare. However, because the rate of elective THA and TKA procedures continues to increase, the overall cost of elective THA and TKA procedure complications is high. Further, for patients undergoing elective procedures, the associated risks are particularly important to understand and weigh during their decision-making process. Current quality improvement measures for patients undergoing elective THA and TKA procedures are generally limited to evidence-based processes of care. Measurement of patient outcomes, such as complications, allows for a more comprehensive view of quality of care, capturing more complex and critical aspects of care, such as communication between providers, prevention of and response to complications, patient safety, and coordinated transitions to the outpatient environment. To date, the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) are the only outcomes measures comparing hospital performance in the care of patients undergoing elective primary THA/TKA. For these reasons, we believe that using a hospital-level risk-adjusted outcome measure is the fairest way to assess quality performance for THA and TKA procedures in the CJR model participant hospitals. As with other CMS quality and payment programs and models, we are constantly monitoring for valid and reliable measures that could be considered for the CJR model. We also may explore the possibility of further measure development to address the inclusion of non-elective THA/TKA procedures.

Comment: Some commenters suggested that there should be adjustment to the quality framework because the CJR model does not provide enough time or data to adequately prepare for the model.

Response: We disagree that there is inadequate time to prepare for the model. We note for the HIQR Program that the THA/TKA Complications measure (NQF #1550) was finalized in FY 2012 IPPS/LTCH Final Rule (77 FR 53534) for implementation in FY 2015, and the THA/TKA Readmissions measure (NQF #1551) and the most updated HCAHPS Survey measure (NQF #0166) were finalized in FY 2014 IPPS/LTCH final rule (78 FR 50807). We believe hospitals have received ample time to identify ways in which to improve their performance on these three measures. In proposing these measures, we specifically considered how familiar hospitals are with the proposed measure, knowing that hospitals will have had enough time to institute appropriate changes in order to perform well on these measures.

Final Decision: After consideration of the public comments, we acknowledge that the current set of measures are hospital-centric in order to be consistent with the goals of this model, one of which is to encourage collaboration between providers (for example, hospitals, PAC facilities, and other types of providers) in order to achieve better care with cost savings while holding the acute care hospitals financially responsible. We recognize the gaps in the current measure set relative to other settings in which patients receive care post-operatively. However, we believe that given the current design of the test model where the hospital is the unit of analysis, that the proposed measures are well developed, hospital-level risk-adjusted outcome measures that do address patient experience and outcomes that are important to patients like complications and readmissions. Further, we believe hospitals, in comparison to other health care facilities, are more likely to have resources that will allow them to appropriately coordinate and manage care throughout the episode, and hospital staff members who are already involved in hospital discharge planning and PAC recommendations for recovery, which are key dimensions of high quality and efficient care for the episode. For these reasons, we believe it is appropriate to implement hospital-level measures. We acknowledge that as CMS gains more experience with this model, there may be future

opportunities to create a more robust set of quality measures for this model where we can broaden the scope of measures to include those applicable to PAC settings. As with any new initiative, we will continue to assess the ever-changing inventory of measures with the goal to build a more robust set of measures that support the intent of this model. We intend to continue to refine the measure set based on future public comments, any changes in the payment methodology that may require specific measures, and recommendations from the participating hospitals as CMS learns more about the impact of the model on quality improvement and cost savings.

b. Public Display of Quality Measures in the CJR Model

In section III.D.5. of the proposed rule, we stated our belief that the display of measure results is an important way to educate the public on hospital performance and increase the transparency of the model, and therefore proposed, for the model, to display quality measure results on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*). We also stated our belief that the public and hospitals are familiar with this Web site and the display of hospital quality measure information, and also noted that the public and hospitals are familiar with the proposed measures, as these measures have been displayed on the *Hospital Compare* Web site over the past few years. Finally, we indicated our intent to align the display of quality measure results and access to this data for the model with other CMS hospital quality programs by proposing to post model quality measure results and data on the *Hospital Compare* Web site (80 FR 41290).

2. Quality Measures for Performance Year 1 (CY 2016) and Subsequent Years

a. Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550)

(1) Background

As stated in the proposed rule (80 FR 41278 through 41280), THA and TKA are commonly performed procedures for the Medicare population that improve quality of life. We indicated that between 2009 and 2012, there were 337,419 total hip arthroplasty (THA) procedures and 750,569 total knee arthroplasty (TKA) procedures for Medicare FFS patients 65 years and older,[57] that the post-operation complications of these procedures are high considering these are elective procedures, and recognized that complications are devastating to patients. We highlighted as an example, the rates for periprosthetic joint infection, which is a rare but devastating complication. We indicated reported rates of 2.3 percent for THA/TKA patients with rheumatoid arthritis after 1 year of follow-up,[58] and 1.6 percent in Medicare patients undergoing TKA after 2 years of follow up.[59] In the proposed rule (80 FR 41278), we also shared complication rates based on studies reporting on 90-day death rates following THA,[60] [61] reported rates for pulmonary embolism following TKA,[62] [63] [64] septicemia during an index admission,[65] and 90-days following discharge for primary TKA,[66] and rates for bleeding and hematoma following TKA.[67] [68] For combined THA and TKA procedures, we also noted in the proposed rule that these two procedures account for the largest payments for procedures under Medicare.[69] We shared our observation that while both hip and knee arthroplasty procedures improve the function and quality of life of patients with disabling arthritis, the volume and cost associated with these procedures are very high, and we believe it is important to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures.

In order to address these concerns and our reasons for proposing the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) measure, we shared historical information about this measure regarding its development, implementation in CMS programs, and its public display. Briefly, we indicated in the proposed rule (80 FR 41278) that the median hospital-level RSCR 2008 was 4.2 percent, with a range from 2.2 percent to 8.9 percent in hospitals and that we believe variation in complication rates suggests that there are important differences in the quality of care delivered across hospitals, and therefore room for quality improvement. In response to noted 2008 variation in complication rates, we developed, in 2010, the proposed measure of Hospital-Level RSCR Following Elective Primary THA and/or TKA, which attained National Quality Forum endorsement (NQF #1550) and recommendations from the NQF Measure Application Partnership (MAP) for use in the HIQR Program.[70] We also shared in the proposed rule that this measure has additionally been implemented in the HVBP program and that CMS has not submitted this measure to the NQF MAP for recommendations on use in the PAC settings since the measure was developed for the acute care hospital setting. Regarding public display of this measure, we indicated that this measure has been publicly reported on *Hospital*

[57] Suter L, Grady JL, Lin Z *et al.:* 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). 2013. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[58] Bongartz, T, Halligan CS, Osmon D, et al. Incidence and risk factors of prosthetic joint infection after total hip or knee replacement in patients with rheumatoid arthritis. Arthritis Rheum. 2008; 59(12): 1713–1720.

[59] Kurtz S, Ong K, Lau E, Bozic K, Berry D, Parvizi J. Prosthetic joint infection risk after TKA in the Medicare population. Clin Orthop Relat Res. 2010;468:5.

[60] Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684. Soohoo NF, Farng E, Lieberman JR, Chambers L, Zingmond, DS. Factors That Predict Short-term Complication Rates After Total Hip Arthroplasty. Clin Orthop Relat Res. Sep 2010;468(9):2363–2371.

[61] Soohoo NF, Farng E, Lieberman JR, Chambers L, Zingmond DS. Factors that predict short term complication rates after total hip arthroplasty. Clin Orthop Relat Res. Sep 2010; 468(9): 2363–2371.

[62] Mahomed NN, Barrett JA, Katz JN, *et al.* Rates and outcomes of primary and revision total hip replacement in the United States Medicare population. J Bone Joint Surg Am. Jan 2003;85–A(1):27–32.

[63] Khatod M, Inacio M, Paxton EW, *et al.* Knee replacement: epidemiology, outcomes, and trends in Southern California: 17,080 replacements from 1995 through 2004. Acta Orthop. Dec 2008;79(6):812–819.

[64] Solomon DH, Chibnik LB, Losina E, *et al.* Development of a preliminary index that predicts adverse events after total knee replacement. Arthritis & Rheumatism. 2006;54(5):1536–1542.

[65] Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152–156.

[66] Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684.

[67] Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152–156.

[68] Huddleston JI, Maloney WJ, Wang Y, Verzier N, Hunt DR, Herndon JH. Adverse Events After Total Knee Arthroplasty: A National Medicare Study. The Journal of Arthroplasty. 2009;24(6, Supplement 1): 95–100.

[69] Bozic KJ, Rubash HE, Sculco TP, Berry DJ., An analysis of Medicare payment policy for total joint arthroplasty. J Arthroplasty. Sep 2008; 23(6 Suppl 1):133–138.

[70] National Quality Forum. MAP Final Reports. Available at: *http://www.qualityforum.org/Publications/2012/02/MAP_Pre-Rulemaking_Report_Input_on_Measures_Under_Consideration_by_HHS_for_2012_Rulemaking.aspx* . Accessed on April 1 6, 2015, page 78.

Compare Web site (*http://www.hospitalcompare.hhs.gov/*) since FY 2014 and in the HIQR Program since FY 2015 (FY 2015 IPPS/LTCH final rule, 79 FR 50062).

Finally, in the proposed rule we explained what the measure assesses, which is a hospital's risk standardized complication rate. We also specifically shared that the measure focuses on the rate of complications occurring 90 days after elective primary THA and TKA surgery. We explained that the 90-day period begins with the date of the index admission for a specific hospital, and that the index admission is the hospitalization to which the complications outcome is attributed. We also explained that either one or more of the following are considered complications in this measure: Acute myocardial infarction, pneumonia, or sepsis/septicemia within 7 days of admission; surgical site bleeding, pulmonary embolism or death within 30 days of admission; or mechanical complications, periprosthetic joint infection or wound infection within 90 days of admission. To highlight more recent data on THA/TKA procedure complications, we shared a comparison of the median hospital-level RSCRs for hospitals between April 1, 2011 and March 31, 2014 and noted a that there continues to be a performance gap (median RSCR of 3.1 percent with a range from 1.4 percent to 6.9 percent) indicating there is still room for quality improvement.[71]

(2) Data Sources

In the proposed rule (80 FR 41279), we proposed to use Medicare Part A and Part B FFS claims submitted by the participant hospital as the data source to calculate the measure. We also explained that the index admission diagnoses and in-hospital comorbidities are assessed using Medicare Part A claims, and that additional comorbidities prior to the index admission are assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 1 to 2 months prior to the index (initial) admission. Finally, in the proposed rule, we stated that enrollment and post-discharge mortality status are obtained from Medicare's enrollment database which contains beneficiary demographic, benefits/coverage, and vital status information.

(3) Cohort

In the proposed rule (80 FR 41279), we proposed that the cohort for the THA/TKA Complications measure (NQF #1550) would include Medicare FFS beneficiaries, aged 65 years or older, admitted to non-federal acute care hospitals for elective primary THA or TKA. We explained that THA and TKA procedures eligible for inclusion are defined using ICD–9–CM codes 81.51 and 81.54, respectively. We also proposed that the cohort would include all hospitals included in the model, but also noted the model cohort may differ slightly from the hospital cohort that is currently captured in the measures through the HIQR Program. We noted this difference because the model cohort is a randomly selected group of acute care hospitals and therefore may not include all of the HIQR Program acute care hospitals (for a detailed discussion on selection of hospitals for the model, see section III.A.4. of the proposed rule).

(4) Inclusion and Exclusion Criteria

We also proposed inclusion and exclusion criteria (80 FR 41279). We indicated that an index admission is the hospitalization to which the complication outcome is attributed. We also proposed that the measure include the following index admissions for patients:

- Enrolled in Medicare FFS.
- Aged 65 or over.
- Enrolled in Part A and Part B Medicare for the 12 months prior to the date of index admission and during the index admission.
- Having a qualifying elective primary THA/TKA procedure; elective primary THA/TKA procedures are defined as those procedures without any of the following:

++ Femur, hip, or pelvic fractures coded in principal or secondary discharge diagnosis fields of the index admission.

++ PHA procedures with a concurrent THA/TKA.

++ Revision procedures with a concurrent THA/TKA.

++ Resurfacing procedures with a concurrent THA/TKA.

++ Mechanical complication coded in the principal discharge diagnosis field.

++ Malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field.

++ Removal of implanted devices/prostheses.

++ Transfer from another acute care facility for the THA/TKA.

In the proposed rule, we indicated that the THA/TKA Complications measure (NQF #1550) would exclude the following admissions:

- Admissions for patients discharged against medical advice (AMA).
- Admissions for patients with more than two THA/TKA procedure codes during the index hospitalization.
- Consistent with the FY 2016 IPPS/LTCH proposed rule, admissions for patients without at least 90 days post-discharge enrollment in FFS Medicare; this exclusion is an update to the measure signaled in the HIQR Program section of the FY2016 IPPS/LTCH proposed rule (80 FR 24572 through 24574) to ensure that disproportionate Medicare FFS disenrollment does not bias the measure results.

We further explained in the proposed rule that once the exclusion criteria were applied, we randomly select one index admission for patients with multiple index admissions in a calendar year. Therefore, we exclude the other eligible index admissions in that year. Identification and use of a single index admission in a calendar year is done because this measure includes mortality as an outcome and the probability of death increases with each subsequent admission, preventing each episode of care from being mutually independent. Therefore only one index admission is selected to maintain measure integrity.

In the proposed rule, we also noted that THA/TKA Complications measure (NQF #1550) does not capture patients undergoing PHA procedures. We explained why we exclude PHA procedures, and this is primarily because PHA procedures are done for hip fractures and therefore are not elective procedures. We also shared that PHA procedures are typically performed on patients who are older, frailer, and have more comorbid conditions. We noted that although this exclusion is not fully harmonized with MS–DRG 469 and 470, which include PHA procedures, this measure still provides strong incentive for improving and maintaining care quality across joint replacement patients as hospitals typically develop protocols for lower extremity joint arthroplasty that will address perioperative and post-operative care for both total and PHA procedures. As previously cited in our discussion of the Episode Definition of the model (80 FR 41212 through 41219), the frequency of administrative claims data using ICD–9 codes for 2014 indicated that PHA (ICD–9 code: 81.52) accounted for 12 percent of the administrative claims, while Total Hip replacement (ICD–9 code: 81.51) and Total Knee replacement (ICD–9 code: 81.54) accounted for 87 percent of the administrative claims for 2014. We also

[71] Suter L, Zang W, Parzynski C, et al. 2015 Procedure-Specific Complication Measures Update and Specifications: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Risk-Standardized Complication Measure (Version 4.0). 2015.

noted that the same surgeons and care teams frequently perform both procedures, and therefore quality improvement efforts initiated in response to the THA/TKA Complications measure (NQF #1550) are likely to benefit patients undergoing similar elective procedures, such as PHA and revision THA/TKA procedures, and possibly even non-elective THA/TKA procedures, such as fracture-related THA.

(5) Risk-Adjustment

We note that we chose to align this measure with the risk-adjustment methodologies adopted for the HIQR Program and the HRRP in accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act (FY 2013 IPPS/LTCH final rule 77 FR 53516 through 53518 and FY 2015 IPPS/LTCH final rule; 79 FR 50024, 50031, and 50202). We also indicated in the proposed rule (80 FR 41279) that the risk-adjustment takes into account the patient case-mix to assess hospital performance. The patient risk factors are defined using the Hierarchical Condition Categories (CC), which are clinically relevant diagnostic groups of ICD–9–CM codes.[72] The CCs used in the risk adjustment model for this measure, are provided on the CMS QualityNet Web site (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772783162*). We noted that the measure uses all Part A and B administrative claims ICD–9 codes for the year prior to and including the index admission. The Part A and B administrative claims ICD–9 codes are used to inform the risk prediction for each patient; diagnostic codes from PAC settings are included in the measure, but this information is only used to identify a hospital's patient case mix in order to adequately adjust for differences in case mix across hospitals. Furthermore, we stated that use of the Part A and B data does not mean the measures are applicable to PAC settings, only that they use comprehensive data to predict the risk of the outcome and adjust for hospital patient case mix. The measure would meet the requirement if it applied, because risk-adjustment adjusts for hospital patient mix, including age and comorbidities, to ensure that hospitals that care for a less healthy patient population are not penalized unfairly. In addition, we indicated that the measure methodology defines ''complications'' as acute myocardial infarction (AMI); pneumonia; sepsis/septicemia; pulmonary embolism; surgical site bleeding; death; wound infection; periprosthetic joint infection; and mechanical complication within 0 to 90-days post the index date of admission, depending on the complication. We explained that the decision to determine appropriate follow-up period of 0 to 90 days was based on our analysis of 90-day trends in complication rates using the 2008 Medicare FFS Part A Inpatient Data. We found that rates for mechanical complications are elevated until 90 days after the date of index admission. We also found that the rates for four other complications—death, surgical site bleeding, wound infection, and pulmonary embolism—are elevated for 30 days, and that rates for AMI, pneumonia, and sepsis/septicemia level off 7 days after the date of index admission.

(6) Calculating the Risk-Standardized Complication Rate (RSCR) and Performance Period

In the proposed rule (80 FR 41280), we shared that analogous to how we calculate hospital risk-standardized readmission rates with all readmission measures and risk-standardized mortality rates with the mortality measures used in CMS hospital quality programs, we also calculate the hospital RSCR by producing a ratio of the number of ''predicted'' complications (that is, the adjusted number of complications at a specific hospital based on its patient population) to the number of ''expected'' complications (that is, the number of complications if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw complication rate. As noted in the proposed rule, the THA/TKA Readmissions measure (NQF #1551) uses a 30-day window of follow-up, which is different from the 90-day window of follow-up used in the THA/TKA Complications measure (NQF #1550).

We also indicated that we would use a 3-year rolling performance period to be consistent with that used for the measure as it is implemented in the HIQR Program (FY 2015 IPPS/LTCH final rule, 79 FR 50208 and 50209). For performance year 1 of the model, we proposed that the performance period for the THA/TKA Complications measure (NQF #1550) would be April 2013 through March 2016. Section III.D.4. of this final rule summarizes performance periods for years 1 through 5 of the CJR model.

We sought public comment on this proposal to assess quality performance through implementation of the Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) measure.

The following is a summary of the comments received and our responses.

Comment: A few commenters supported CMS's payment reform efforts and specifically focused on the need to improve complication rates through improvement of wound healing. They supported the use of the THA/TKA Complications measure (NQF #1550) as a means to change behavior and reduce complications.

Response: We thank these commenters for their support of payment reform and our efforts to reduce complications through the THA/TKA Complications measure (NQF #1550).

Comment: Commenters questioned the use of a 90-day episode timeframe for measuring patient outcomes following THA/TKA. One of the commenters specifically questioned the use of 2008 data to define the 90-day THA/TKA Complications measure (NQF #1550) timeframe, noting there may have been a significant shift in the occurrence of complications in the past 7 years.

Response: From a quality measure perspective, we note that the THA/TKA Complications measure (NQF #1550) uses different follow-up timeframes, up to 90 days, to assess different complications. We noted our rationale for the 90-day timeframe in the preamble of the proposed rule (80 FR 41217). Our measure development contractor consulted a Technical Expert Panel to review appropriate follow-up timeframes for each complication. Clinical experts agreed that the specified complications are more likely to be attributable to the index procedure if they occur within the specified timeframes. Additionally, we requested public comments during measure development, the rulemaking process, and regular measure maintenance during NQF and MAP review. We conduct annual and comprehensive reevaluation of the measure's methodology. We will take the commenter's suggestion to evaluate shifts in the occurrence of complications into consideration during the annual measure reevaluation process.

Comment: A commenter sought confirmation that CMS has quality improvement efforts that included the use of intermittent pneumatic

[72] Pope G, Ellis R, Ash A, et al., Principal Inpatient Diagnostic Cost Group Models for Medicare Risk Adjustment. Health Care Financing Review. 2000;21(3):26.

compression devices (IPCD) to minimize medical and surgical complications during surgery and the postoperative period.

Response: We appreciate this inquiry regarding the inclusion of IPCD in CMS quality improvement efforts. We note that HIQR Program implemented two of The Joint Commission's venous thromboembolism measures that cover the use of IPCDs: 1) Venous thromboembolism prophylaxis measure 1 (VTE–1) (NQF #0371); and 2) Intensive Care Unit VTE Prophylaxis (VTE–2) (NQF #0372). We refer reviewers to FY 2016 IPPS/LTCH final rule (80 FR 49649) for discussion of use of these measures in the HIQR Program. These results are also available on *Hospital Compare* (available at: *https://www.medicare.gov/hospitalcompare/search.html*).

Comment: There were many comments requesting risk-adjustment of the payment methodology and/or the risk-adjustment at the measure level for socio-economic status or socio-demographic status. We noticed the terms socio-economic status and socio-demographic status were used interchangeably throughout many of the public comments. For clarity and simplicity, we will use socio-demographic status (SDS) to signify both socio-economic status and socio-demographic status. Some stakeholders indicated that the SDS of patients should be taken into account in the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551). These stakeholders indicated that income factors such as percentage of dual eligible patients or Supplemental Security Income percentage, and family size or other post-discharge support measures should be risk adjusted. Some stakeholders shared their anecdotal data that demonstrated lower SDS was associated with poorer patient outcomes compared to other levels of SDS status.

Response: We continue to align our policy on SDS risk adjustment at the measure level across our quality and payment programs. Consistent with statements made in the FY 2016 IPPS/LTCH final rule (80 FR 49531 through 49532) and final rules related to PAC quality programs (IRF, 80 FR 47088; LTCH, 80 FR 49731; and SNF, 80 FR 46435), while we appreciate the importance of the role that SDS plays in the care of patients, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures. To date, we have found that hospitals that care for large proportions of patients of low sociodemographic status are capable of performing well on our measures (for example, we refer readers to the 2014 Chartbook pages 48–57, 70–73, and 78 at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf*).

NQF is currently undertaking a two-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate for each measure. For two years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, ASPE is conducting research to examine the impact of socioeconomic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of these reports and related Secretarial recommendations and consider how they apply to our quality programs and the CJR model at such time as they are available.

Comment: A commenter expressed concern that the penalty for the quality threshold is biased against low-volume hospitals. The commenter stated that one or two readmissions or complications at a low-volume hospital would have a larger impact on the quality threshold, which would make it more difficult for to become eligible for incentive payments.

Response: We appreciate the commenter's concern, and note that we adopted a risk adjustment modeling methodology that takes into account volume. We acknowledge that smaller hospitals typically have less certain estimates because they have fewer cases for use in assessing quality. Our approach to modeling addresses the concern that the measures are biased against small hospitals due to random variation, and this challenge is inherent in outcome measurements. However, one advantage of the statistical model used for the measures is that it allows for the inclusion of small hospitals while characterizing the certainty of their estimates. The hierarchical logistic regression model that we use to calculate the risk-standardized measures allows the inclusion of hospitals with relatively few observations, but takes into account the uncertainty associated with sample size in estimating their risk-standardized outcome rates. The model takes into account the uncertainty in the estimate of outcome rates for low-volume hospitals by assuming that each hospital is a typically performing hospital. It weighs that assumption along with the outcomes for the particular hospital in calculating the outcome rate. Therefore, the estimated outcome rates for smaller hospitals will likely be closer to the national average because the limited number of eligible cases in the hospital indicated relatively little about that hospital's true outcome rate.

Comment: A commenter recommended that CMS incorporate pre-operative global physical function, BMI, smoking status, musculoskeletal comorbidities and Charlson comorbidity index into the existing THA/TKA Complications (NQF #1550) and Readmissions (NQF #1551) measures' risk models.

Response: In addition to risk adjusting for multiple comorbid medical conditions, these measures currently risk adjust for ICD–9–CM codes 278.01 Morbid Obesity, 755.63 Skeletal Deformities and 716.15/716.16 Post-Traumatic Osteoarthritis, as well as a large number of other musculoskeletal conditions. We undertake a comprehensive measure reevaluation of our existing publicly reported outcome measures each year. Currently, these measures utilize administrative claims data for risk adjustment. When additional risk factor data sources become widely available, we will take these recommendations under advisement for incorporation into future iterations of these measures through rulemaking.

Final Decision: After consideration of the public comments we received, we are finalizing and adopting the THA/TKA Complications measure (NQF #1550) as proposed. Regarding the requests for socio-demographic risk-adjustment at the measure level, we will not be risk-adjusting the CJR model measures for socio-demographic variables at this time. As previously noted, we await further information from ASPE's research and recommendations. Finally, we are codifying adoption of the Hospital-Level

Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) in § 510.400(a)(1).

b. Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551)

(1) Background

In the proposed rule (80 FR 41280), we stated that the objective of CMS's Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) (as referred to as THA/TKA Readmissions measure (NQF #1551)) measure is to assess readmission from any cause within 30 days of discharge from the hospital following elective primary THA and TKA. As previously stated, outcome measures such as complications and readmissions are the priority areas for the HIQR Program, and elective primary THA and TKA are commonly performed procedures that improve quality of life. We also stated our belief that THA and TKA readmissions are disruptive to patients' quality of life, costly to the Medicare program, and that data support that readmission rates can be improved through better care coordination and other provider actions.[73] Furthermore, we stated our belief that there is an opportunity for hospitals to improve quality of life for the patient. We shared in the proposed rule that from July 1, 2011 to June 30, 2014, Medicare FFS claims data indicate that 30-day hospital-level risk-standardized readmission rates ranged from 2.6 percent to 8.5 percent among hospitals with a median rate of 4.8 percent with a mean risk-standardized readmission rate of 4.9 percent.[74] This range in variation suggests there are important differences in the quality of care received across hospitals, and that there is room for improvement. We shared our belief that a measure that addresses readmission rates following THA and TKA procedures not only provides an opportunity to provide targets for efforts to improve the quality of care and reduction in costs for patients undergoing these elective procedures, but also increases transparency for consumers and provides patients with information that could guide their choices. We indicated our belief that a risk-adjusted readmission outcome measure can provide a critical perspective on the provision of care, and supports improvements in care for the Medicare patient population following THA/TKA hospitalization. In the proposed rule, we provided historical background on the THA/TKA Readmissions measure (NQF #1551), indicating that the measure has wide stakeholder support, with NQF endorsement in January 2012, and recommendations by the NQF MAP for use in the HIQR Program (2012 Pre-Rulemaking report [19]), and in the HRRP (2013 Pre-Rulemaking report).[75] Finally, we shared that the THA/TKA Readmissions Measure (NQF #1551) has been publicly reported since FY 2014 (79 FR 50062), and was implemented in both the HIQR Program (77 FR 53519 through 53521) and HRRP (78 FR 50663 and 50664).

(2) Data Sources

In the proposed rule (80 FR 41280), we proposed to use Medicare Part A and Part B FFS claims submitted by the participant hospital as the data source for calculation of the THA/TKA Readmissions measure (NQF #1551). We stated that index admission diagnoses and in-hospital comorbidity data are assessed using Medicare Part A claims and that additional comorbidities prior to the index admission are assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to index (initial) admission. We shared that enrollment status is obtained from Medicare's enrollment database which contains beneficiary demographic, benefit/coverage, and vital status information.

(3) Cohort

In the proposed rule (80 FR 41281), we indicated that THA/TKA Readmissions measure (NQF #1551) includes Medicare FFS beneficiaries, aged 65 years or older, admitted to non-federal acute care hospitals for elective primary THA or TKA. We explained that the THA and TKA procedures eligible for inclusion are defined using ICD–9–CM codes 81.51 and 81.54, respectively, and proposed that the cohort will include all hospitals included in the model, but the model cohort may differ slightly from the hospital cohort that is currently captured in the measures through the HIQR Program. That is, the model cohort is a randomly selected group of acute care hospitals and therefore may not include all of the HIQR Program acute care hospitals (for a detailed discussion on selection of hospitals for the model see section III.A. of the proposed rule).

(4) Inclusion and Exclusion Criteria

In the proposed rule (80 FR 41281), we proposed that an index admission is the anchor hospitalization to which the readmission outcome is attributed. The measure includes the following index admissions for patients:

- Enrolled in Medicare FFS.
- Aged 65 or over.
- Discharged from non-federal acute care hospitals alive.
- Enrolled in Medicare Part A and Part B for the 12 months prior to the date of index admission and during the index admission.
- Having a qualifying elective primary THA/TKA procedure; elective primary THA/TKA procedures are defined as those procedures without any of the following:

++ Femur, hip, or pelvic fractures coded in principal or secondary discharge diagnosis fields of the index admission.

++ PHA procedures with a concurrent THA/TKA.

++ Revision procedures with a concurrent THA/TKA.

++ Resurfacing procedures with a concurrent THA/TKA.

++ Mechanical complication coded in the principal discharge diagnosis field.

++ Malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field.

++ Removal of implanted devices/prostheses.

++ Transfer from another acute care facility for the THA/TKA.

- This measure excludes index admissions for patients—

++ Without at least 30 days post-discharge enrollment in FFS Medicare;

++ Discharged against medical advice (AMA);

++ Admitted for the index procedure and subsequently transferred to another acute care facility; and

++ With more than two THA/TKA procedure codes during the index hospitalization.

[73] Mistiaen P, Francke AL, Poot E. Interventions aimed at reducing problems in adult patients discharged from hospital to home: A systematic meta-review. *BMC Health Services Research*. 2007;7:47.

[74] Suter L, Desai N, Zang W, *et al.* 2015 Procedure-Specific Readmission Measures Updates and Specifications Report: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Risk-Standardized Readmission Measure (Version 4.0), Isolated Coronary Artery Bypass Graft (CABG) Surgery—Version 2.0. 2015; *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[75] National Quality Forum. MAP Final Reports. Available at: *http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-__-_February_2013.aspx.* Accessed on April 16, 2015, page 143.

Finally, we also indicated that for the purpose of this measure, admissions within 30 days of discharge from an index admission are not eligible to also be index admissions. Thus, no hospitalization will be counted as both a readmission and an index admission in this measure.

In the proposed rule, we also stated that this measure does not capture patients undergoing PHA procedures, as partial hip arthroplasties are primarily done for hip fractures and are typically performed on patients who are older, frailer, and have more comorbid conditions. We also shared that although this exclusion is not fully harmonized with MS–DRG 469 and 470, which include PHA procedures, this measure would still provide strong incentive for improving and maintaining care quality across joint replacement patients. We shared our belief that the THA/TKA Readmissions measure (NQF #1551) provides strong incentive for quality improvement because hospitals typically develop protocols for lower extremity joint arthroplasty that will address perioperative and post-operative care for both total and partial hip arthroplasties, and the same surgeons and care teams frequently perform both procedures. Therefore, quality improvement efforts initiated in response to the THA/TKA Readmissions measure (NQF #1551) are likely to benefit patients undergoing similar elective procedures, such as PHA and revision THA/TKA procedures, and possibly even non-elective THA/TKA procedures, such as fracture-related THA.

(5) Risk-Adjustment

In the proposed rule (80 FR 41281), we noted that we chose to align this measure with the risk-adjustment methodologies adopted for Readmissions measure (NQF #1551) under the HIQR Program in accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act, as finalized in FY 2013 IPPS/LTCH PPS final rule (77 FR 53519 through 53521). We also noted that the measure risk-adjustment takes into account patient age and comorbidities to allow a fair assessment of hospital performance. Further, we noted that the measure defines the patient risk factors for readmission using diagnosis codes collected from all patient claims 1 year prior to patient index hospitalization for THA and TKA. We also indicated that as previously noted for the THA/TKA Complications measure (NQF #1550), Parts A and B administrative claims ICD–9 codes are used to inform the risk prediction for each patient; diagnostic codes from PAC settings are included in the measure, but this information is only used to identify a hospital's patient case mix in order to adequately adjust for differences in case mix across hospitals. We stated that use of the Part A and B data does not mean the measures are applicable to PAC settings, only that they use comprehensive data to predict the risk of the outcome and adjust for hospital patient case mix. We noted that the patient diagnosis codes are grouped using Hierarchical Condition Categories (CCs), which are clinically relevant diagnostic groups of ICD–9–CM codes.[76] The CCs used in the risk adjustment model for this measure, are provided on the CMS QualityNet Web site (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069856694*). We concluded with the summary that age and comorbidities present at the time of admission are adjusted for differences in hospital case mix (patient risk factors), and that the measure uses the hierarchical logistic regression model (HLM) statistical methodology for risk adjustment.

(6) Calculating the Risk-Standardized Readmission Rate and Performance Period

In the proposed rule (80 FR 41281), we proposed to calculate hospital risk-standardized readmission rates consistent with the methodology used to risk standardize all readmission measures and mortality measures used in CMS hospital quality programs. We stated that using HLM, we calculate the hospital-level elective primary THA/TKA risk-standardized readmission rate by producing a ratio of the number of ''predicted'' readmissions (that is, the adjusted number of readmissions at a specific hospital) to the number of ''expected'' readmissions (that is, the number of readmissions if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw readmission rate. We also indicated that use of the 3-year rolling performance period would be consistent with that used for the HIQR Program (FY 2015 IPPS/LTCH final rule 79 FR 50208 and 50209). For performance year one of the model, we proposed that the performance period for the THA/TKA Readmissions measure (NQF #1551) would be July 2013 through June 2016. As noted in the proposed rule for the section on the THA/TKA Complications measure (NQF #1550), there is a 90-day window of follow-up, which is different from the THA/TKA Readmissions measure (NQF #1551). Section III.D.4. of this final rule summarizes performance periods for years 1 through 5 of the model years.

We invited public comments on this proposal to include Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) or both in the model to assess quality performance. We also invited public comment on inclusion of other potential quality measures in the model.

The following is a summary of the comments received and our responses.

Comment: A commenter noted the variation in 30-day readmission rates (80 FR 41280) and stated that the variation may not only be due to differences in quality of care, but also patient age, comorbid conditions, and geographic location.

Response: We appreciate the commenter's input. We note that the THA/TKA Readmissions measure (NQF #1551) risk adjusts for patients' risk factors, including age and comorbid conditions, thereby taking into account case mix differences across providers. Adjusting for case mix is an important aspect for measuring a RSRR that accurately reflects factors that can confound an outcome rate when not adequately adjusted. The goal of risk adjustment for this measure is to account for patient and procedure characteristics and comorbid conditions that are clinically relevant and have strong relationships with readmission, while illuminating important quality differences between hospitals. The measure does not adjust for geographic location because location is associated with the different care patterns than those the measure seeks to illuminate.

Comment: A commenter sought clarification regarding the readmission exclusions described in section III.D.2.b.(4). of this final rule for the CJR model episode definition. The commenter stated that they were unclear on the rationale that CMS used to determine that all medical MS–DRGs for readmission be included in the episodes as related services with the exception of oncology and trauma medical MS–DRGs.

Response: We note that there are two separate discussions about readmissions in the CJR model proposed rule found in sections III.B. and III.D. of this final rule, in which the episode definition and the THA/TKA Readmissions measure (NQF #1551) are, respectively,

[76] Pope G, Ellis R, Ash A, *et al.,* Principal Inpatient Diagnostic Cost Group Models for Medicare Risk Adjustment. Health Care Financing Review. 2000; 21(3):26.

discussed in detail. In section III.B. of the proposed rule, the discussion of the Episode Definition and its related services describes the services included and excluded in an episode of care for this model (80 FR 41213 through 41215). We note that section III.B.2.b. of this final rule is specific to the discussion of readmission exclusions related to the oncology and trauma MS–DRGs. In section III.D. of the proposed rule, we detailed the measure specifications of the THA/TKA Readmissions measure (NQF #1551). We note, from the measure perspective, two important aspects of what is included or excluded from the measure: (1) The THA/TKA Readmissions measure (NQF #1551) does count all unplanned readmissions, including those related to trauma since a trauma patient is not considered a planned readmission; and (2) the THA/TKA Readmissions measure (NQF #1551) is designed to capture readmissions that arise from acute clinical events requiring urgent readmission within 30 days of discharge. These two important aspects of the measure exist because we use all-cause *unplanned* readmission for several reasons. First, from the patient perspective, readmission for any cause is a key concern. Second, limiting the measure to THA/TKA-related readmissions may make it susceptible to gaming. Moreover, it is often hard to exclude quality issues and accountability based on the documented cause of readmission. For example, a THA/TKA patient who develops a hospital-acquired infection may ultimately be readmitted for sepsis. It would be inappropriate to treat this readmission as unrelated to the care the patient received during their admission for a THA/TKA procedure. Finally, while the measure does not presume that each readmission is preventable, appropriate interventions have generally shown reductions in all-cause readmission. Examples of appropriate interventions include, but are not limited to, adherence to clinical guidelines to prevent hospitals-acquired infections and surgical complications, as well as coordination of follow-up care at the time of discharge, patient education regarding the dosing and purpose of their medications, and ensuring appropriate follow-up. Planned readmissions, which are generally not a signal of quality of care, are not counted in the measure outcome. The measure uses CMS's Planned Readmission Algorithm Version 3.0—THA/TKA Population to define planned readmissions for exclusion from the measure outcome. Therefore, from a measure perspective, oncology patients who are readmitted to receive maintenance chemotherapy are not counted as being readmitted by the algorithm and are therefore not considered readmissions in the 30-day all cause THA/TKA RSRR measure. As previously stated, a trauma patient is not considered a planned readmission and will be counted in the measure outcome for the reasons stated previously.

Comment: We received a comment from the MedPAC with which many other commenters cited and with which they expressed agreement. The commenters encouraged CMS not to use the THA/TKA Readmissions measure (NQF #1551) in more than one payment program. A few of the commenters also recommended to not use the HCAHPS Survey measure (NQF #0166) in two payment programs. Some commenters made suggestions to remove the THA/TKA Readmissions measure (NQF #1551) from the Hospital Readmission Reduction Program or the HCAHPS Survey measure (NQF #0166) from the Hospital Value-Based Purchasing program if these measures were implemented in the CJR model.

Response: We acknowledge the request of many commenters to remove the THA/TKA Readmissions measure (NQF #1551) from the CJR model due to the incentives, already in place by the HRRP, for hospitals to lower excess readmission rates. Upon further consideration of the quality measure set proposed for use in the CJR model, and to be responsive to stakeholder concerns, we have decided not to finalize inclusion of the THA/TKA Readmissions measure (NQF #1551) for the CJR model. We believe that finalizing the THA/TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0166) effectively supports the intent of the CJR model to decrease cost while ensuring that quality of care for LEJR episodes is maintained or improved. We note that the THA/TKA Complications measure (NQF #1550) focuses on primary elective THA and TKA procedure cases that will help to provide necessary information about quality performance for patients and providers considering an elective procedure and that the HCAHPS Survey measure (NQF #0166) will help provide important information about patient experience during hospitalizations. We still consider THA/TKA Readmissions measure rates to be an important metric for providing information about hospital performance, and while we did not propose any changes to the HIQR Program or HRRP, we note that we will continue to use the THA/TKA Readmissions measure (NQF #1551) in the HIQR Program and HRRP for public reporting and payment purposes. We note that there is still room for hospitals to improve on this measure based on the previously discussed distribution of hospital measure results in the proposed rule (80 FR 41280 section III.D.2.b.(1)).

With respect to some commenters' concerns regarding the overlap of the measures chosen for the CJR model with measures used in other Medicare payment programs, we acknowledge that there is some overlap in quality measures between the CJR model and the HVBP program and HRRP. While we are aware that commenters object to the possibility of scoring hospitals on certain measures under more than one program or model, we note that the measures we are finalizing for the CJR model cover topics of critical importance to quality improvement for THA/TKA patients, namely, post-surgical complications and patient experience during hospitalizations, as well as the CJR model's broader goals of improving care coordination while lowering costs. In light of the CJR model's goals, we believe it is appropriate to provide strong incentives for hospitals to improve these aspects of patient care quality by using the finalized measures under more than one program or model.

We also note that the CJR model is separate and distinct from the HVBP program and HRRP, which have different purposes and policy goals. The CJR model aims to improve the care experience of Medicare patients who receive joint replacements by focusing on coordinated, patient-centered care while also lowering costs. On the other hand, the HVBP Program is an incentive program that redistributes a portion of the Medicare payments made to hospitals based on their performance on various measures. HRRP is an incentive program that links Medicare payments to hospitals based on their performance on readmission measures compared to the national rate for excess readmissions. Therefore, although the measures finalized for the CJR model exist in more than one program, the measures are used and calculated for distinct purposes. Accordingly, we believe that the critical importance of these measures to THA/TKA patient safety and experience warrant their inclusion in more than one program. We will monitor the use of the THA/TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0166) in the CJR model, including any unintended consequences of having a measure in more than one program, and

will revise the measure set in one or more programs if needed through rulemaking. We will not be finalizing the THA/TKA Readmissions measure (NQF #*1551) in the CJR model.*

Final Decision: After consideration of the many public comments received on the proposal to adopt the THA/TKA Readmissions measures (NQF #1551) for the CJR model, we are not finalizing the THA/TKA Readmissions measure (NQF #1551) for the CJR model for the reasons discussed in this section.

c. Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey (NQF #0166)

(1) Background

In the proposed rule (80 FR 41282), we proposed to adopt the HCAHPS Survey (NQF #0166) measure. We indicated that the HCAHPS Survey measure (NQF #0166) is a CMS survey and a national, standardized, publicly reported survey of patients' experience of hospital care, and that CMS is the measure steward. We also shared that the HCAHPS Survey measure is endorsed by the NQF (#0166), and stated that the HCAHPS survey (NQF #0166), also known as CAHPS® Hospital Survey, is a survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience. We explained how the HCAHPS survey asks recently discharged patients 32 questions about aspects of their hospital experience that they are uniquely suited to address, where the core of the survey contains 21 items that ask ''how often'' or whether patients experienced a critical aspect of hospital care. We also indicated that the survey also includes four items to direct patients to relevant questions, five items to adjust for the mix of patients across hospitals, and two items that support Congressionally-mandated reports (see 77 FR 53513 through 53515).

In the proposed rule, we noted that eleven HCAHPS measures (seven composite measures, two individual items and two global items) are currently publicly reported on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) for each hospital participating in the HIQR Program (see 79 FR 50259.) Each of the seven currently reported composite measures is constructed from two or three survey questions. The seven composites summarize the following:

- How well doctors communicate with patients.
- How well nurses communicate with patients.
- How responsive hospital staff are to patients' needs.
- How well hospital staff helps patients manage pain.
- How well the staff communicates with patients about medicines.
- Whether key information is provided at discharge.
- How well the patient was prepared for the transition to post-hospital care.

Lastly, the two individual items address the cleanliness and quietness of patients' rooms, while the two global items report patients' overall rating of the hospital, and whether they would recommend the hospital to family and friends. We proposed to adopt a measure in the model that uses HCAHPS survey data to assess quality performance and capture patient experience of care.

(2) Data Sources

In the proposed rule (80 FR 41282), we explained that the HCAHPS survey is administered to a random sample of adult inpatients between 48 hours and 6 weeks after discharge. As discussed in section III.D.5. of the proposed rule, we noted the following: (1) The HCAHPS survey data is collected on inpatient experience, is not limited to Medicare beneficiaries, and does not distinguish between types of Medicare beneficiaries; (2) patients admitted in the medical, surgical and maternity care service lines are eligible for the survey; the survey is not restricted to Medicare beneficiaries; (3) hospitals may use an approved survey vendor, or collect their own HCAHPS data (if approved by CMS to do so) (for a detailed discussion, see 79 FR 50259); and (4) to accommodate hospitals, the HCAHPS survey can be implemented using one of the following four different survey modes:

- Mail.
- Telephone.
- Mail with telephone follow-up.
- Active Interactive Voice Recognition (IVR).

We also noted that regardless of the mode used, hospitals are required to make multiple attempts to contact patients, and that hospitals may use the HCAHPS survey alone, or include additional questions after the 21 core items discussed previously. We also indicated the timeframes (that is, surveying must begin from 48 hours to 42 days following hospital discharge) and number of patients that hospitals must survey patients monthly throughout the year (80 FR 41282 in section III.D.2.c.(2) and III.D.2.c.(3) of the proposed rule), and that hospitals participating in the HIQR Program must target at least 300 completed surveys over 4 calendar quarters in order to attain the reliability criterion CMS has set for publicly reported HCAHPS scores (see 79 FR 50259). Finally we noted that the survey itself and the protocols for sampling, data collection, coding, and file submission can be found in the current HCAHPS Quality Assurance Guidelines manual, available on the HCAHPS Web site located at: *http://www.hcahpsonline.org.* (The HCAHPS survey is available in several languages, and all official translations of the HCAHPS survey instrument are available in the current HCAHPS Quality Assurance Guidelines at *http://www.hcahpsonline.org/qaguidelines.aspx*.)

(3) Cohort

In the proposed rule (80 FR 41282), we noted that hospitals, or their survey vendors, submit HCAHPS data in calendar quarters (3 months). Consistent with other quality reporting programs, we proposed that HCAHPS scores would be publicly reported on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) based on 4 consecutive quarters of data. For each public reporting, the oldest quarter of data is rolled off, and the newest quarter is rolled on (see 79 FR 50259).

(4) Inclusion and Exclusion Criteria

In the proposed rule (80 FR 41282), we stated that the HCAHPS survey is broadly intended for patients of all payer types who meet the following criteria:

- Eighteen years or older at the time of admission.
- Admission includes at least one overnight stay in the hospital.
- Non-psychiatric MS–DRG/principal diagnosis at discharge.
- Alive at the time of discharge.

There are a few categories of otherwise eligible patients who are excluded from the sample frame as follows:

- ''No-Publicity'' patients—Patients who request that they not be contacted.
- Court/Law enforcement patients (that is, prisoners); patients residing in halfway houses are included.
- Patients with a foreign home address (U.S. territories—Virgin Islands, Puerto Rico, Guam, American Samoa, and Northern Mariana Islands are not considered foreign addresses and are not excluded).
- Patients discharged to hospice care (Hospice-home or Hospice-medical facility).
- Patients who are excluded because of state regulations.
- Patients discharged to nursing homes and SNFs.

We also indicted that the HCAHPS survey is intended for short-term, acute care hospitals. Both IPPS and CAHs

participate in the survey; specialty hospitals, psychiatric hospitals and children's hospitals do not.

(5) Case-Mix-Adjustment

In the proposed rule (80 FR 41282 through 41283), we stated that to ensure that HCAHPS scores allow fair and accurate comparisons among hospitals, CMS adjusts for factors that are not directly related to hospital performance but which affect how patients answer survey items. This includes the mode of survey administration and characteristics of patients that are out of a hospital's control. Patient-mix adjustments (also known as case-mix adjustment) control for patient characteristics that affect ratings and that are differentially distributed across hospitals. Most of the patient-mix items are included in the ''About You'' section of the survey, while others are taken from hospital administrative records. Based on the HCAHPS mode experiment,[77] and consistent with previous studies of patient-mix adjustment in HCAHPS and in previous hospital patient surveys, we employ the following variables in the patient-mix adjustment model:

- Self-reported general health status (specified as a linear variable).
- Education (specified as a linear variable).
- Type of service (medical, surgical, or maternity care).
- Age (specified as a categorical variable).
- Admission through emergency room (discontinued in 2010).
- Lag time between discharge and survey completion.
- Age by service line interaction.
- Language other than English spoken at home.

Finally, we indicated that once the data are adjusted for patient-mix, there is a fixed adjustment for the mode of survey administration (mail, telephone, mail with telephone follow-up, and active Interactive Voice Response) and information on patient-mix adjustment (risk adjustment) and survey mode adjustment of HCAHPS scores can be found at *http://www.hcahpsonline.org/modeadjustment.aspx*.

(6) HCAHPS Scoring

In the proposed rule (80 FR 41283), we outlined the methodology used to assess hospitals in the HIQR Program as reasonable for use in the model since this is a survey that many hospitals and patients are familiar with. In determining HCAHPS performance, we proposed to utilize the HLMR score because the HLMR summarizes performance across the 11 publicly reported HCAHPS measures for IPPS hospitals with 100 or more completed HCAHPS surveys in a 4-quarter period. We stated that the HLMR is calculated by taking the average of the linear mean scores (LMS) for each of the 11 publicly reported HCAHPS measures. We noted that the LMS, which was created for the calculation of HCAHPS Star Ratings, summarizes all survey responses for each HCAHPS measure; a detailed description of LMS can be found in HCAHPS Star Rating Technical Notes, at *http://www.hcahpsonline.org/StarRatings.aspx*.

We proposed that hospitals participating in the model also have at least 100 completed HCAHPS surveys over a given 4-quarter period to be evaluated on HCAHPS for the model.

We noted in the proposed rule that responses to the survey items used in each of the 11 HCAHPS measures described previously are combined and converted to a 0 to 100 linear-scaled score (LMS) as follows:

- ''Never'' = 0; ''Sometimes'' = 33⅓; ''Usually'' = 66⅔; and ''Always'' = 100 (For HCAHPS Survey items 1–9, 11, 13–14, and 16–17).
- ''No'' = 0; and ''Yes'' = 100 (For items 19 and 20).
- Overall Rating ''0'' = 0; Overall Rating ''1'' = 10; Overall Rating ''2'' = 20; . . . ; Overall Rating ''10'' = 100 (For item 21).
- ''Definitely No'' = 0; ''Probably No'' = 33⅓; ''Probably Yes'' = 66⅔; and ''Definitely Yes'' = 100 (For item 22).
- ''Strongly Disagree'' = 0; ''Disagree'' = 33⅓; ''Agree'' = 66⅔; and ''Strongly Agree'' = 100 (For items 23, 24, and 25).

The 0 to 100 linear-scaled HCAHPS scores are then adjusted for patient mix, survey mode, and quarterly weighting, see *http://www.hcahpsonline.org/files/HCAHPS_Stars_Tech_Notes_Apr2015.pdf*.

The HLMR summarizes performance across the 11 HCAHPS measures by taking an average of each of the LMS of the 11 HCAHPS measures, using a weight of 1.0 for each of the 7 HCAHPS composite measures, and a weight of 0.5 for each of the single item measures (Cleanliness, Quietness, Overall Hospital Rating and Recommend the Hospital). The HLMR is calculated to the second decimal place. Once the HLMR score is determined for a participant hospital, the hospital's percentile of performance can be determined based on the national distribution of hospital performance on the score.

(7) Performance Period

In the proposed rule (80 FR 41283), we proposed to be consistent with the HIQR Program, which uses four quarters of data (79 FR 50259). For the model, we proposed to use the most recently available HCAHPS 4-quarter roll-up to calculate the HLMR score for the initial year of the model. The performance period would assess data on patients discharged from July 1, 2015 through June 30, 2016 for the first year of the model. Section III.D.4. of this final rule summarizes performance periods for years 1 through 5 of the model years.

We invited public comments on this proposal to include HCAHPS Survey measure (NQF #0166) in the model to assess quality performance and capture patient experience of care.

The following is a summary of the comments received and our responses.

Comment: Several commenters supported the inclusion of the HCAHPS Survey measure in the model and strongly recommended increasing the relative weighting of the HCAHPS Survey measure (NQF #0166) in the model. Commenters also cited the fact that the proposed HCAHPS Survey measure (NQF #0166) assesses both access to care and pain management. By contrast, many commenters said that the proposed HCAHPS Survey measure (NQF #0166) should not be included in the model because it does not capture the patient experience of care during the full 90-day episode.

Response: We thank the commenters for these observations and agree with the commenters supporting inclusion of the measure, as we believe it represents an important patient experience measure. We acknowledge that this survey is restricted to the inpatient population by capturing inpatients' experience of care at acute care hospitals. While we do not have an outpatient experience of care survey, we note that the acute care hospitals are the unit of analysis for the model from a measure perspective. Based on the currently available hospital-level patient experience measures, the HCAHPS Survey measure (NQF #0166) is the best available measure for capturing, assessing and comparing the inpatient experience of joint replacement patients at the hospital-level. Regarding the suggestion to increase the weighting of the HCAHPS Survey measure (NQF #0166) in the CJR model we refer readers to section III.C.5.b.(5)(c)(iii) in this final rule for detailed discussion of the relative weighting of this measure in reconciliation payment.

[77] The Effects of Survey Mode, Patient Mix, and Nonresponse on CAHPS Hospital Survey Scores.'' M.N. Elliott, A.M. Zaslavsky, E. Goldstein, W. Lehrman, K. Hambarsoomian, M.K. Beckett and L. Giordano. *Health Services Research,* 44(2): 501–518. 2009.

Comment: Many commenters stated that the HCAHPS Survey measure (NQF #0166) is inappropriate because it will capture a wide range of hospital inpatients along with hip and knee replacement surgery inpatients. CMS, they stated, should collect HCAHPS data on only patients who had undergone an elective THA/TKA, or had procedures captured by MS–DRG 469 and 470 who were involved in the CJR model and compensate hospitals for any additional costs incurred in this effort. A commenter stated that participating hospitals with a ''center of excellence'' program for total joint replacement patients may have in that dedicated unit excellent patient satisfaction scores, but other inpatient units may have less satisfied patients. Thus, HCAHPS scores derived from patients in the joint replacement unit would be undermined by combination at the hospital level with lower scores from other units. Another commenter stated essentially the opposite: That better patient experience of care in other hospital units would mask poorer performance in the joint replacement unit.

Response: We appreciate the concerns from the commenters about the broad patient population covered by this measure. Although the HCAHPS Survey encompasses a broader range of patients than does the model episode definition, we are not aware of evidence that such patients' experience of care differs markedly from those of the larger group of eligible patients after patient-mix adjustment for service line (surgery) and age have been applied. From a survey implementation standpoint, it is not feasible to target only Medicare beneficiaries who had hip or knee replacement surgery, or to calculate the HCAHPS Linear Mean Roll-up score on the basis of only those hip or knee replacement surgical patients. In addition to complicating the administration of the survey, the number of completed surveys from such a narrow set of patients would be, for many hospitals, too small to support reliable measurement or comparison. The inclusion of the HCAHPS Survey measure (NQF #0166) as currently implemented and the HLMR derived from it in the CJR model will present participating hospitals with a further incentive to improve experience of care for all patients.

We are finalizing our proposal to employ the HCAHPS Survey measure (NQF #0166) as currently implemented. HCAHPS, which was launched in 2006 and has been continuously administered ever since, is familiar to over 4,000 hospitals. Modifications to the standardized implementation protocols would be disruptive to the other programs that employ HCAHPS data, which include the HIQR Program and Hospital Value-Based Purchasing program.

Comment: Some commenters had questions about the HCAHPS Linear Mean Roll-up score proposed as the patient experience of care measure in the model, specifically regarding how it was calculated.

Response: We note that the HLMR summarizes in one statistic all survey responses to all 11 HCAHPS measures from all eligible patients discharged in a four-quarter period. As such, it is an efficient and complete summary of hospital patients' experience of care. The HLMR is created in the production of the HCAHPS Summary Star Ratings now displayed on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) and is derived directly from the linear mean scores of the 11 publicly reported HCAHPS measures. Information on the calculation of the HCAHPS linear mean scores can be found in the HCAHPS Star Rating Technical Notes on the HCAHPS On-Line Web site, *http://www.hcahpsonline.org/StarRatings.aspx*. The HLMR summarizes performance across the 11 HCAHPS measures by taking an average of each of the linear mean scores of the 11 HCAHPS measures, using a weight of 1.0 for each of the 7 HCAHPS composite measures, and a weight of 0.5 for each of the single-item measures (Cleanliness, Quietness, Overall Hospital Rating and Recommend the Hospital). The HLMR is calculated to the second decimal place (x.xx) and can range from 0.00 to 100.00.

Comment: Some commenters suggested that the HCAHPS Survey be modified to encompass patients discharged to nursing homes and SNFs before being used in the model.

Response: Patients discharged to nursing homes and SNFs are excluded from HCAHPS survey administration because of the difficulty contacting such patients and consistently surveying them in a timely manner. We are not aware of evidence that patients discharged to a nursing home or SNF have different experience of care than other inpatients in the hospital.

Comment: Some commenters stated that the HCAHPS Survey was arbitrarily biased against certain categories of hospitals such as urban hospitals, major teaching hospitals, safety-net hospitals, hospitals that receive a high proportion of their inpatients through the emergency department, and hospitals that serve a disproportionate share of uninsured, Medicaid, or Medicare dual-eligible patients.

Response: We have not seen evidence that the HCAHPS Survey is biased against any particular category of hospital. Both rural and urban hospitals and teaching and non-teaching hospitals have been found to perform well on the HCAHPS survey.[78] Currently, major teaching hospitals' performance on HCAHPS measures are sometimes lower, sometimes the same, and sometimes higher than that of minor teaching hospitals and non-teaching hospitals (available at: *http://www.hcahpsonline.org/SummaryAnalyses.aspx*). The hospital characteristic definitions are derived from a survey of hospitals conducted by the American Hospital Association (AHA) in 2012 and published in the *AHA Guide 2014 Edition.*

Comment: A commenter stated that the HCAHPS Survey would not be informative because of its low response rate.

Response: We do not believe that the response rate of the HCAHPS Survey degrades its ability to fairly capture patient experience of care. The national response rate for the HCAHPS Survey is currently 31 percent. The patient-mix adjustment that is applied to HCAHPS results prior to public reporting adequately addresses the non-response bias that would otherwise exist.[79] Recent meta-analyses suggest that non-response bias is less related to response rate per se than to the use of rigorous and standardized survey protocols.[80] [81]

Comment: Many commenters suggested that CMS replace the HCAHPS Survey with a patient experience of care measure targeted at only surgical patients, such as the CAHPS Surgical Care Survey, or only those patients eligible for the CJR model. A commenter stated that, while it would be inappropriate to use the CAHPS Surgical Care Survey as a pay-for-reporting or pay-for-performance tool because CMS had not tested this survey for national implementation, the

[78] Lehrman WG, Elliott MN, Goldstein E, Beckett MK, Klein DJ, Giordano LA. Characteristics of Hospitals Demonstrating Superior Performance in Patient Experience and Clinical Process Measures of Care. *Medical Care Research and Review,* 67(1): 38–55. 2010.

[79] Elliott MN, Zaslavsky AM, Goldstein E, Lehrman WG, Hambarsoomian K, Beckett MK, Giordano LA. The Effects of Survey Mode, Patient Mix, and Nonresponse on CAHPS Hospital Survey Scores. *Health Services Research,* 44(2): 501–518. 2009.79.

[80] Groves RM. Nonresponse rates and nonresponse bias in household surveys. Public Opin Q. 2006; 70:646–675.

[81] Groves RM, Peytcheva E. ''The impact of nonresponse rates on nonresponse bias: a meta-analysis''. Public Opin Q. 2008; 72:167–189.

CAHPS Surgical Care Survey could be used for model evaluation purposes in the context of the CJR model's bundled payment approach. Many commenters suggested that CMS create a new survey instrument specifically for the CJR model that would capture the 90-day episode of care and combine patient experiences of care across all the providers that a patient encountered during that period.

Response: The CAHPS Surgical Care Survey is focused on the physician who performed inpatient or outpatient surgery, not the hospital, and encompasses a range of surgical patients, not just those included in the CJR model. We do not believe the CAHPS Surgical Care Survey measure is feasible or appropriate to adopt for the CJR model.

While a patient experience survey customized for only LEJR patients might have a tighter focus, developing and implementing such a measure would require significant resources and take a number of years. Given the relatively small number of patients at a hospital who undergo LEJR, collecting enough completed surveys to attain acceptable levels of reliability for such a measure would also be a challenge. Segregating HCAHPS Surveys from patients who had undergone LEJR surgery would often result in a small number of completed surveys as well as demand modifications in well-established survey implementation protocols. Tracing a patient over a 90-day episode through a number of different types of healthcare providers would be very difficult given the de-identified nature of HCAHPS data. Replacement of the HCAHPS Survey measure (NQF #0166) with a physician-based survey would remove the hospital experience from the model.

We have no reason to believe that patients undergoing LEJR differ in their patient experience compared with other HCAHPS-eligible patients in the same hospital. Similarly, we have no evidence that patients who are excluded from the HCAHPS Survey measure (NQF #0166) because of discharge to nursing homes or SNFs have different experience of care than other inpatients, but we have found that consistently contacting and surveying such patients is difficult. Thus, we believe that the HCAHPS Survey is the most viable and practical measure of patient experience of care available for the model at this time.

Comment: A commenter suggested using an electronic platform to capture and report the HCAHPS Survey for only the patients in the bundled episodes.

Response: The HCAHPS Survey currently permits four modes of survey administration: mail, telephone, mail with telephone follow-up (mixed mode), and Interactive Voice Response. CMS has tested the feasibility of offering an Internet mode for the HCAHPS Survey but determined that issues related to low response rates and poor comparability with the other existing survey modes preclude implementation of a Web-based mode at this time.[82]

Comment: Concerned that the proposed measures are disproportionately hospital-focused, many commenters suggested that CMS develop a CAHPS measure that would capture both the in-hospital and post-hospital phases of the 90-day episode for Medicare beneficiaries who had experienced joint replacement surgery and devise a blended CAHPS score across all settings involved with the 90-day episode.

Response: CMS patient experience of care surveys are targeted toward providers (hospitals, HHAs, etc.) and assess performance at the provider level. CMS does not possess a survey instrument that tracks hospital inpatients across a 90-day episode or across different types of providers or other settings. Developing such an instrument would be difficult because HCAHPS data submitted to CMS by hospitals or their survey vendors are patient de-identified in order to ensure HIPAA compliance. As such, it would not be feasible to link patient-level HCAHPS results to the same patient-level results on other surveys or other measures from other settings or providers.

Comment: A commenter requested that CMS publicly report the HCAHPS Linear Mean Roll-up score of all hospitals on a quarterly basis in order for hospitals to be able to understand where they stand on this measure relative to other hospitals and to facilitate hospitals' ability to rapidly improve performance and assess financial risk.

Response: We plan to share information with hospitals on their scores on the quality measures included in the model, including the HCAHPS Linear Mean Roll-up score, on an annual basis. Information on performance will be shared with hospitals through their ongoing *Hospital Compare* Preview Reports on an annual basis. Hospital scores on the model measures will be publicly reported on *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) on an annual basis. We note that a goal for the CJR model is to align as many quality measure processes (including public reporting) as is reasonably possible with the HIQR program and for this reason we will be publicly reporting HCAHPS Survey measure (NQF #0166) annually instead of quarterly.

Comment: A commenter suggested that CMS implement the quality thresholds in performance year 2 or later, especially for HCAHPS, to help hospitals to understand their quality performance compared to the thresholds and allow them time to make meaningful improvements to quality of care.

Response: Hospitals participating in the CJR model have had several years of experience with the HCAHPS survey. Since July 2007, hospitals subject to the IPPS annual payment update provisions have been required to collect and submit HCAHPS data in order to receive their full annual payment update (71 FR 48037). Non-IPPS hospitals, such as CAHs, may voluntarily participate in HCAHPS. The incentive for IPPS hospitals to improve patient experience was further strengthened by the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), which specifically included HCAHPS performance in the calculation of the value-based incentive payment in the Hospital Value-Based Purchasing program beginning with October 2012 discharges.

With respect to the HCAHPS Linear Mean Roll-up score measure that CMS has proposed for the model, hospitals began receiving HCAHPS Summary Star Rating in their December 2014 *Hospital Compare* Preview Report. The HLMR is the basis for the HCAHPS Summary Star Rating; see HCAHPS Star Rating Technical Notes at *http://www.hcahpsonline.org/StarRatings.aspx*. While the HLMR is a new calculation from the existing measures, hospitals have been using the HCAHPS survey for many years and have had time to become familiar with it, with their results, and with their standing relative to other hospitals through information presented on the HCAHPS On-Line Web site such as the HCAHPS Percentiles tables (*http://www.hcahpsonline.org/SummaryAnalyses.aspx*). IPPS hospitals have available their HCAHPS scores' relative rank compared to other hospitals participating in the HVBP program. As such, we believe that hospitals are familiar with their individual and relative performance on

[82] Elliott MN, Brown JA, Lehrman WG, Beckett MK, Hambarsoomian LA, Giordano LA, Goldstein E. A Randomized Experiment Investigating the Suitability of Speech-Enabled IVR and Web Modes for Publicly Reported Surveys of Patients' Experience of Hospital Care. *Medical Care Research and Review,* 70(2): 165–184. 2013.

the HCAHPS Survey measure (NQF #0166).

Comment: A commenter suggested that the HCAHPS Survey measure (NQF #0166) be removed from the CJR model unless adjusted for socio-economic status.

Response: As discussed in our responses to public comments on the Complications measure (NQF #1550), we do not adjust the measure for patients' socio-economic status directly. However, the patient-mix adjustment of HCAHPS survey scores does include an adjustment for patients' self-reported level of education, which is correlated with other SES indicators; see HCAHPS On-Line Web site: *http://www.hcahpsonline.org/modeadjustment.aspx*.

The intent of the HCAHPS survey is to provide a standardized survey instrument and data collection methodology for measuring patients' perspectives of hospital care. In order to achieve the goal of fair comparisons across all hospitals that participate in HCAHPS survey, it is necessary to adjust for factors that are not directly related to hospital performance but do affect how patients answer HCAHPS survey items. These factors include the mode of survey administration and the characteristics of patients in participating hospitals, often referred to as patient-mix.

Patient-mix refers to patient characteristics that are not under the control of the hospital that may affect patient reports of hospital experiences. The goal of adjusting for patient-mix is to estimate how different hospitals would be rated if they all provided care to comparable groups of patients. In developing the HCAHPS patient-mix adjustment (PMA) model, we sought important and statistically significant predictors of patients' HCAHPS ratings that also vary meaningfully across hospitals. The following PMA variables are included in the HCAHPS patient-mix models: Service line (medical, surgical, or maternity care), age, education, self-reported health status, language other than English spoken at home, age by service line interactions, and percentile response order, also known as ''relative lag time,'' which is based on the time between discharge and survey completion. This adjustment approach is grounded in more than ten years of CAHPS research of case-mix/patient-mix adjustment, reflects the input of a wide variety of stakeholders, has been subject to extensive empirical testing, and has been accepted in the peer-reviewed scientific literature.[83]

Comment: A commenter stated that the HCAHPS survey represents a significant delay in reporting results and that the reporting time frame does not coincide with the reporting time for the model.

Response: The HCAHPS surveys used to construct the HCAHPS Linear Mean Roll-up score measure in the CJR model corresponds to a similar time frame as that proposed for the Complications and Readmissions measures illustrated in Table 17 of the proposed rule (80 FR 41290). We note that the HCAHPS uses a one year performance period closer to the CJR model initiation date in 2016, and therefore we do not believe the proposed one year performance period of July 1, 2015–June 30, 2016 represents a significant delay in reporting results for the CJR model.

Comment: Several commenters suggested that inclusion of the HCAHPS Survey measure (NQF #0166) in the CJR model could harm ''essential'' hospitals because hospitals with higher volume of patients admitted through the emergency department may score lower on the HCAHPS survey. Commenters also stated that hospitals with high proportions of Medicaid, Medicare dual-eligible, and uninsured patients would be adversely affected by the inclusion of the HCAHPS Survey measure (NQF #0166) in the model.

Response: We have examined the performance of so-called ''safety net'' hospitals, sometimes referred to as ''essential'' hospitals, on the HCAHPS component of the HVBP program. Although we do not have an official definition or designation of ''safety net'' hospital, we understand that a safety net status typically entails one or more of three criteria: High Medicaid share; high proportion of uncompensated patients; and high county-associated poverty rate.

In general, after all HCAHPS adjustments are applied (patient mix and survey mode), we believe that so-called safety net hospitals, as we understand the term perform similarly to other hospitals. The current adjustment approach that CMS employs is both well-validated and necessary to ensure fair comparisons of HCAHPS scores across hospitals. When these adjustments are applied according to the rules currently in place, the performance of safety net hospitals for the HCAHPS portion of HVBP is typical of hospitals in general.

Comment: Many commenters stated that there is an inherent bias in the HCAHPS survey that is difficult to adjust for. A few commenters pointed out that California hospitals rank in the bottom quartile of HCAHPS scores.

Response: We do not believe that there is an inherent bias in the HCAHPS survey. We do not believe that there is an inherent bias in the HCAHPS Survey. Along these lines, we have noted over the years that some stakeholders believe that patient experience of care surveys are subjective or that patients are unable to judge the quality of care provided (76 FR 26502). However, CAHPS surveys are designed to measure topics where the patient is the best or only source of information. Beginning in 2002, CMS partnered with the Agency for Healthcare Research and Quality (AHRQ), another agency in the federal Department of Health and Human Services, to develop and test the HCAHPS survey. AHRQ and its CAHPS Consortium carried out a rigorous and multi-faceted scientific process, including a public call for measures; literature review; cognitive interviews; consumer focus groups; stakeholder input; a three-state pilot test; extensive psychometric analyses; consumer testing; and numerous small-scale field tests. We provided three opportunities for the public to comment on the HCAHPS survey and responded to over a thousand comments. The survey, its methodology and the results published by CMS are in the public domain.

In May 2005, the HCAHPS survey was endorsed by the National Quality Forum, a national organization that represents the consensus of many healthcare providers, consumer groups, professional associations, purchasers, federal agencies, and research organizations. In December 2005, the federal Office of Management and Budget gave its final approval for the national implementation of the HCAHPS survey for public reporting purposes. The NQF has twice re-endorsed the HCAHPS survey, most recently in 2014. Performance on the HCAHPS survey varies nationally. CMS believes that this variation reflects true differences in patient experience of care, not inherent bias.

Comment: A commenter recommended that the HCAHPS survey measures used in the CJR model and the Hospital Value-Based Purchasing program be the same and that the HCAHPS survey measures used to evaluate performance be harmonized across programs.

[83] Elliott, MD, Zaslavsky AM, Goldstein E, Lehrman,WG, Hambarsoomian K, Beckett, MK, Giordano L. The Effects of Survey Mode, Patient Mix, and Nonresponse on CAHPS Hospital Survey Scores.'' *Health Services Research,* 44(2): 501–518. 2009.

Response: The HCAHPS survey measures used in the HIQR Program, HVBP program and the model are tailored to reflect the respective purposes of those programs. CMS chose to use the HCAHPS Linear Mean Roll-up score for the model because it efficiently captures the full range of survey responses in a single statistic. The Patient and Caregiver-Centered Experience of Care/Care Coordination Domain score in the HVBP program is more complicated, comprising achievement, improvement and consistency components and entailing a comparison between a baseline year and a later performance year (76 FR 26516). The HIQR Program includes a wider and deeper array of measures and provides more detailed information about HCAHPS survey performance, which may be useful to consumers.

In the CJR model, the HCAHPS survey measures and their relative weighting are very similar to the HVBP program. Both the CJR model and the HVBP program use a four-quarter roll-up of HCAHPS scores and set a threshold of 100 completed HCAHPS surveys for hospital participation (76 FR 26502). The two programs are also similar in that their HCAHPS component is created from the data submitted for the HIQR Program, thus requiring no additional data collection or submission. While there are differences in the HCAHPS survey measures used in the HVBP program and the CJR model, the measures are strongly correlated. Given that the HIQR and HVBP programs and the CJR model all employ the same HCAHPS survey data, patient experience quality improvement efforts targeted toward hospital performance on any one of these programs will redound to the benefit of all programs.

Comment: A commenter suggested that a functional measurement, such as HOOS, KOOS or VR–12, replace the proposed HCAHPS measures in the CJR model so to provide a valid assessment of improvement in patient health and status.

Response: The HCAHPS survey (NQF #0166) measures hospital inpatients' experience of care. The HCAHPS survey is not a functional measurement. As such, the HCAHPS survey could not be adequately replaced by a functional measurement because these two types of measure assess different aspects of patient care. We note that the CJR model has included the THA/TKA voluntary data submission initiative (section III.D.3.a. of this final rule) which includes functional patient-reported outcome assessment.

Final Decision: After consideration of the public comments we received, we are finalizing the proposal to implement the HCAHPS Survey measure (NQF #0166), as it is the best available measure of patient experience of care for hospitals that perform LEJR procedures. Over 4,000 hospitals currently participate in the HCAHPS survey, and the instrument is also familiar to patients. The HCAHPS survey was carefully designed, developed and implemented, is subject to continuous oversight, has been found to meet high standards of reliability and validity, has been endorsed and re-endorsed by the National Quality Forum, and is currently used in both the HIQR and Hospital Value-Based Purchasing programs. We believe that HCAHPS Survey measure (NQF #0166) is a fair and unbiased measure of patient experience of care at all types of hospitals.

We have no reason to believe that patients undergoing LEJR differ in their patient experience compared with other HCAHPS-eligible patients in the same hospital. Similarly, we have no evidence that patients who are excluded from the HCAHPS Survey measure (NQF #0166) because of discharge to nursing homes or SNFs have different experience of care than other inpatients, but we have found that consistently contacting and surveying such patients is difficult. Thus, we believe that the HCAHPS survey is the most viable and practical measure of patient experience of care available for the model at this time. Finally, we are codifying adoption of the HCAHPS Survey measure (NQF #0166) in § 510.400(a)(2).

d. Applicable Time Period

In the proposed rule (80 FR 41283), in order to align as much as is reasonably possible with other CMS hospital quality and public reporting programs in which these three measures are implemented, we proposed for the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) performance time periods to be consistent with the HIQR Program, HVBP program and HRRP. We noted that these programs use a 3-year rolling performance period (that is, the applicable period; see section III.D.2.b.(6) of the proposed rule) for the Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) and the Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) measures. We proposed a 3-year rolling performance period for the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) because a 3-year performance period yields the most consistently reliable and valid measure results. We also proposed the 3-year rolling performance periods for the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) because hospitals are intimately familiar with these measures. We noted that reconciliation payments to hospitals as part of the CJR model are dependent upon both cost and quality outcome measures, and that making reconciliation payments solely based on cost has the potential to lead to reduced access and stinting of care. We stated that in order to address these possibilities the inclusion of performance on outcome measures is critical to ensure access and high-quality care for patients undergoing these procedures, and that the only way to include reliable quality measures in the model upon which to base reconciliation payments for 2016, is to use measures that have a performance period that precedes the start date of the model. We explained that, from a measure reliability and validity perspective, it is imperative to have at least 4 quarters of data for HCAHPS survey measures and 3 years of data for the THA/TKA readmissions and complications measures. We intentionally chose outcome and patient experience measures for which hospitals that are already financially accountable in other IPPS programs. Consequently, the performance periods are the same periods for the THA/TKA Readmissions and Complications measures between the model, HIQR Program, HVBP program and HRRP. For the HCAHPS survey measures, there is overlap with the performance periods for the model and the HIQR Program.

We stated our belief that it is appropriate and necessary to use performance periods that precede the start date of the model because: (1) There is no downward payment adjustment associated with the model; (2) hospitals are already familiar with these measures as part of the HIQR Program, HVBP program, and HRRP; and (3) hospitals are already held financially accountable for these measures. For the HCAHPS Survey measure (NQF #0166), we would continue to use a 4 quarter performance period as in the HIQR Program, but would not align with the HIQR Program performance period. We shared how we

initially considered using the same HIQR Program performance period for the HCAHPS Survey measure (NQF #0166), but realized that should we use the same HIQR Program performance periods for the model, other model timeframes and policy goals would not be met. We indicated such policy goals like calculating reconciliation payment adjustments in a timely fashion during the 2nd quarter of each year might not be met, and we also noted that HCAHPS survey results are not available until the 3rd quarter of each year. For these reasons, we did not propose that the HCAHPS survey performance period follow the HIQR Program performance periods. We also proposed that HCAHPS survey scores be calculated from 4 consecutive quarters of survey data. We closed the proposal by indicating that public reporting of HCAHPS survey results are also based on 4 quarters of data (79 FR 50259).

The following is a summary of the comments received and our responses.

Comment: Some commenters supported the three-year rolling period of performance for the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551). Others did not support the three-year rolling performance period for these two measures and expressed concerns because—(1) With a start date of January 1, 2016, hospitals would only have three months to improve on the performance for the three measures; (2) the three-year rolling performance period does not coincide with the 12-month performance period used by the CJR model to determine the reconciliation payment; (3) a three-year rolling performance period exacerbates the lack of correlation between the CJR model 12-month performance and the measure performance periods; (4) the three-year rolling performance period includes a significant amount of data that pre-date the start of the model proposed for January 1, 2016 ; and (5) the potential impact that a single year of poor performance may have on the subsequent 2 years of performance. Most commenters recommended that the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) coincide with the CJR model 12-month performance period used to determine the reconciliation payment.

Response: We appreciate the concerns regarding the use of the three-rolling performance period for the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551). We note that these measures rely on administrative claims data that are at least a year old because providers have up to one year to submit administrative claims for payment and that the measures are designed to include only administrative claims that are final action claims. The measures use final action claims in order to ensure consistency in the type of hospital data is used in the measures. Additionally, use of performance periods up to 3 years ensures adequate sample size for administrative claims based measures. For these reasons we believe it is reasonable to use a 3 year-rolling performance period, and in order to have sufficient data for the first year of the model use of data that precedes the start of the CJR model will help to provide a reliable estimate of a hospital's performance on the THA/TKA Complications measure (NQF #1550).

Regarding the concern that hospitals would only have 3 months to improve on the performance for the three proposed measures, we note for the HIQR Program that the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) were finalized in the FY 2013 IPPS/LTCH Final Rule (77 FR 53534) for implementation in FY 2015, and the most updated HCAHPS Survey measure (NQF #0166) was finalized in FY 2014 IPPS/LTCH final rule (78 FR 50807) and in the HVBP program (76 FR 26502). We therefore believe hospitals have received ample time to identify ways in which to improve their performance on these three measures. Finally, we specifically considered this aspect of the measures knowing that hospitals were familiar with these measures and had more than likely instituted quality improvement activities in order to perform well on these measures.

Regarding the request to use a 12-month performance period, we note that from a measure reliability perspective—(1) A rolling 3-year performance period consistently identifies more eligible index admissions for each hospital as compared to a single year of hospital performance data or a 3-month period of data. Using a larger number of index admissions improves the precision of the estimation of each hospital's results for the THA/TKA Readmissions measure (NQF #1551) and THA/TKA Complications measure (NQF #1550). We note that if we were to have a 12-month performance period, the reliability of these measure results would become questionable; (2) a rolling 3-year performance period provides larger sample sizes, which will allow the calculation of measure results that are better able to more meaningfully distinguish hospital performance; and (3) in order to provide meaningful measures results that use claims data, we believe it is important to use claims data that has completed the appropriate opportunities for appeal and correction through the CMS administrative claims submission process. Without opportunities for hospitals to correct claims errors, the measure results may not be valid and reliable for making quality improvements in hospital processes. For these reasons we believe that having a rolling 3-year performance period is reasonable for the THA/TKA Complications measure (NQF #1550). We note that the THA/TKA Readmissions measure (NQF #1551) is not finalized for the CJR model.

After review of public comments, we are finalizing the three-year rolling performance period as proposed for the THA/TKA Complications measure (NQF #1550). Similarly, for the HCAHPS Survey measure (NQF #0166), we are finalizing our proposal that the HCAHPS survey scores be calculated from 4 consecutive quarters of survey data and that publicly reported HCAHPS results are based on 4 quarters of data (79 FR 50259). Since we are not finalizing the THA/TKA Readmissions measure (NQF #1551), as discussed in section III.D.2.b. of this final rule, we will not be finalizing any applicable period for this measure.

3. Possible New Outcomes for Future Measures

a. Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty

(1) Background

In the proposed rule (80 FR 41284), we stated that part of our goal to move towards outcome measures that assess patient-reported outcomes, we had begun development on a measure to assess improvement in patient-reported outcomes following THA/TKA procedures. We shared that the Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (hereinafter referred to as ''THA/TKA patient-reported outcome-based measure'') is currently under development. In our proposal, we shared that we specifically chose to focus on THA/TKA procedures since THA/TKAs are important, effective procedures performed on a broad population, and the patient outcomes for these procedures (for example, pain, mobility, and quality of life) can be

measured in a scientifically sound way and are also influenced by a range of improvements in care.[84] [85] [86] We also shared that THA/TKA procedures are specifically intended to improve function and reduce pain, making patient-reported outcomes the most meaningful outcome metric to assess for these common, costly procedures. We outlined that patient-reported outcomes will be assessed separately for THA and TKA procedures, though these results may be combined into a single composite measure for reporting, and indicated that we would refer to a single measure, while acknowledging the possibility of two measures, one for THA patients and one for TKA patients.

In the proposed rule we provided background on measure development, and shared our discovery that in order to complete measure development, we would need access to a nationally representative sample of THA and TKA inpatient surgical procedure patient-reported outcome data set that is also consistently collected at the hospital-level and contains risk variables identified by orthopedists. Further, we noted that our rationale for requesting access to a national THA and TKA inpatient surgical procedures patient-reported data source was twofold—(1) A national data source would provide us with hospital-level data representative of the total number of THA and TKA procedures performed in hospitals, as well as representative data on hospital-level case-mix; and (2) access to a national THA and TKA inpatient surgical procedures patient-reported data source would allow us to assess and identify a set of parsimonious data elements that will minimize the data collection burden by patients, physicians and hospitals. We shared our belief that—(1) Access to such data would allow for completion and testing of the current measure under development so that it could be appropriately used for nationwide hospital performance evaluation; and (2) the model provides a unique opportunity to resolve these measure development issues through the collection of THA and TKA patient-reported outcome data. We stated that access to this data through the model would address the following:

- Current data sources are not consistently collected nor collected in a uniform process and in a standardized format (that is, data elements are not consistently defined across different data sources). We note that currently available data sources tend to be limited to single hospitals or regional registries which are associated with complex data access sharing requirements.
- Current lack of uniform hospital-level data that can be used in measure development.
- Lack of incentive for physicians and hospitals to collect patient-reported outcome data such as that through the model's financial incentives associated with voluntary data submission.
- Current lack of a technically simple and feasible mechanism for hospitals to submit patient-reported data to CMS. This model would help create and optimize such a mechanism, potentially enabling future measure implementation.

Additionally we stated that the voluntary data collection initiative in the model would provide an opportunity to collect data from the patient's perspective, data that is necessary to finalize and test the measure specifications, including the risk model. In the proposed rule, we shared how access to this national representative voluntarily submitted data would enable us to do the following:

- Determine a parsimonious set of risk factors that are statistically adequate for risk adjustment for patient-reported outcome.
- Examine the differences in hospital performance related to different components in the patient-reported outcome (such as functional status, pain, etc.) to finalize the statistical modeling methodology for risk adjustment.
- Evaluate the reliability of the patient-reported outcome measure.
- Examine validity of the patient-reported outcome measure upon finalization of the risk adjustment model via potential testing methods such as face validity testing with national experts, comparing the measure results to similar results based on other data sources if feasible, etc.

We also addressed the importance of encouraging participation with voluntary data submission of patient-reported outcome data, so we proposed to reward voluntary participation in submission of THA/TKA patient-reported outcome-based measure data as outlined in section III.D.3.a. of the proposed rule. We also indicated that we would not publicly report the THA/TKA voluntary data.

Finally, we shared our intention to use a fully tested and completed THA/TKA patient-reported outcome-based measure in CMS models or programs when appropriate. We stated that if there is a decision to implement the fully developed THA/TKA patient-reported outcome-based measure, such as in the CJR model, we would propose to adopt the measure through notice-and-comment rulemaking. We also referenced draft measure specifications in the Downloads section of the Measure Methodology Web page at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

The following is a summary of the comments received and our responses. Please note the use of the following acronyms: (1) Patient-reported outcome will be noted as PRO; (2) patient-reported outcome measure (PROM) is a patient-reported outcome survey instrument; and (3) patient-reported outcome-based performance measure will be noted as PRO–PM. These terms are consistent with the National Quality Forum Patient Reported Outcomes (PROs) in Performance Measurement, January 10, 2013 (available at: *http://www.qualityforum.org/Publications/2012/12/Patient-Reported_Outcomes_in_Performance_Measurement.aspx*).

Comment: Many commenters supported CMS's goal to measure and improve patient-reported outcomes. Many commenters supported the PRO data voluntary reporting proposal. Multiple commenters specifically urged CMS to adopt the proposal to gather PRO data for the purpose of completing development of the hospital-level THA/TKA PRO–PM. A commenter supported linking the reconciliation payment to quality performance. A commenter supports the financial incentive for hospitals that participate in the voluntary data collection initiative.

Response: For a detailed discussion of the payment perspective for use of the THA/TKA voluntary PRO data in determining reconciliation payment, including our responses to public comments, we refer readers to section III.C.5.b.(5)(b) through III.5.b.(5)(c) of this final rule.

Comment: Several commenters recommended that CMS fully develop the PRO–PM before implementing the

[84] Monticone M, Ferrante S, Rocca B, et al. Home-based functional exercises aimed at managing kinesiophobia contribute to improving disability and quality of life of patients undergoing total knee arthroplasty: A randomized controlled trial. *Archives of physical medicine and rehabilitation.* Feb 2013;94(2):231–239.

[85] Galea MP, Levinger P, Lythgo N, et al. A targeted home- and center-based exercise program for people after total hip replacement: A randomized clinical trial. *Archives of physical medicine and rehabilitation.* Aug 2008;89(8):1442–1447.

[86] Moffet H, Collet JP, Shapiro SH, Paradis G, Marquis F, Roy L. Effectiveness of intensive rehabilitation on functional ability and quality of life after first total knee arthroplasty: A single blind randomized controlled trial. *Archives of physical medicine and rehabilitation.* Apr 2004;85(4):546–556.

measure's use in a payment model. Several commenters stated that the proposed quality measures are not rigorous in the way in which they were developed and the selection of specifications such as PROM instruments in the PRO–PM.

Response: We note that the purpose of this voluntary PRO and risk variable data collection is to complete the development of a THA/TKA PRO–PM. We will not use the THA/TKA voluntary and limited risk variable data to assess hospitals' performance, but instead will use the voluntary submitted data to complete development of a PRO–PM measure for future use in the CJR model. Finally, we would like to use the innovative strategy to encourage THA/TKA voluntary PRO and risk variable data submission by rewarding hospitals that successfully submit THA/TKA voluntary and risk variable data. We believe our measure development process is rigorous and transparent. We created a list of candidate PROM instruments following an environmental scan and literature review. Our measure development contractor convened a Technical Expert Panel through a public process. Based on input from the Technical Expert Panel and a public comment period, we proposed validated, non-proprietary PROMs that have been tested in patients undergoing THA/TKA or, in the case of the PROMIS-Global, had undergone rigorous testing during development with plans to test in patients undergoing THA/TKA. The final rule is limited to a voluntary PRO data collection initiative that will inform our standard measure development process set forth in NQF guidance for outcome measures,[87] CMS Measures Management System (MMS) guidance,[88] and the guidance articulated in the American Heart Association Statement ''Standards for Statistical Models Used for Public reporting of Health Outcomes.'' [89] Once finalized, the THA/TKA PRO–PM that will be developed using the voluntary PRO and risk variable data will be incorporated into the CJR model through rulemaking to address public comments strongly recommending the model include a measure of functional status. The application of a patient-reported outcome measure in the CJR model is important for providers to understand where they can adjust or change their processes in order to improve the care they are providing. Having a PRO–PM measure will also provide important information about provider care for the beneficiaries and their families and caretakers.

Comment: A commenter recommended that CMS facilitate collaboration among hospitals to share best practices for PRO data collection.

Response: We agree with the commenter's recommendation. We intend to support hospitals that choose to collect PRO data as part of the CJR model by providing education and dissemination of successful practices.

Comment: A commenter recommended reporting separate total hip and knee arthroplasty PRO–PMs.

Response: We appreciate the recommendation to report separate total hip and knee arthroplasty measures. As indicated on pages 14 and 16 in the Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure(s) Phase 3 Measure Methodology Report posted on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*, we agree with the commenter that hospital performance for the care of THA and TKA patients be assessed using separate PRO–PMs and intend to develop a THA/TKA PRO–PM that assesses THA and TKA PROM results separately and then combine them into a composite score that preserves the distinctions in clinical outcomes between these patient groups if needed for adequate sample sizes to ensure stable performance estimates. The PRO-based measure remains under development, and this input will inform future measure development work.

Comment: A commenter noted a high response rate within their group, and cautioned that poor response rates will undermine validity and comparisons across settings.

Response: We appreciate the commenter's support of measuring PROs and concerns about obtaining adequate PROM response rates and applaud the commenter's success in this realm. We encourage the commenter to share any insights regarding optimizing PRO response rates with CMS to further this important measurement effort. We appreciate the concern that poor response rates will undermine the validity of the data collected and the ability to compare outcomes across settings. We note that section III.D.3.a.(9) of this final rule addresses this concern by finalizing a different definition of successful THA/TKA voluntary data submission.

Comment: Some commenters recommended that the THA/TKA PRO–PM should be tested, reviewed, and endorsed by the NQF.

Response: We plan to submit the THA/TKA PRO–PM to the appropriate NQF project upon completion of measure development.

Comment: A commenter urged CMS to validate the risk adjustment methodology before hospitals' results on the PRO–PM are reported on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) or the *Physician Compare* Web site (*https://www.medicare.gov/physiciancompare/*).

Response: We note that the THA/TKA PRO–PM is currently under development. We plan to validate the risk adjustment methodology prior to implementing the measure into any public reporting program. As noted in the proposed rule (80 FR 41290), the THA/TKA voluntary data will not be publicly reported, but instead a symbol will used to acknowledge CJR model hospitals that successfully submitted the voluntary data.

Final Decision: After consideration of the public comments, we wanted to express our appreciation for the support for this THA/TKA voluntary PRO data submission initiative. As with all of our measures in development, when appropriate, they are reviewed by NQF for endorsement and by the NQF Measure Applications Partnership for implementation in programs. Finally, we appreciate the recommendations to facilitate collaboration among hospitals to share best practices for PRO data collection and, as stated previously, will be looking for ways to support this recommendation. We are finalizing the THA/TKA voluntary PRO and risk variable data submission initiative as previously discussed.

(2) Data Sources

In the proposed rule (80 FR 41285), we shared that this measure is under development, and we proposed to reward participant hospitals that volunteer to submit provider- and patient-level data elements. We shared our observation that currently, there is

[87] National Quality Forum. Measure Evaluation Criteria and Guidance. April 2015. Available at: *http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx.* Accessed on September 22, 2015.

[88] Measures Management System Overview.2015; *http://www.cms.gov/Medicare/Quality-Initiatives Patient-AssessmentInstruments/MMS/index.html ?redirect=/MMS/19_MeasuresManagementSystem Blueprint.asp.* Accessed September 8, 2015.

[89] Krumholz H, Brindis R, Brush J, *et al.* Standards for Statistical Models Used for Public Reporting of Health Outcomes: An American Heart Association Scientific Statement from the Quality of Care and Outcomes Research Interdisciplinary Writing Group: Cosponsored by the Council on Epidemiology and Prevention and the Stroke Council. Endorsed by the American College of Cardiology Foundation. *Circulation.* Jan 24 2006;113(3):456–462.

little uniformity across hospitals regarding collection of specific provider- and patient-level data elements that are used to assess patient outcomes after THA and TKA inpatient procedures. We also shared for the voluntary data submission for the THA/TKA patient-reported outcome-based measure initiative, our goal to identify a uniform set of provider- and patient-level data elements that are accurate, valid, and reliable pieces of information that can be used in the determination of improvement in various patient characteristics like those previously listed (that is, pain, mobility, and quality of life). We also shared our goal to minimize patient, provider and hospital burden associated with data collection and submission of provider- and hospital-level data elements, by proposing a variety of data sources for measure development. We provided the following three categories of anticipated data sources for public comment:

- Patient-reported data.
- Administrative claims-based data.
- One or both physician-reported and electronic health record data.

As a way to minimize burden on patients, providers, and hospitals we proposed to request that participant hospitals provide administrative claims-based data whenever possible; we also requested that participant hospitals submit either hospital documentation, chart abstraction, or abstraction from the electronic health records. The list of proposed data elements are summarized in the proposed rule (80 FR 41285).

Finally, we stated that as the measure continues to undergo development that the list of data elements may be simplified consistent with our previously stated goal in this section entitled Data Sources, that we intend to identify a uniform set of provider- and patient-level data elements that are accurate, valid and reliable pieces of information that can be used in the determination of improvement in various patient-reported outcomes like those previously listed (that is, pain, mobility, and quality of life). We shared our anticipation that via public comment and experience with the voluntary data submission, that the set of data elements listed previously will be simplified.

In accordance with, and to the extent permitted by, the HIPAA Privacy Rule and other applicable law, we proposed to request that participant hospitals submit the data specified in the request, which we would limit to the minimum data necessary for us to conduct quality assessment and improvement activities. Regarding the process for data collection, we proposed the THA/TKA voluntary data will be submitted to and collected by a CMS contractor in a manner and format similar to existing CMS data submission processes. For example, CMS would supply applicable hospitals with a file template and instructions for populating the file template with data and submitting the data; the hospitals will populate the template, log in to a secure portal, and transmit the file to the appropriate CMS contractor; the CMS contractor would also match the submitted data to Medicare administrative claims-based data and calculate completeness for determination of the reconciliation payment as noted in section III.C.5. of the proposed rule (or validated subscales or abbreviated versions of these instruments). We stated our belief that participation in the submission of THA/TKA—voluntary data will provide the minimum information we would need that would inform us on how to continuously improve the currently specified measure in development.

Finally, we noted that some of these data elements are closely aligned with data elements in electronic clinical quality measures submitted by eligible professionals for the Medicare EHR Incentives Program for Eligible Professionals. Specifically these EHR Incentives Program measures for eligible professionals are: (1) Functional Status Assessment for Knee replacement (CMS 66); and (2) Functional Status Assessment for Hip replacement (CMS 56). We refer reviewers to CMS.gov EHR Incentives Program 2014 Eligible Professional June 2015 zip file update at *http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/eCQM_2014_EP_June2015.zip* for full measure specifications. We stated our belief that it is possible that many health IT vendors are already certified to capture, calculate and report these provider-level measures of functional status on total knee and total hip arthroplasty, and therefore we anticipate that the provider-level data elements that are identical to the THA/TKA patient-reported outcome voluntary data elements previously listed may not be as burdensome for the CJR model participant hospitals to voluntarily submit.

The following is a summary of the comments received and our responses. We received many public comments on the Data Sources section and have divided the public comments and our responses into two categories—(1) Public comments not specifically related to the proposed PRO and risk variable data elements (80 FR 41825); and (2) public comments specifically related to the proposed PRO and risk variable data elements.

The following are public comments made that are not specifically on the proposed instruments (80 FR 41825) and our responses.

Comment: A commenter questioned whether CMS will include economic or clinician-reported outcomes in addition to clinical outcomes.

Response: We will be capturing generic health-related quality of life assessments with the VR–12 and PROMIS-Global, which will supplement the clinical outcomes of the HOOS/KOOS Jr. or specified HOOS/KOOS subscales (see Table 28). We will not be capturing patient-reported economic or clinician-reported outcomes. The purpose of this voluntary PRO data collection is to complete the development of a THA/TKA PRO–PM. We will not use the THA/TKA voluntary data to assess hospitals' performance during Years 1–3 of the CJR model, but instead will use the submitted data to complete development of a PRO–PM measure. Finally, we would like to use the innovative strategy to encourage THA/TKA voluntary data submission by rewarding hospitals that successfully submit THA/TKA voluntary data during Years 1–3. Comparisons with other outcome measures can be made when such a measure is fully developed. Once finalized, the THA/TKA PRO–PM that will be developed using the voluntary PRO and risk variable data will be incorporated into the CJR model through rulemaking to address public comments strongly recommending the model include a measure of functional status.

Comment: A few commenters recommended that CMS use existing measures, such as Functional Status Change for Patients with Knee Impairments (NQF #0422) and Functional Status Change for Patients With Hip Impairments (NQF #0423), both of which are stewarded by Forum on Therapeutic Outcomes, Inc. (FOTO), to measure patients' functional status in the CJR model. The commenters stated that these NQF-endorsed measures are in the public domain, are economical and are not burdensome to patients or clinicians. The commenters noted that these measures are already in use in the PQRS and that developing a new measure instrument is an imprudent use of government resources.

Response: To the best of our knowledge, the FOTO measures (NQF #0422 and #0423) are not specifically tested in THA/TKA patients, but rather medical patients with hip or knee complaints who initiated rehabilitation

treatment. We also note that, to the best of our knowledge, the FOTO measures lack data demonstrating the validity in the elective primary THA/TKA patient population. Furthermore, although the FOTO measures are NQF-endorsed and in the public domain, to the best of our knowledge, the measures can only be reported using a proprietary web-based patient assessment system to collect the data. In keeping with our goal to minimize burden for hospitals and after receiving input in previous rulemaking urging CMS to avoid adoption of rules that require or incentivize that hospitals use proprietary tools, such as interoperability standards (71 FR 68198), or pay to participate in a specific registry (73 FR 48609), we have decided not to pursue these measures. As such, we prioritized the use of non-proprietary PROM instruments as part of the PRO data collection initiative. Finally, we note that we are not developing a PROM instrument and therefore disagree that CMS is acting unwisely with government resources. On the contrary, we have investigated using instruments that are in the public domain and are non-proprietary. The purpose of this voluntary PRO and risk variable data collection is to complete the development of a THA/TKA PRO–PM. We will not use the THA/TKA voluntary and risk variable data to assess hospitals' performance, but instead will use the voluntary submitted data to complete development of a PRO–PM measure. Finally, we would like to use the innovative strategy to encourage THA/TKA voluntary and risk variable data submission by rewarding hospitals that successfully submit THA/TKA voluntary data. We note that the THA/TKA voluntary and risk variable data will assess hospital quality of care for patients undergoing elective primary THA/TKA procedures. Once finalized, the THA/TKA PRO–PM that will be developed using the voluntary PRO and risk variable data will be incorporated into the CJR model through rulemaking to address public comments strongly recommending the model include a measure of functional status.

Comment: A commenter stated developing a new measurement instrument for this project and specifically for THA and TKA patients is unnecessary, time-consuming, and costly.

Response: To clarify, we are not developing a PROM instrument. We will use existing, validated, non-proprietary PROM instruments for a voluntary PRO data collection for the development of a future hospital-level patient-reported outcomes performance measure.

Comment: A few commenters recommended expanding the PRO–PM to capture patients' experience in PAC settings.

Response: The purpose of this voluntary PRO data collection is to complete the development of a THA/TKA PRO–PM. We will use the THA/TKA voluntary data to complete development of a PRO–PM measure. We note that, the intention of the future PRO–PM measure is to capture patient-reported outcomes that are meaningful to patients undergoing elective primary THA/TKA procedures. As the purpose of a majority of elective primary THA/TKA procedures is the long-term improvement in pain and functional outcomes, we believe that measuring such outcomes and attributing them to the hospital where the procedure is performed is most appropriate. We will consider adapting any future measure to other care settings as appropriate.

Comment: A few commenters recommended that CMS consider performance-based measures of function, such as the 6-minute walk test.

Response: We appreciate the commenter's input. The decision to focus on patient-reported assessments rather than functional performance assessment reflects CMS's commitment to patient-centered care. The validated PRO instruments that are proposed for voluntary data collection reflect outcomes meaningful to patients. A functional performance assessment offers an objective evaluation of function, but may not accurately reflect the patient's own experience and health status; one individual may experience a marked improvement in their 6-minute walk test after THA, but they may be unable to rise from a seated position or bend over to tie their shoes or pick up an object, which are critical functional outcomes not necessarily captured by a 6-minute walk test. Once fully developed, the THA/TKA PRO–PM, which will be developed using the voluntary PRO and risk variable data and will capture functional outcomes such as those stated in the text (ability to rise from a seated position or bend, to tie their shoes), will be incorporated into the CJR model in the future, through rulemaking, and therefore will address public comments strongly recommending the model include a measure of functional status.

Comment: A commenter expressed concern that data obtained from PROMs are mostly comprised of patient-subjective responses.

Response: We believe that patient-reported outcomes are a critical type of outcome needed for healthcare quality assessment. PROMs are intended to capture patients' self-assessments of their health. They provide a direct way to capture patients' experience of care and its results. PROMs can assess multiple health domains, including physical health, emotional well-being, and social functioning, through measuring outcomes relevant to each domain, such as symptoms, functional status, and mental status. As a result, they provide rich information on how care affects multiple dimensions of patients' well-being. PROMs can provide timely information on patient health status, function, and symptoms over time that can be used to improve patient-centered care and inform clinical decision-making.[90]

Comment: A commenter recommended using the PRO data to develop three registries: Hip implants, knee implants, and surgeon-specific performance.

Response: The purpose of this voluntary PRO data collection is to complete the development of a THA/TKA PRO–PM. We will not use the THA/TKA voluntary PRO and risk variable data to assess hospitals' performance, but instead will use the voluntary submitted data to complete development of a PRO–PM measure. Finally, we would like to use the innovative strategy to encourage THA/TKA voluntary and risk variable data submission by rewarding hospitals that successfully submit THA/TKA voluntary data. Once finalized, the THA/TKA PRO–PM, that will be developed using the voluntary PRO and risk variable data, will be incorporated into the CJR model through rulemaking to address public comments strongly recommending the model include a measure of functional status. There are several existing regional and national registries, many in collaboration with surgical specialty societies, which are collecting data on a variety of outcomes and information about patients undergoing THA/TKA procedures.

Comment: Several commenters suggested that CMS work with joint registries to which hospitals voluntarily report to reduce burden by using existing mechanisms of data collection. A commenter suggested CMS partner with the California Joint Replacement Registry (CJRR). Other commenters suggested CMS partner with the

[90] Cella D, Hahn EA, Jensen SE., Butt Z, Nowinski CJ, Rothrock N. *Methodological Issues In The Selection, Administration And Use Of Patient-Reported Outcomes In Performance Measurement In Health Care Settings: Final Manuscript.* Prepared for the National Quality Forum Consensus Development Project on Patient-Reported Outcomes. September 28, 2012.

American Joint Replacement Registry (AJRR).

Response: We note that we have been collaborating with CJRR and AJRR as part of the development of the THA/TKA PRO–PM. However, at this time we are not requiring hospitals to pay to participate in specific registries as part of the PRO data collection initiative. We note that previous public comments regarding the use of proprietary registries urged CMS to avoid adoption of policies that require or incentivize hospitals to join a specific registry (73 FR 48609) in order to provide data for CMS quality and payment programs.

Comment: Several commenters requested that CMS make patient-reported data collection a mandatory component of the CJR model. Some of the commenters suggested significantly increasing incentives for patient-reported data collection under the proposed voluntary approach. Commenters suggested a phase-in approach to fully implementing the fully developed patient-reported outcome performance-based measure as part of the CJR model.

Response: We appreciate the suggestion to make the THA/TKA voluntary data collection mandatory and may consider it as we continue to improve the model. We did not make this initiative to collect THA/TKA PRO data mandatory for the following reasons: (1) This is a measure in development; and (2) we sought not to burden hospitals with additional financial costs while testing a new payment structure. We believe this is consistent with a phase-in approach to fully implementing the fully developed patient-reported outcome performance-based measure as part of the CJR model.

The following are public comments that specifically address the proposed instruments and our responses include the following:

Comment: A few commenters recommended the use of Oxford Hip and Knee Scores (OHS/OKS) which are two separate PROM instruments. A commenter suggested the Oxford PROMs have been evaluated independently and found to be the most reliable systems for assessment of hip and knee replacement.

Response: We appreciate the commenter's recommendation to use the OHS/OKS. We considered the OHS/OKS as candidate PROM instruments. In the early phases of measure development, we created a list of candidate PROMs through an environmental scan and literature review. Then, a Technical Expert Panel convened by our measure development contractor reviewed the list of candidate PROMs. The Technical Expert Panel questioned the usability of the OHS/OKS and expressed concern over their proprietary nature, and recommended removing them from the list of candidate PROMs. The condition-specific PROMs recommended by the Technical Expert Panel and proposed for this model represent validated, non-proprietary PROMs that have been tested in patients undergoing THA/TKA. For additional rationale for the selected PROM instruments, we refer readers to page 20 of the Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure(s) Phase 3 Measure Methodology Report posted on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Comment: A few commenters requested that CMS use non-proprietary (or open access) PROM instruments to avoid requiring purchasing and maintenance costs.

Response: We agree with the commenters and note that the proposed PROM instruments are non-proprietary instruments. We received similar input in previous rulemaking urging CMS to avoid adoption of rules that require or incentivize that hospitals use proprietary tools, such as interoperability standards (71 FR 68198), or pay to participate in a specific registry (73 FR 48609). As such, we prioritized the use of non-proprietary PROM instruments as part of the PRO data collection initiative.

Comment: A commenter shared, and did not suggest, a list of THA PROM instruments currently in use at their health system: VR–12, HOOS, UCLA Activity Level Rating Form, and Modified Harris Hip Form. The commenter also shared a list of instruments that are in development to be used across their health system's orthopedic sites: FAAM Sport, quick DASH, Forgotten Joint Score, KOOS, Knee Society Score, Neck Disability Index, SRS–22, DASH, Pelvic Floor Disability Inventory-20, and PODCI.

Response: We appreciate the list of instruments in use at the commenter's health system. We note that we reviewed many of these instruments, as did the Technical Expert Panel convened by our measure development contractor. Among the listed instruments, the Technical Expert Panel strongly favored the VR–12, HOOS, and KOOS because of their appropriateness for the primary elective THA/TKA patient population. We provide further rationale on our selection of PROM instruments in response to other comments within this rule. Nonetheless, we applaud the commenter's use of PROM THA instruments to assess quality and patient outcomes on those under their care. We also appreciate the added knowledge shared by the commenters regarding their instruments under development.

Comment: A commenter recommended obtaining PROM data as early as 90 days postoperative. Another commenter recommended obtaining postoperative PROM data not less than 6 months after discharge for the THA or TKA. A commenter recommended obtaining postoperative PROM data not less than nine months after discharge for the THA or TKA.

Response: The window for post-operative data collection was selected based upon consultation with national clinical experts and empiric data from literature indicating that patients continue to improve until approximately 180 days post-operatively and have generally experienced the full benefit of their surgery by 270 to 365 days after THA/TKA. Moreover, the post-operative data collection period between 270 to 365 days aligns with one-year follow-up visits and thus, addresses the concern of low post-operative PROM completion rate if administered prior to 270 days. For additional rationale and citations, we refer readers to page 18 in the Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure(s) Phase 3 Measure Methodology Report posted on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Comment: A commenter recommended that CMS consider using the Forgotten Joint Knee Score. Another commenter recommended the SF–36.

Response: We considered the SF–36 and SF–12, a shorter version of the SF–36, as alternative to the VR–12, as did the Technical Expert Panel convened by our measure development contractor. The Forgotten Joint Knee Score had not been published at the time of our literature review and environmental scan and was not raised by the Technical Expert Panel as an option. The SF–36, SF–12 and the Forgotten Joint Knee Score are all proprietary instruments, and after consideration of these instruments and prior situations in which proprietary tools or databases were suggested and not found favorable with the public, we decided on the non-

proprietary VR–12, PROMIS-Global, HOOS Jr. and KOOS Jr. (or HOOS/KOOS subscales listed in Table 28). We believe using non-proprietary instruments will not place an added financial burden on CJR model participant hospitals.

Comment: A commenter requested that CMS develop a ''gold standard'' PROM instrument that is easily administered and has a small and targeted number of questions.

Response: We appreciate the commenter's recommendation, and we note that we are not currently developing a PROM instrument. CMS is developing a PRO–PM outcomes measure and not the instrument to collect functional outcome data. The purpose of this voluntary PRO data collection is to collect the data required to develop the future PRO-based performance measure that will assess hospital quality of care for patients undergoing elective primary THA/TKA procedures. We believe that there are numerous instruments already available in the public domain, which through our Technical Expert Panel have been recommended for our consideration in the THA/TKA PRO–PM in development.

Comment: A commenter supported the proposal to collect the VR–12 and PROMIS Global instruments. Several commenters supported the proposal to use the HOOS and KOOS instruments. Many commenters recommended allowing participating hospitals to submit either the VR–12 or the PROMIS Global instruments to satisfy the PRO data collection requirement because the proposed required PRO data elements for the voluntary PRO data collection are too burdensome. Several commenters specifically recommended PROMIS Global, but not VR–12 because it is duplicative and does not add value.

Response: We appreciate the commenters' input on the PRO voluntary data collection proposal. We appreciate the support of our proposal to collect the VR–12 and PROMIS Global instruments and the HOOS or KOOS instruments.

We also appreciate the public comments that indicated that the proposed required PRO data elements for the voluntary PRO data collection are too burdensome. We acknowledge evidence indicating that the PROMIS-Global and VR–12 are highly correlated.[91] Based on the supporting evidence, and in response to public comments, we will allow CJR model hospital participants to collect and submit either the VR–12 or the PROMIS-Global for purposes of determining ''successful'' voluntary patient-reported outcome data collection. These data must be collected both pre-operatively (90 to 0 days prior to the THA/TKA procedure) and post-operatively (270 to 365 days after the THA/TKA procedure). As hospitals may already be collecting VR–12 or PROMIS-Global data for other purposes, we believe providing this option for submitting to CMS data using either instrument is the least burdensome option for hospitals.

Comment: Several commenters supported CMS's consideration of an abbreviated version of HOOS/KOOS. Commenters recommended the HOOS/KOOS pain and function subscales, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), or the HOOS Jr/KOOS Jr as possible alternatives to the full HOOS/KOOS, and cautioned that both pain relief and functional gain are important outcomes and that both should be measured. Specifically, a joint statement from multiple surgical specialty societies indicated new data validating shortened versions of the HOOS/KOOS instruments in THA/TKA patients. These shortened versions have been named the HOOS Jr. (6 items) and KOOS Jr. (7 items); both shorter versions are highly responsive in the THA/TKA patient population (standardized response means 1.7 to 2.4). In addition, the HOOS/KOOS Jr. were highly correlated with the Pain and Function, Daily Living subscales of the full HOOS/KOOS instruments and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (Spearman's correlation 0.80–0.94). These findings on the HOOS/KOOS Jr. were presented at the 2015 AAOS Annual Meeting [92] and 2015 International Society of Arthroplasty Registries (ISAR) Annual Meeting, respectively.

Response: We note that the WOMAC is a proprietary instrument. As previously discussed, we sought not to burden hospitals with a proprietary instrument and therefore did not consider this instrument.

Regarding the HOOS/KOOS PROMs, we appreciate the consistent comment that the HOOS/KOOS instruments for this specific voluntary PRO data submission proposal are too burdensome. These instruments were recommended by a diverse, nationally convened Technical Expert Panel assisting our contractor with the development of this measure. During review of these instruments, the Technical Expert Panel acknowledged the length of the instruments as a limitation for its use. For reasons outlined in prior responses, the Technical Expert Panel recommended these instruments over shorter, proprietary joint-specific PROM instruments. We noted in review of the public comments, a joint statement from multiple surgical specialty societies indicated new data validating shortened versions of the HOOS/KOOS instruments in THA/TKA patients. Further, the HOOS/KOOS instruments were originally developed to create five specific subscale scores: Pain, other Symptoms, Function in daily living (ADL), Function in sport and recreation (Sport/Rec) and knee related Quality of life (QOL) (*http://www.koos.nu/*).

Based upon the fact that the HOOS/KOOS instruments were developed to create specific subscale scores intended for independent scoring as well as additional evidenced-based data supporting the use of meaningful information on THA/TKA PROMs gathered in substantially less burdensome, non-proprietary instruments and broadly supported by the orthopedic community, we believe it is reasonable to replace the previously proposed collection of the full HOOS or KOOS survey with the shorter HOOS Jr. and KOOS Jr. or with the following list of HOOS and KOOS subscales.

For hospitals seeking to voluntarily collect and submit PRO data on THA patients, we would require collection and submission of all of the following for purposes of determining ''successful'' voluntary patient-reported outcome data collection:

- Either VR–12 or PROMIS-Global [collected both pre-operatively (90 to 0 days prior to the THA procedure) and post-operatively (270 to 365 days after the THA procedure], the revised list of risk variables [Table 28, collected only pre-operatively (90 to 0 days prior to the THA procedure)], and
- Either (A) the HOOS Jr. (6 items total) [collected both pre-operatively (90 to 0 days prior to the THA procedure) and post-operatively (270 to 365 days after the THA procedure] or (B) the original HOOS Pain Subscale (10 items), AND the original HOOS Function, Daily Living Subscale (17 items, for a total of 27 items) [collected both pre-operatively (90 to 0 days prior to the THA procedure) and post-operatively (270 to 365 days after the THA procedure].

[91] Schalet BD, Rothrock NE, Hays RD, Kazis LE, Cook KF, Rutsohn JP, Cella D. Linking Physical and Mental Health Summary Scores from the Veterans RAND 12-Item Health Survey (VR–12) to the PROMIS® Global Health Scale. J Gen Intern Med. 2015 Jul 16. [Epub ahead of print]

[92] Lyman S, Lee YY, Padget DE. HOOS, JR. a shorter hip outcomes survey. Podium (#413) AAOS 2015 Annual Meeting, Las Vegas, NV.

For hospitals seeking to voluntarily collect and submit PROM data on TKA patients, we will require collection and submission of all of the following for purposes of determining ''successful'' voluntary patient-reported outcome data collection:

- Either VR–12 or PROMIS-Global [collected both pre-operatively (90 to 0 days prior to the TKA procedure) and post-operatively (270 to 365 days after the TKA procedure)], the revised list of risk variables [Table 28, collected only pre-operatively (90 to 0 days prior to the TKA procedure)], and
- Either (A) the KOOS Jr. (7 items total) [collected both pre-operatively (90 to 0 days prior to the TKA procedure) and post-operatively (270 to 365 days after the TKA procedure)] or (B) the original KOOS Stiffness Subscale (2 items), AND the original KOOS Pain Subscale (9 items) and the original KOOS Function, Daily Living Subscale (17 items, for a total of 28 items) [collected both pre-operatively (90 to 0 days prior to the TKA procedure) and post-operatively (270 to 365 days after the TKA procedure)].

Finally, the PROM instrument data will be collected both pre-operatively (90 to 0 days prior to the THA/TKA procedure) and post-operatively (270 to 365 days after the THA/TKA procedure); the risk variables (Table 28) will be collected only pre-operatively (90 to 0 days prior to the THA/TKA procedure). The HOOS/KOOS domain of Quality of Life will be captured by the validated generic instruments (VR–12 or PROMIS-Global); the HOOS/KOOS domain of Function, Sports and Recreational Activities includes questions regarding activities (for example, running) that THA/TKA patients are commonly advised to restrict or avoid after surgery and, as such, is less applicable to this patient population.

Comment: A few commenters raised concerns with the HOOS and KOOS instruments, stating that summary scores are not available and the data may not be usable by clinicians. These commenters recommended CMS use generic PROM instruments in place of the HOOS and KOOS, specifically recommending the PROMIS Physical Function Scale, Activity Measure for Post-Acute Care (AM–PAC) Basic Mobility Scale, and OA-Function and Disability Computer Adaptive Tests. In addition, they recommended CMS consider instruments that utilize item response theory (IRT) to develop calibrated item banks to measure physical function and mobility.

Response: We appreciate the commenters' concerns about the HOOS/KOOS instruments and have changed the PROM instruments to be submitted as part of the voluntary PRO data collection. Please see our preceding response to other comments for details about the revised PROM instruments for submission that we will be finalizing. The new HOOS/KOOS Jr. instruments provide a single summary score that is strongly correlated with pain and function. In addition, each of the HOOS/KOOS subscales yields its own score. These data, combined with input from this public comment, will be used to develop the THA/TKA PRO–PM. During development of the THA/TKA PRO–PM, we will work with patients, clinicians and technical experts to produce a final measure that provides meaningful information on patients' function and symptoms following elective primary THA/TKA. We also appreciate the commenters' recommendation to use the PROMIS Physical Function Scale, AM–PAC Basic Mobility Scale, and OA-Function and Disability Computer Adaptive Tests for the voluntary PRO data collection. The Technical Expert Panel convened by our measure development contractor discussed the PROMIS Physical Function Scale but favored selection of a combination of joint-specific and generic PROM instruments to capture the domains of pain and function most relevant to patients and clinicians. The Technical Expert Panel also endorsed the use of item response theory with computer adaptive testing (CAT), specifically in reference to non-THA/TKA PROMs developed by NIH, such as the PROMIS® Computer Adaptive Test (*http://www.nihpromis.org/software/demonstration*), as a means to reduce the number of questions while still obtaining meaningful outcome information. However, the Technical Expert Panel acknowledged that CAT instruments are relatively new and still under-developed for use in performance measurement for THA/TKA patient outcomes and require specific software and/or hardware to collect the data. In order to minimize provider as well as patient burden, we have reduced the number of data elements to be submitted for the voluntary PRO data collection and have chosen to avoid proprietary instruments, and at this time chosen to delay using instruments that require specific technology to complete collection. We will continue to review the selection of PROM instruments as the technology and science advances for its ease of use and degree of burden on hospitals.

Comment: A commenter suggested that CMS assess the patient-acceptable symptom state (''the highest level of symptom beyond which patients consider themselves well'') and minimum clinically important change (''the smallest change in measurement that signifies an important improvement'') [93] in addition to the proposed PRO data elements.

Response: These options were discussed with our contractor's Technical Expert Panel, and, based upon the Technical Expert Panel's aim to utilize the most parsimonious list of required data elements possible and our goal to minimize the burden for hospitals, we decided to delay collecting additional data for this model.

Comment: A commenter recommended that CMS publish, as part of the final rule, specific operational definitions of all risk variables, such as quantified spinal pain and knee extensor strength, in order to allow facilities to educate staff prior to data collection.

Response: We agree that hospitals cannot be expected to collect meaningful clinical data for risk adjustment without clear, reliable specifications. Please refer to Table 28 that lists the revised list of risk variables required for successful voluntary patient-reported outcome data collection. These variables will be accompanied by one or more unique patient identifier(s) as necessary to enable matching of the PRO data with administrative claims data.

[93] Kvien TK, Heiberg T, Hagen KB. Minimal clinically important improvement/difference (MCII/MCID) and patient acceptable symptom state (PASS): what do these concepts mean? Ann Rheum Dis. 2007 Nov; 66(Suppl 3): iii40–iii41. doi: 10.1136/ard.2007.079798.

TABLE 28—SUMMARY OF PROPOSED AND FINALIZED LIMITED RISK VARIABLE AND PATIENT-REPORTED OUTCOME DATA ELEMENTS TO BE SUBMITTED FOR SUCCESSFUL PARTICIPATION IN VOLUNTARY PATIENT-REPORTED OUTCOMES DATA COLLECTION

Proposed voluntary PRO * and risk variable data elements	Finalized PRO and risk variable data elements	Definition of finalized PRO and risk variable data elements	Timing of collection
Age	N/A	(Will be captured by linking to claims data).	N/A.
Date of Birth **	Date of Birth	(MM/DD/YYYY)	−90 to 0 days prior to and 270 to 365 days after THA/TKA procedure (to be used for linking to claims data).
Gender	N/A	(Will be captured by linking to claims data).	N/A.
Race and Ethnicity **	Race and Ethnicity	Race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White.	−90 to 0 days prior to THA/TKA procedure.
		Ethnicity: Hispanic or Latino, Not Hispanic or Latino.	
THA or TKA procedure	N/A	(Will be captured as possible by linking to claims data).	N/A.
Date of admission to anchor hospitalization **.	Date of admission to anchor hospitalization.	(MM/DD/YYYY)	270 to 365 days after THA/TKA procedure (to be used for linking to claims data).
Date of discharge from anchor hospitalization.	N/A	(Will be captured as possible by linking to claims data).	N/A.
Date of eligible THA/TKA procedure **.	Date of eligible THA/TKA procedure.	(MM/DD/YYYY)	270 to 365 days after THA/TKA procedure (to be used for linking to claims data).
Medicare Health Insurance Claim Number **.	Unique Identifier	Medicare Health Insurance Claim Number.	−90 to 0 days prior to and 270 to 365 days after THA/TKA procedure (to be used for linking to claims data).
PROMIS Global (all items)	Generic PROM Instrument for THA and TKA Procedures.	VR–12 OR PROMIS-Global	−90 to 0 days prior to and 270 to 365 days after THA/TKA procedure.
VR–12 (all items.)	Generic PROM Instrument for THA and TKA Procedures.	VR–12 OR PROMIS-Global	−90 to 0 days prior to and 270 to 365 days after THA/TKA procedure.
For TKA patients Knee injury and Osteoarthritis Outcome Score (*KOOS*[75]) (all items).	Knee-Specific PROM Instrument for TKA Procedures.	KOOS Jr. Only OR KOOS Stiffness Subscale AND KOOS Pain Subscale AND KOOS Function, Daily Living Subscale.	−90 to 0 days prior to and 270 to 365 days after TKA procedure.
For THA patients Hip disability and Osteoarthritis Outcome Score (*HOOS*[76]) (all items).	Hip-Specific PROM Instrument for THA Procedures.	HOOS Jr. Only OR HOOS Pain Subscale AND HOOS Function, Daily Living Subscale.	−90 to 0 days prior to and 270 to 365 days after THA procedure.
Body Mass Index **	Body Mass Index (or height in cm and weight in kg).	Body Mass Index (or height in cm and weight in kg).	−90 to 0 days prior to THA/TKA procedure.
Presence of live-in home support, including spouse.	N/A	(Will be captured by linking to claims data).	N/A.
Use of chronic (≥90 day) narcotics **.	Pre-operative use of narcotics	Provider-reported yes/no	−90 to 0 days prior to THA/TKA procedure.
American Society of Anesthesiologists (ASA) physical status classification.	N/A	N/A	N/A.
Charnley Classification	N/A	N/A	N/A.
Presence of retained hardware	N/A	(Will be captured by linking to claims data).	N/A.
Total painful joint count[94] **	Patient-Reported Pain in Non-operative Lower Extremity Joint.	"What amount of pain have you experienced in the last week in your other knee/hip?" (none, mild, moderate, severe, extreme).[95]	−90 to 0 days prior to THA/TKA procedure.
Quantified spinal pain **	Patient-Reported Back Pain (Oswestry Index question).	"My BACK PAIN at the moment is" (none, very mild, moderate, fairly severe, very severe, worst imaginable).[96] [97]	−90 to 0 days prior to THA/TKA procedure.
Joint range of motion in degrees (specify hip or knee).	N/A	N/A	N/A.
Use of gait aides	N/A	N/A	N/A.
For THA patients abductor muscles strength.	N/A	N/A	N/A.

TABLE 28—SUMMARY OF PROPOSED AND FINALIZED LIMITED RISK VARIABLE AND PATIENT-REPORTED OUTCOME DATA ELEMENTS TO BE SUBMITTED FOR SUCCESSFUL PARTICIPATION IN VOLUNTARY PATIENT-REPORTED OUTCOMES DATA COLLECTION—Continued

Proposed voluntary PRO * and risk variable data elements	Finalized PRO and risk variable data elements	Definition of finalized PRO and risk variable data elements	Timing of collection
For THA patients presence of Trendelenberg gait.	N/A	N/A	N/A.
For THA patients history of congenital hip dysplasia or other congenital hip disease.	N/A	(Will be captured as possible by linking to claims data).	N/A.
For THA patients presence of angular, translational, or rotational deformities of the proximal femur (in degrees).	N/A	(Will be captured as possible by linking to claims data).	N/A.
For TKA patients anatomic angle (femoro-tibial angle) in degrees with varus/valgus.	N/A	N/A	N/A.
For TKA patients knee extensor strength.	N/A	N/A	N/A.
Single Item Health Literacy Screening (SILS2) questionnaire.**	Patient-Reported Health Literacy	''How comfortable are you filling out medical forms by yourself?'' (extremely, quite a bit, somewhat, a little bit, or not at all).[98]	−90 to 0 days prior to THA/TKA procedure.

* PRO: Patient-reported outcome survey instrument (see National Quality Forum. Patient reported outcomes (PROs) in Performance Measurement. January 10, 2013. Available at: *http://www.qualityforum.org/docs/measure_evaluation_criteria.aspx*.
** Risk variable data element.

Final Decision: After consideration of the public comments we received, and in response to many recommendations from the public commenters, we are finalizing fewer THA/TKA voluntary PRO data submission variables summarized in Table 28 for purposes of ''successful'' voluntary patient-reported outcome data collection. We based our decision to simplify the list of PROM instruments on the numerous public comments recommending simplification of list to be the least burdensome. While we appreciate the many suggestions for other PROM instruments and to use established joint replacement databases and PRO-based measures, we note that many of the suggestions included proprietary instruments, databases and measures. As discussed throughout our responses, when developing measures, we seek to balance requests from the public, the needs of the hospitals, the recommendations from the Technical Expert Panel convened by our measure development contractor regarding identification of the most efficacious and least burdensome PROM instruments for the hospitals, and finally financial cost. For these reasons, we believe that finalizing the PROM instruments listed in Table 28 is the most prudent way to address the concerns voiced by the majority of the public commenters to simplify the list of PROM instruments while also keeping financial burden in mind. Finally, we refer to section III.D.3.a.(9) of this final rule, Requirements for ''Successful'' Submission of THA/TKA Voluntary Data, for an explanation of the requirements that must be met in order to successfully submit THA/TKA PRO data on a voluntary basis and be eligible for a reconciliation payment.

(3) Cohort

In the proposed rule (80 FR 41286), we stated that the measure cohort(s) includes Medicare FFS beneficiaries, aged 65 years or older, admitted to non-federal acute care hospitals for elective primary THA or TKA. We also indicated that we would exclude from the cohort patients with fractures and mechanical complications or those undergoing revision procedures. We stated again that THA and TKA patient-reported outcomes will be assessed separately but may be combined into a single composite measure for reporting.

Final Decision: We did not receive public comments on the cohort proposed for the THA/TKA voluntary data submission. We are finalizing the cohort as proposed.

(4) Inclusion and Exclusion Criteria

In the proposed rule (80 FR 41286), we stated that the measure cohort inclusion criteria are all patients undergoing elective primary THA/TKA procedures. Exclusion criteria will consist of patients undergoing non-elective procedures (that is, patients with fractures resulting in THA/TKA), as it is unfeasible to routinely capture pre-operative patient-reported assessments in these patients; patients with mechanical complications of prior hip and knee joint procedures and those undergoing revision THA/TKA will also be excluded, as their patient-reported outcomes may be influenced by prior care experiences and therefore may not adequately represent care quality of the hospital performing the revision procedure.

Final Decision: We did not receive public comments on the inclusion or exclusion criteria for the THA/TKA voluntary data submission. We are finalizing the inclusion or exclusion criteria as proposed.

(5) Outcome

In the proposed rule (80 FR 41286), we stated that the measure will assess change between pre- and post-operative

[94] Wallace LS, Rogers ES, Roskos SE, Holiday DB, and Weiss BD. BRIEF REPORT: Screening Items to Identify Patients with Limited Health Literacy Skills. J Gen Intern Med. 2006;21(8):874–7.

[95] Ayers DC, Li W, Oatis C, Rosal MC, Franklin PD. Patient-reported outcomes after total knee replacement vary on the basis of preoperative coexisting disease in the lumbar spine and other nonoperatively treated joints: The need for a musculoskeletal comorbidity index. J Bone Joint Surg Am. 2013 Oct 16;95(20):1833–7.

[96] Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine 2000 Nov 15;25(22):2940–52.

[97] Ayers DC, Li W, Oatis C, Rosal MC, Franklin PD. Patient-reported outcomes after total knee replacement vary on the basis of preoperative coexisting disease in the lumbar spine and other nonoperatively treated joints: The need for *a musculoskeletal comorbidity index*. J Bone Joint Surg Am. 2013 Oct 16;95(20):1833–7. doi: 10.2106/JBJS.L.01007.

[98] Wallace LS, Rogers ES, Roskos SE, Holiday DB, and Weiss BD. BRIEF REPORT: Screening Items to Identify Patients with Limited Health Literacy Skills. J Gen Intern Med. 2006;21(8):874–7.

patient-reported outcomes for THA and TKA separately or as a composite measure for both procedures. We also stated that the measure will use one or more of the following patient-reported outcome instruments (or validated subscales or abbreviated versions of these instruments) to calculate the measure score: The Patient Reported Outcomes Measurement Information Systems (PROMIS)-Global or the Veterans Rand 12 Item Health Survey (VR–12), and the Hip dysfunction and Osteoarthritis Outcome Score/Knee injury and Osteoarthritis Outcome Score (HOOS/KOOS) instruments to measure pre- and postoperative improvement or both. These candidate instruments were selected by a Technical Expert Panel convened by our measure development contractor based upon their meaningfulness to patients and clinicians, performance characteristics such as reliability, responsiveness and validity, and their perceived burden to both patients and providers. The pre-operative data collection timeframe will be 90 to 0 days before surgery, and the post-operative data collection timeframe will be 270 to 365 days following surgery. We also indicated that the approach to calculating the improvement or worsening of patient outcomes represented by the pre- and postoperative patient-reported survey results has not yet been determined, but will use one or more surveys to define the improvement or worsening of patient-reported outcomes to reliably identify differences between hospitals of varying performance.

Final Decision: We did not receive public comments on the outcomes for the THA/TKA voluntary data submission. We are finalizing the outcomes for the THA/TKA voluntary data as proposed.

(6) Risk-Adjustment (If Applicable)

In the proposed rule (80 FR 41286), we stated that the measure's risk model has yet to be developed. We shared that in order to develop the risk model, final risk variable selection for the risk model will involve empirical testing of candidate risk variables as well as consideration of the feasibility and reliability of each variable. The risk model will account for the hospital level response rate as well as measureable patient-level factors relevant to patient-reported outcomes following elective THA/TKA procedures. We indicated that to the extent feasible, the risk model methodology will adhere to established statistical recommendations.[99]

Final Decision: We did not receive public comments on the risk model for the THA/TKA voluntary data submission which has yet to be developed. Please see the following section III.D.3.a.(7) of this final rule for details on how we have reduced the number of voluntary risk variables for collection.

(7) Calculating the Risk-Standardized Rate

In the proposed rule (80 FR 41286) we stated that the approach to reporting this measure(s) has yet to be developed. We outlined in the propose rule that the measure will assess change in patient-reported outcomes between the pre-operative (90 to 0 days prior to the elective primary THA/TKA procedure) and post-operative (270 to 365 days following the elective primary THA/TKA procedure) periods.

We invited public comments on this proposal to seek voluntary participation in submitting data for a Hospital-Level Performance Measure of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty. We also welcomed comments on the appropriateness of this voluntary data collection for this model and the specific data collection requirements (see section III.D.3.a.(9) of the proposed rule) and data elements proposed.

The following is a summary of the comments received and our responses.

Comment: Several commenters expressed concern about the amount of data that CMS requested hospitals to report. Some commenters expressed concern that administrative costs of data collection and submission will burden hospitals. Several commenters provided specific risk factors to consider including in the PRO data collection initiative and risk factors to evaluate during future PRO-based measure development. Specifically, a joint statement from multiple surgical specialty societies listed a prioritized list of 11 risk variables: Body Mass Index (BMI), Race/Ethnicity, Smoking Status, Age, Sex, Back Pain, Pain in Non-operative Lower Extremity Joint, Health Risk Status, Depression/Mental Health Status, Chronic or Pre-operative Narcotic Use, and Socioeconomic Status. These variables were also highlighted by other commenters as being important, priority risk variables for consideration for a THA/TKA PRO–PM. Additional specific recommendations included the following potential risk factors: Literacy, marital status, live-in home support, health risk status identified by appropriate comorbid conditions in the Charlson morbidity index or Elixhauser morbidity measure as well as all inpatient and outpatient diagnosis codes for the year prior to the THA/TKA procedure, Charnley classification, retained hardware, total painful joint count, joint range of motion, abductor muscle strength (for THA patients), presence of Trendelenberg gait (for THA patients), history of congenital hip dysplasia or other congenital hip disease (for THA patients), presence of angular, translational, or rotational deformities of proximal femur (in degrees for THA patients), anatomic angle (femero-tibial angle) in degrees with varus/valgus (for TKA patients), knee extensor strength (for TKA patients), baseline pain, function and/or mental/emotional health as assessed by the HOOS/KOOS and VR–12/PROMIS Global, respectively.

Response: We note that the submission of patient-reported outcomes data in the CJR model is voluntary and therefore does not impose a mandatory data collection burden on patients or providers. Nevertheless, it is our goal to minimize any additional data collection beyond the PROM surveys, if possible. We considered ease of collection while developing the list of proposed data for collection. Specifically, we considered the estimate of time and effort by the patient and provider to collect data beyond the additional burden of de novo collection of the proposed PROM surveys. If a variable creates a data collection burden to patients, surgeons, hospitals, or the healthcare system, the value of including the variable in the risk model should outweigh the burden.

We appreciate commenter's recommendations regarding specific risk variables for collection. We note the commenter's input that several of these variables can be feasibly collected by self-report and will consider this information when finalizing the data elements for collection.

We appreciate the public comments that the proposed list of current required risk variable data elements for the voluntary PRO data collection is too burdensome. Based upon multiple commenters supporting the risk

[99] Ash AS, Fiengerg SE, Louis TA, Normand ST, Stukel TA, Utts J. STATISTICAL ISSUES IN ASSESSING HOSPITAL PERFORMANCE, Commissioned by the Committee of Presidents of Statistical Societies. Original report submitted to CMS on November 28, 2011, Revised on January 27, 2012. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Statistical-Issues-in-Assessing-Hospital-Performance.pdf.* Accessed on April 15, 2015.

variables prioritized in a joint statement from multiple surgical specialty societies, we have used their list to narrow the risk variable data to be collected in the THA/TKA voluntary data. We believe that several of the specified variables can be adequately captured using administrative claims data (Smoking Status, Age, Sex, Health Risk Status, and Socioeconomic Status, using patient- or community-level factors identifiable by patient zip code), and others (Depression/Mental Health Status) can be captured using the generic PROM instruments (VR–12/PROMIS Global). Therefore, we have removed risk variables not highlighted in the joint statement from multiple surgical specialty societies, as well as, risk variables captured by claims data or by the specified PROM instruments from the voluntary PRO data collection. This leaves eleven risk variables that will be collected, along with the PRO instruments as previously detailed, within −90 to 0 days prior to the THA/TKA procedure for successful completion of the voluntary PRO data collection. These eleven risk variables are defined in Table 28.

We will request that all PRO and risk variable data be submitted through a secure file transfer mechanism using a file template. Hospitals will be able to populate the file template according to their own data collection method and format. CMS will plan to augment the risk model development for the future PRO-based measure with administrative claims, enabling many of the proposed risk variables not selected for voluntary collection to be captured without additional data collection burden. The proposed risk variables for which administrative codes or claims data are available will be considered for possible inclusion in the future PRO-based measure risk model. These individual codes will be considered in addition to the publicly available CMS hierarchical condition categories (CCs) that group the more than 15,000 ICD–9 codes into clinically coherent CCs.[100] Consistent with existing claims-based measures, candidate claims-based risk-adjustment variables will be obtained from inpatient, outpatient, and physician Medicare administrative claims data extending 12 months prior to, and including, the index THA/TKA admission.[101] [102]

Final Decision: After consideration of the public comments we received, we are finalizing the Hospital-Level Performance Measure of Patient-Reported Outcomes following Elective Primary Total Hip and/or Knee Arthroplasty cohort, inclusion and exclusion criteria as proposed. In response to our request for comment on the data elements to be collected, we are finalizing the shortened list of PROM instrument elements, and eleven risk variables listed in Table 28.

(8) Performance Period

In Table 16 of the proposed rule (80 FR 41286 through 41288), we proposed defining performance periods for each year of the model (see Table 29 of this final rule). A performance period for the voluntary THA/TKA data submission, are those timeframes in which an anchor hospital admission occurs for eligible THA/TKA voluntary data submission procedure. For the first year of the CJR model, hospitals voluntarily submitting data will only be requested to submit data for a 3-month period. The 3-month period for THA/TKA voluntary data reporting was identified due to data processing and coordination of other proposed timelines in this model. We stated that data submitted for the first year would be for cases that fulfill the measure specifications described in section III.D.3.a. of the proposed rule, and would be restricted to the pre-operative data elements on cases performed between April 1, 2016 and June 30, 2016. The proposed timing allows matching of the patient-reported data with relevant administrative claims-based data in order to accurately calculate the percent of eligible elective primary THA/TKA patients for which THA/TKA voluntary data was successfully submitted. The April 1st date acknowledges the measure requirement of the 90-day window prior to surgery during which hospitals can collect pre-operative data. The June 30th end date was selected because it correlates with the THA/TKA Readmissions measure (NQF #1551) performance period end date currently implemented for the HIQR program and the HRRP. Both of these dates provide the greatest feasibility for data collection.

We went on to explain how the THA/TKA voluntary data reporting periods would change based on the year of the model and whether the data submitted was related to pre- or post-operative THA/TKA assessments. Specifically, we stated that for year 2, THA/TKA voluntary data reporting would be 3 months of post-operative data for cases performed between April 1, 2016 and June 30, 2016, and 12 months of pre-operative data for cases performed between July 1, 2016 and June 30, 2017. We completed our explanation of the duration of performance periods by indicating for year 3 and subsequent years of the model, the performance periods for submission of voluntary data will consist of 12-month time periods. We finally noted in our proposal that the proposed performance period enables hospitals to receive incentives for data collection starting in performance year-one, even though complete pre-operative and post-operative data collection requires a minimum 9- through 12-month time period. This 9- through 12-month time period, between the procedure and post-operative data collection, was defined through clinician and stakeholder input and provides for both sufficient elapsed time for maximum clinical benefit of THA/TKA procedures on patient-reported outcomes and accommodates common clinical care patterns in which THA/TKA patients return to their surgeon one year after surgery. We invited public comments on our proposal of defining performance year-one episodes for a participating hospital as an anchor hospital admission for an eligible THA/TKA procedure between April 1, 2016 and June 30, 2016, with subsequent year performance time periods each being 12-month periods and starting every July 1st.

[100] Pope G, Kautter J, Ingber M, *et al.* 2011 Report: Evaluation of CMS–HCC Risk Adjustment Model. Centers for Medicare & Medicaid Services. 2011. Available at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.html.*

[101] Suter LG, Zhang W, Parzynski CS, *et al.* 2015 Procedure-Specific Complication Measure Updates and Specifications Report: Report prepared for the Centers for Medicare & Medicaid Services. 2015. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[102] Suter LG, Desai N, Zhang W, *et al.* 2015 Procedure-Specific Readmission Measures Updates and Specifications Report: Report prepared for the Centers for Medicare & Medicaid Services. 2015. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

TABLE 29—PROPOSED POTENTIAL PERFORMANCE PERIODS FOR PER- AND POST-OPERATIVE THA/TKA VOLUNTARY DATA SUBMISSION *

Model year	Performance period	Duration of the performance period	Patient population eligible for THA/TKA voluntary data submission	Requirements for successful THA/TKA voluntary data submission **
2016	April 1, 2016 through June 30, 2016*.	3 months **	All patients undergoing elective primary THA/TKA procedures performed between April 1, 2016 and June 30, 2016.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between April 1, 2016 and June 30, 2016.
2017	April 1, 2016 through June 30, 2016.	15 months	All patients undergoing elective primary THA/TKA procedures performed between April 1, 2016 and June 30, 2016.	Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between April 1, 2016 and June 30, 2016.
2017	July 1, 2016 through June 30, 2017.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2016 and June 30, 2017	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2016 and June 30, 2017.	
2018	July 1, 2016 through June 30, 2017.	24 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2016 and June 30, 2017.	Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2016 and June 30, 2017.
2018	July 1, 2017 through June 30, 2018.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2017 and June 30, 2018	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2017 and June 30, 2018.	
2019	July 1, 2017 through June 30, 2018.	24 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2017 and June 30, 2018.	Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2017 and June 30, 2018
2019	July 1, 2018 through June 30, 2019.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2018 and June 30, 2019	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2018 and June 30, 2019..	
2020	July 1, 2018 through June 30, 2019.	24 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2018 and June 30, 2019.	Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2018 and June 30, 2019.
2020	July 1, 2019 through June 30, 2020.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2019 and June 30, 2020	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2019 and June 30, 2020.	

* Due to the new start date of the CJR model of April 1, 2016 (III.C.2.a.) the finalized performance period for the first year of the model will be July 1, 2016 through August 31, 2016 with the duration of performance being 2 months. See Table 30 in section III.D.3.a.(9) of this final rule response to comments.

** Requirements for determining successful submission of THA/TKA voluntary data are located in section III.D.3.a.(9). of the proposed rule.

We did not receive comments on the proposed THA/TKA voluntary data submission Performance Period in Table 16 of the proposed rule or for Table 29 of this final rule, and will be finalizing the THA/TKA voluntary PRO and limited risk variable data submission Performance Period as proposed with the exception of the performance periods for the first year of the model (that is, 2016). We note in section III.C.2.a. of this final rule that the date of implementation will be delayed until April 1, 2016. Previously, we had proposed for 2016 the data collection periods of April 1, 2016 and June 30, 2016. Due to the delay in the implementation date from January 1, 2016 to April 1, 2016, we similarly implement a three month delay for the THA/TKA voluntary PRO and risk variable data submission Performance Period, with the result that we will collect only 2 months of data in 2016 from July 1, 2016 through August 31, 2016. The finalized THA/TKA voluntary PRO and limited risk variable data submission Performance Periods are provided in Table 30 of this final rule.

(9) Requirements for ''Successful'' Submission of THA/TKA Voluntary Data

In proposed rule (80 FR 41286), we stated that in order for CMS to assess if participant hospitals are eligible for reconciliation payment after receiving the THA/TKA voluntary data, requirements to determine if the submitted data would inform measure development had been identified (80 FR 41288 through 41289). We stated our belief that the following criteria should be used to determine if a participant hospital has successfully submitted

THA/TKA voluntary data. We noted that successful THA/TKA voluntary data submission, as stated briefly in section III.C.5.b.(5)(b) (80 FR 41240) and section III.D.3.a.(9) (80 FR 41288) of the proposed rule, required completion of all of the following:

- Submission of the data elements listed in section III.D.3.a.(2) of the proposed rule.
- Data elements listed in section III.D.3.a.(2) of the proposed rule must be submitted on at least 80 percent of their eligible elective primary THA/TKA patients (as described in section III.D.3.a.(3) of the proposed rule).
- THA/TKA voluntary data submission must occur within 60 days of the end of the most recent data collection period.

We proposed that in order to fulfill THA/TKA voluntary data collection criteria for performance year-one, only pre-operative data collection and submission on at least 80 percent of eligible elective primary THA/TKA patients would be required. We further explained that to successfully submit THA/TKA voluntary data for performance years 2 through 5, hospitals would have to submit both pre-operative and post-operative patient reported outcome data on at least 80 percent of eligible elective primary THA/TKA patients. A potential example of the performance periods for which we would like to have THA/TKA voluntary data submitted by participant hospitals were summarized in section III.D.3.a. of the proposed rule.

Table 16 of the proposed rule (80 FR 41287 through 41288) summarized the performance periods for pre-operative and post-operative THA/TKA voluntary data. We also proposed that hospitals volunteering to submit THA/TKA data would be required to submit pre-operative data on all eligible patients and post-operative data elements only on those patients at least 366 days out from surgery. Therefore, hospitals would not be expected to collect and submit post-operative THA/TKA voluntary data on patients who are fewer than 366 days from the date of surgery.

We also stated that a THA/TKA eligible patient is described in section III.D.3.a.(3) of the proposed rule, and noted that this description is important since these patients were those for which we proposed to seek submission of voluntary data. We also selected the requirement of submitting 80 percent of eligible elective primary THA/TKA patients' data because this volume of cases would result in a high probability that we would have a national sample of THA/TKA patient data representative of each hospital's patient case mix. We stated that having 80 percent of the eligible elective primary THA/TKA patients would enable an accurate and reliable assessment of patient-reported outcomes for use in measure development. We noted that data used for outcome measure development must adequately represent the population that is anticipated to be measured, and in this case that population would be those experiencing elective primary THA/TKA inpatient surgical procedures. Data that more accurately reflects the patient outcomes and case mix of the population to be measured would allow, during measure development, a more scientifically accurate and reliable measure. We stated our belief that having 80 percent of eligible elective primary THA/TKA recipient data would result in a more reliable measure that is better able to assess hospital performance than a measure created from a less representative patient sample. Furthermore, we considered setting the requirement at 100 percent of the eligible elective primary THA/TKA patients, but concluded that a requirement of 100 percent data collection may not be feasible for all hospitals or may be excessively burdensome to achieve. Therefore we proposed to set the requirement at 80 percent of the eligible elective primary THA/TKA patients. We believed acquisition of 80 percent of the eligible elective primary THA/TKA patients would provide representative data for measure development while decreasing patient, provider and hospital burden. We sought public comment of these requirements to determine successful voluntary submission of THA/TKA data. We also sought public comment specifically on the requirement for data on 80 percent of the eligible elective primary THA/TKA patients.

The following is a summary of the comments received and our responses.

Comment: Many commenters expressed concern over the proposed successful criterion of 80 percent; some noted they had successfully achieved PROM response rates over 80 percent but still expressed concern that hospitals would be able to meet this criterion. Several commenters recommended that CMS wait to establish the successful criterion until CMS has further experience with the measure and sufficient data to determine an appropriate number. Several commenters recommended CMS lower the successful criterion from 80 percent in Year 1 (A commenter specifically noted 50 percent), and then phase-in higher successful criterion over time. A commenter recommended lowering the successful criterion because the proposed number would add a substantial added cost for active surveillance to achieve 80 percent. A commenter recommended a 40 percent successful criterion because an 80 percent successful criterion—(1) Might prohibit hospitals from participating in the voluntary data reporting effort; and (2) might prohibit otherwise compliant hospitals from receiving additional reconciliation payments through discounted target rates. Another commenter recommended that the 2 percent discount should not be lowered to pay for the voluntary data submission, but instead the 80 percent successful criterion should be lowered. A few commenters recommended CMS pay for every case that has data submitted. Some commenters recommended that CMS increase the successful criterion. Other commenters urged CMS to ensure that the collected data are not biased by high-performing providers or selective reporting of cases that have positive outcomes.

Response: We thank the commenters for their input on the proposed 80 percent criterion that defines successful voluntary data submission of voluntary patient-reported outcome data (80 FR 41288). We refer reviewers to section III.C.5. of this final rule for the finalized policies on how hospital performance on finalized measures and successful submission of THA/TKA voluntary data will be assessed for purposes of reconciliation payment eligibility.

We appreciate the commenter's suggestion to increase the successful criterion based upon the concern that lowering the successful criterion (that is, the patient-reported outcome instrument response and risk variable submission rates required for successful participation) may produce biased data that are not generalizable to all patients undergoing elective primary THA/TKA procedures at a given hospital. To assess the amount of data bias, the collected and submitted patient-reported outcome and risk variable data will be matched to administrative claims data, which will allow CMS to determine the proportion of a hospital's patients for which the hospitals collected and submitted patient-reported outcome and risk variable data. In addition, it will allow CMS to determine how representative this sampling of patients is of all of the hospital's eligible THA/TKA patients, by comparing the number and type of comorbid conditions, sociodemographic factors, and post-discharge outcome (for example, complication and readmission) rates. This information will be factored into any measure development work that

utilizes the voluntary patient-reported outcome data.

While there are a few commenters supporting the feasibility of pre- and post-operative patient-reported outcome instrument response rates exceeding 80 percent for elective THA/TKA procedures, we understand that many hospitals may not be able to meet this criterion as proposed in the first year of the CJR model. Therefore, based on public comments we are finalizing a lower criterion for the ''successful'' voluntary patient-reported outcome and limited risk variable data collection for year 1, which will entail each participating hospital submitting the required pre- and post-operative data elements (see Table 28 for the final list of voluntary patient-reported outcomes and limited risk variable data elements) on either of the following

- 50 percent of eligible procedures during the data collection period; or
- A total of 50 eligible procedures during the data collection period.

This will allow hospitals the opportunity to actively engage in data collection but, consistent with the experiences reported by several commenters, acknowledges the realities that such systematic data collection efforts require time to implement. It also responds to commenters' suggestion for CMMI to pursue a ''phase-in'' approach to collecting PRO data. As previously noted, CMS will actively evaluate the submitted data for evidence of reporting bias.

Eligible patients (henceforth for purposes of this discussion, patients will be described as procedures) are described in section III.D.3.a. of the proposed rule (80 FR 41286). The post-operative data collected in year 2 will correspond to the pre-operative data collected in year 1 and, similarly, for years 3 through 5. That is, participant hospitals will collect and submit post-operative data for the same cases for which the hospital submitted pre-operative data in the preceding year.

Based upon commenters' input to reduce the successful criterion, including a recommendation specifically to reduce the successful criterion to 50 percent, we believe a '50 percent or 50 eligible procedures' successful criterion in year 1 provides hospitals with flexibility to minimize the data collection burden; using a 50 percent or 50 eligible procedures successful criterion in year 1 will also allow participant hospitals to submit data regardless of their case volume. A 50 percent or 50 eligible procedures successful criterion in year 1 also allows participant hospitals an opportunity for financial reward for this voluntary initiative. We note having the 50 percent or 50 eligible procedures successful criterion in year 1 in conjunction with a simplified list of PROM instruments and list of risk variables (Table 28) markedly decreases the burden of collecting and submitting the THA/TKA voluntary PRO and limited risk variable data. We believe after the first year of the model, hospitals will become more adept at collecting this data, and the public comments indicate that much higher patient-reported outcome data collection rates are feasible. For example, a commenter shared that its institution reported a reliable 85 percent response rate for its PROM data collection. Therefore, we believe it is reasonable to gradually increase the expected response rates to successfully fulfill the THA/TKA voluntary PRO and limited risk variable data collection in years 2 through 5 of the model, as listed in Table 30. We note that the phase-in approach was suggested by a few public commenters. We agree that phasing in of higher percentage eligible procedures with each year is a more realistic expectation for participating hospitals to meet and a more encouraging manner to enhance the THA/TKA voluntary PRO and limited risk variable data submission.

We anticipate completion of measure development for the future hospital-level THA/TKA PRO–PM during or before year 3 of the model. The measure specifications will be finalized in accordance with our standard measure development process set forth in NQF guidance for outcome measures,[103] CMS Measures Management System (MMS) guidance,[104] and the guidance articulated in the American Heart Association Statement ''Standards for Statistical models Used for Public reporting of Health Outcomes.'' [105] Given the support for the PRO data collection and support for mandatory inclusion of a PRO–PM in this model from several commenters during public comment, we anticipate integrating this new measure as a mandatory measure in the CJR model in years 4 and 5 through future rulemaking. We anticipate that the PRO–PM would be considered similarly in the CJR model to the THA/TKA Complications measure (NQF #1550), with better performing hospitals receiving higher quality scores and therefore higher reconciliation payments. The current quality measure weighting system would be reconfigured to give this PRO–PM equal weighting with the other quality measures included in years 4 and 5 of the model, again through future rulemaking. Hospitals participating in the voluntary PRO data collection in years 1 through 3 would be better prepared for the addition of the hospital-level THA/TKA PRO–PM to the model in years 4 and 5. The anticipated use of this PRO–PM in this model is consistent with stakeholder feedback during public comment strongly encouraging mandatory integration of PRO-based measures into the model. We will also consider adding or removing patient-reported outcome and/or risk variable data elements as indicated by clinical practice and empirical analyses supporting or refuting their utility in performance measurement. For further discussion on the use of PRO–PM measure, see section III.C.5. of this proposed rule.

[103] National Quality Forum. Measure Evaluation Criteria and Guidance. April 2015. Available at: *http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx*. Accessed on September 22, 2015.

[104] Measures Management System Overview.2015; *http://www.cms.gov/Medicare/Quality-InitiativesPatient-AssessmentInstruments/MMS/index.html?redirect=/MMS/19_MeasuresManagementSystemBlueprint.asp*. Accessed September 8, 2015.

[105] Krumholz H, Brindis R, Brush J, *et al.* Standards for Statistical Models Used for Public Reporting of Health Outcomes: An American Heart Association Scientific Statement from the Quality of Care and Outcomes Research Interdisciplinary Writing Group: Cosponsored by the Council on Epidemiology and Prevention and the Stroke Council. Endorsed by the American College of Cardiology Foundation. *Circulation*. Jan 24 2006;113(3):456–462.

TABLE 30—FINALIZED PERFORMANCE PERIODS FOR PRE- AND POST-OPERATIVE THA/TKA VOLUNTARY DATA SUBMISSION

Model year	Performance period	Duration of the performance period	Patient population eligible for THA/TKA voluntary data submission	Requirements for successful THA/TKA voluntary data submission
2016	July 1, 2016 through August 31, 2016.	2 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2016 and August 31, 2016.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥50% or ≥50 eligible procedures performed between July 1, 2016 and August 31, 2016.
2017	July 1, 2016 through August 31, 2016.	13 months ...	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2016 through August 31, 2016.	Submit POST-operative data on primary elective THA/TKA procedures for ≥50% or ≥50 eligible procedures performed between July 1, 2016 through August 31, 2016.
2017	September 1, 2016 through June 30, 2017.	.....	All patients undergoing elective primary THA/TKA procedures performed between September 1, 2016 through June 30, 2017.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥60% or ≥75 procedures performed between September 1, 2016 through June 30, 2017.
2018	September 1, 2016 through June 30, 2017.	22 months ...	All patients undergoing elective primary THA/TKA procedures performed between September 1, 2016 and June 30, 2017.	Submit POST-operative data on primary elective THA/TKA procedures for ≥60% or ≥75 procedures performed between September 1, 2016 and June 30, 2017.
2018	July 1, 2017 through June 30, 2018.		All patients undergoing elective primary THA/TKA procedures performed between July 1, 2017 and June 30, 2018.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥70% or ≥100 procedures performed between July 1, 2017 and June 30, 2018.
2019	July 1, 2017 through June 30, 2018.	24 months ...	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2017 and June 30, 2018.	Submit POST-operative data on primary elective THA/TKA procedures for ≥70% or ≥100 procedures performed between July 1, 2017 and June 30, 2018.
2019	July 1, 2018 through June 30, 2019.	.....	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2018 and June 30, 2019.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2018 and June 30, 2019.
2020	July 1, 2018 through June 30, 2019.	24 months ...	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2018 and June 30, 2019.	Submit POST-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2018 and June 30, 2019.
2020	July 1, 2019 through June 30, 2020.		All patients undergoing elective primary THA/TKA procedures performed between July 1, 2019 and June 30, 2020.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2019 and June 30, 2020.

Comment: A commenter recommended the use of ''Advanced Procurement Technology'' for submission of PRO data and to alleviate burden of data submission by physicians and patients. Specifically, the commenter recommended the use of a cloud-based central server to reduce administrative costs.

Response: We note that the future PRO–PM measure will potentially employ multiple platforms for data collection, including electronic health records (EHRs), as well as other data collection mechanisms, but will not be limited to EHRs. We aim to construct a secure data collection system that reduces the amount of data submission burden on hospitals. We encourage hospitals to collect and transfer the PRO data in the most economically efficient mode for individual hospitals.

Comment: Several commenters suggested CMS consider a pay-for-reporting approach, which would allow hospitals that successfully submit data to be eligible for savings.

Response: We have been careful to identify a way in which to reward hospitals that participated in this initiative, as we understand that this could be a potential added burden, but the composite quality score methodology initiative also becomes a way for hospitals to learn about their patients' outcomes post-primary elective THA/TKA procedures. We believe that section III.C.5.b. in this final rule provides a full discussion of voluntary PRO data collection from a payment perspective.

Final Decision: After consideration of the public comments we received, we will not be finalizing the proposed successful criterion on 80 percent of eligible procedures. In response to public comments we are finalizing a modification to the requirements for what will be considered as ''successful'' submission of THA/TKA voluntary PRO data, as noted in Table 30, in conjunction with a simplified list of PROM instruments and list of risk variables (Table 28). We are also finalizing the proposed requirement that the required THA/TKA voluntary PRO data and the limited list of risk variables be submitted to CMS within 60 days of the end of the most recent performance period. We believe requirements for the THA/TKA voluntary PRO data and limited list of risk variables that we are finalizing will markedly decrease the burden of collecting and submitting the THA/TKA voluntary PRO data by participant hospitals. We also believe that reducing the data collection and submission burden will enhance the opportunity for participant hospitals to improve their composite quality score that is being finalized for the CJR model.

We are codifying requirements for successful data submission of THA/TKA patient reported outcomes and limited risk variable data in § 510.400(b).

b. Measure That Captures Shared Decision-Making Related to Elective Primary Total Hip and/or Total Knee Arthroplasty

In the proposed rule (80 FR 41289), we shared our belief that, in addition to the patient-reported functional status outcomes, shared-decision making is an important aspect of care around elective patient-reported outcome procedures such as primary total hip and total knee arthroplasty. We also noted that lower episode expenditures achieved through improved patient-reported outcome efficiency may yield the unintended consequence of a compensatory increase in the number of episodes initiated. We stated that use of shared decision-making prior to episode initiation can serve as an important tool to ensure appropriate care. Though there are no developed measures, we sought feedback on the opportunity to capture quality data related to shared decision-making between patients and providers. Examples of such a measure could include concepts such as a trial of conservative medical therapy prior to elective procedures or broader shared decision-making measures. We invited public comment on whether such a measure concept would be appropriate for the CJR model. If we develop a measure that captures shared decision-making related to elective primary total hip and total knee arthroplasty or both, we would propose through rulemaking or other means to add that measure to the CJR model.

The following is a summary of the comments received and our responses.

Comment: Many commenters supported the development and use of measures related to shared decision-making. Most commenters agreed that shared decision-making is critical for the patient-reported outcome when patients are deciding whether or not to undergo elective TKA/THA procedures, and that CMS should promote shared decision-making as part of a way to optimize patient-reported outcomes. A commenter recommended that a shared decision-making measure should be documented within the referral visit by the primary care physician. Another commenter recommended that a shared decision making measure have both a pre- and post-intervention component. A commenter recommended that shared decision-making be required as part of the model. Multiple commenters suggested additional measures that should be paired with shared decision-making measures, including a functional outcome measure, a measure for risk adjustment, a measure for care planning, quality measures that assess clinical excellence, and the pairing of the measure with patient-reported outcome criteria to evaluate patterns of care. Many commenters recommended that shared decision-making measures require or document the use of certified or patient-reported outcome decision aids, though no specific decision aids were suggested. Finally, a number of commenters recommended that CMS use this opportunity to further the research agenda related to shared decision-making and its measurement.

Response: We appreciate all of the responses on how we might address shared-decision making from the quality measure perspective. For a detailed discussion of shared decision-making as it relates to beneficiary patient-reported outcomes and experience, please refer to beneficiary patient-reported outcome sections in section III.D.3.a. of this final rule. We agree that shared decision-making is important for patient-reported outcomes, as well as meaningfully measuring shared decision-making. Based on the comments we received, we will consider the future development of measures related to shared decision-making. Should we decide to implement a shared decision-making measure in the future, we will do so through notice-and-comment rulemaking.

c. Future Measures Around Care Planning

In the proposed rule (80 FR 41289), we stated that person-centered shared care plan is an important tool that can help providers across settings collaborate around a customized plan that reflects a patient's goals and offers providers critical information about all of the treatment a beneficiary has received. We shared that health IT solutions are increasingly supporting the exchange of care plan information across settings so that providers and individuals have access to necessary information whenever and wherever it is needed. We also indicated that in the 2015 Edition of certification criteria for health information technology (80 FR 16842), the Office of the National Coordinator for Health Information Technology (ONC) proposed the adoption of a new criterion to ensure health IT can capture, display, and exchange a robust care plan document in accordance with new standards released in the Consolidated Clinical Document Architecture Release 2.1; this proposal has now been finalized (80 FR 62648). While further measure development is needed, we sought comment on the appropriateness of a future quality measure which would assess the use of shared care plans in the care of beneficiaries participating in the CJR model.

The following is a summary of the comments received and our responses.

Comment: Several commenters supported the future inclusion of a measure focused on shared care planning in the model, pending further measure development. A commenter noted that a shared care plan measure could help to ensure that hospitals are taking steps to assist patients in understanding the potential tradeoffs associated with surgical interventions. Another commenter focused specifically on the need for advance care planning within a bundled payment model, noting that CMS should seek to require the hospital initiating the episode to conduct advance care planning discussions and offer beneficiaries the opportunity to complete an advance directive. Commenters encouraged CMS to incentivize providers to voluntarily submit data that would support future measure development in this area.

Response: While we did not propose to include a measure of care planning activities, we will consider these comments as we explore any future action in the CJR model. Should we decide to implement a measure of care planning activities in the future, we will do so through notice-and-comment rulemaking.

d. Future Measures for Use of Health IT and Health Information Exchange

In the proposed rule (80 FR 41289), we shared our belief that the use of health IT tools is a critical component of effective coordination across settings of care. Under bundled payment models, in which providers across the continuum of care share accountability for the clinical management and total cost of an episode of care, the capacity to share information electronically across disparate provider systems is essential for delivering efficient, safe, high quality care. As discussed in the August 2013 Statement ''Principles and Strategies for Accelerating Health Information Exchange'' (available at *http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf*), we believe that all individuals, their families, their healthcare and social service providers, and payers should have consistent and timely access to health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the individual's care. ONC has released a document entitled ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap'' (available at *https://www.healthit.gov/*

sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf), which describes barriers to interoperability across the current health IT landscape, the desired future state that will be necessary according to the industry to enable a learning health system, and a suggested path for moving forward. ONC will focus on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017. Under section 1833(z)(3)(D)(i)(I) of the Act, as amended by section 101(e) of the MACRA, providers participating in qualifying APMs under Medicare will be required to use certified EHR technology beginning in 2019. As this date approaches, we believe it will be important for providers working in these models to demonstrate adoption of health IT.

We shared our belief that use of certified health IT tools and the interoperable exchange of health information is a critical capability for model participants to be able to deliver the high-quality care and effective coordination across settings that will be required to demonstrate success under the model. Moreover, we believe that it will be important to incentivize adoption and use of these enabling technologies among model participants including PAC providers, by linking these activities to participant eligibility to receive reconciliation payments.

While we did not propose to add a measure for certified health IT use for the program's initial performance year, we sought comment on how we might incorporate such a measure beginning in the 2017 performance year. We invited stakeholder comment on the following questions:

- Is successful attestation as part of the EHR Incentive Program for Medicare hospitals in the applicable reporting year the most appropriate quality measure for assessing hospital performance on the use of health IT and interoperable health information in the model?
- Should the model include a performance measure that would be specific to the ability of hospitals to conduct electronic care coordination using certified health IT, for instance, the measure of transitions of care which hospitals currently report on as part of the EHR Incentive Program for Medicare Hospitals?
- What other measures could be used to assess hospital performance on the use of health IT and interoperable health information while minimizing program and provider collection and reporting burden?

We sought public comments on how we might incorporate an electronic measure beginning in the 2017 performance year, and public comments on the questions posed previously in this rule.

We also sought public comment on the appropriateness of quality measures for PAC patients, physicians and facilities that care for THA/TKA surgical procedure patients.

The following is a summary of the comments received and our responses.

Comment: While commenters noted the importance of health IT systems and health information exchange to support the care coordination required to succeed under a bundled payment approach, a number of commenters expressed concerns about introducing a measure of health IT utilization or health IT requirements within the model. A commenter suggested that the model should focus on outcomes rather than introducing measures of the care delivery process, such as the use of health IT. Another commenter believed that health IT requirements would restrict the flexibility of model participants to explore different modes of care delivery needed to succeed within the model. Another commenter noted that a measure of health IT use would not be appropriate because hospitals already participate in the EHR Incentive Program, and a similar measure under the program would create a duplicative penalty.

Several commenters noted that hospitals have substantially increased their adoption of health IT systems in recent years, and that participants will need to rely on electronic tools, including EHRs, health information exchange services, and other systems, in order to deliver effective care for beneficiaries under the model. Commenters also noted that many hospitals are seeking to address challenges around electronically exchanging patient information with PAC providers. As these PAC providers were not eligible for the EHR Incentive Programs, many have not yet established health IT systems. However, bundling programs such as the CJR model are likely to further incentivize hospitals to develop strategies to share information with these providers to support care coordination across an episode of care.

Response: We appreciate the insights and concerns expressed around utilizing a measure of health IT tied to participation in the EHR Incentive Programs. While we did not propose to include a measure of health IT utilization, we will consider these comments as we assess any future action for the model. As future measures become available, such as measures which focus directly on electronic exchange between all providers participating in a bundle, we will continue to explore whether there are opportunities to address this important aspect of care delivery for model participants. Should we decide to implement a measure of health IT utilization in the future, we will do so through notice-and-comment rulemaking.

Final Decision: After seeking comments on shared decision-making, and on future measures around Care Planning and future considerations for use of electronic health records, we thank the public for these comments and will evaluate the suggestions for future consideration.

4. Form, Manner, and Timing of Quality Measure Data Submission

In the proposed rule (80 FR 41289), we stated that it is important to be transparent and to outline the form, manner and timing of quality measure data submission so that accurate measure results are provided to hospitals, and that timely and accurate calculation of measure results are consistently produced to determine annual reconciliation payment.

We proposed that data submission for Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) and Hospital-Level Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551) (or both) be accomplished through the existing HIQR Program processes. Since these measures are administrative claims-based measures, hospitals will not need to submit data. We proposed that the same mechanisms used in the HIQR Program to collect HCAHPS Survey measure (NQF #0166) data also be used in the CJR model (79 FR 50259). For the hospitals that voluntarily submit data for the THA/TKA patient-reported outcome-based performance measure, we anticipated, if it is technically feasible, for data submission processes to be broadly similar to those summarized for the HIQR Program for chart abstracted and administrative claims-based measures. We indicated that we would create a template for hospitals to complete with the THA/TKA voluntary data, provide a secure portal for data submission, and provide education and outreach on how

to use these mechanisms for data collection and where to submit the THA/TKA voluntary data. We also repeated our description of potential processes for voluntary data collection in section III.D.3.a.(2) of the proposed rule, and noted that these were broadly similar to those used by the HIQR Program.

We invited public comment on the proposal to collect quality measure data through mechanisms similar to those used in the HIQR Program.

The following is a summary of the comments received and our responses.

Comment: Some commenters requested quarterly releases of measure results for the purposes of continuous quality improvement since they believed that an annual release of measure results would not facilitate effective continuous quality improvement.

Response: We acknowledge the request for hospitals to more frequently receive their measure results in order to enhance effective quality improvement. With respect to the measures that we are finalizing for the CJR model, we note that hospitals already receive their measure results on the THA/TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0166) through the HIQR Program on an annual and quarterly basis, respectively (69 FR 49082 and 78 FR 50783). With respect to the THA/TKA Complications measure (NQF #1550), CMS provides hospitals with their confidential preview reports and hospital-specific reports with discharge level information used in the calculation of their measure result around April each year before the results are publicly reported on the *Hospital Compare* Web site (77 FR 53598). We note that the *Hospital Compare* Web site is the vehicle that provides public reporting and within this Web site we indicate that this Web site fulfills section 1886(b)(3)(B)(viii)(VII) of the Act, as amended by section 3001(a)(2) of the Affordable Care Act, which requires the Secretary to establish procedures for making information regarding measures submitted available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. Prior to the release of data on *Hospital Compare,* hospitals are given the opportunity to review data during a 30-day preview period via the *QualityNet Secure Portal* (*http://www.qualityreportingcenter.com/wp-content/uploads/2015/07/IQR_FY-2017_Hospital-IQR-Program-Reference-Checklist_Tool_7.21.2015_FINAL508.pdf*).

With respect to the HCAHPS Survey measure (NQF #0166), CMS similarly provides hospitals with their confidential preview reports on a quarterly basis, before the results are publicly reported on Hospital Compare Web site (*http://www.hospitalcompare.hhs.gov/*) (*78 FR 50778*). We believe that the current frequency of sharing measure results data with hospitals is also appropriate for the CJR model and does allow effective quality improvement for the following reasons. First of all, we note that other CMS IPPS quality programs besides the HIQR Program, such as HVBP (77 FR 53579), the HRRP (77 FR 53399), and the Hospital-Acquired Condition Reduction Program (78 FR 50725), similarly use an annual cycle for sharing measure results with hospitals and publicly reporting quality measure performance as we are finalizing for the CJR model. For example, the HIQR Program and the HRRP release annual measure results data to hospitals on their excess readmissions (77 FR 53399). The acute myocardial infarction, heart failure, pneumonia, chronic obstructive pulmonary disease, and ischemic stroke readmission measure results have all shown improvements in hospital performance between 2010 and 2013 (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf*). This strongly suggests that effective continuous quality improvement is possible with annual review of measure results by hospitals. Secondly, because the THA/TKA Complications measure (NQF #1550) uses a 3-year rolling performance period that is 'rolled forward' by 12 months each HIQR Program year, quarterly updates to the 3-year performance period would yield minimal actionable information to hospitals from one quarter to the next, while increasing administrative burden for hospitals to download and review their hospital-specific reports and discharge-level data. We remind readers that the 3-year performance period is used for the THA/TKA Complications measure (NQF #1550) in order to identify a greater number of eligible index admissions for each hospital. Increasing the sample size by using a larger number of index admissions to identify the measure cohort improves the reliability and precision of the estimation of each hospital's results for the THA/TKA Complications measure (NQF #1550), as well as allow for the calculation of measure results that more meaningfully distinguish hospital performance. For these reasons, we do not believe that providing more frequent measure results data to participant hospitals in the CJR model than are already provided to them in the HIQR Program will provide sufficiently new, actionable information to meaningfully enhance their continuous improvement processes.

Comment: A commenter recommended that CMS establish the low-volume thresholds for the quality measures prior to the first performance year and exclude low-volume hospitals from the CJR model.

Response: As noted in the proposed rule (80 FR 41242), a participant hospital with an insufficient volume of episodes on which to determine performance on an individual measure will be assigned to the 50th percentile so as not to disadvantage a participant hospital based on its low volume because that hospital may in actuality provide high quality of care. Additionally, we proposed that data submission for Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) be accomplished through the existing HIQR program processes (80 FR 41290). By using existing HIQR program processes we intend to apply the same low-volume case thresholds applied to all claims based measures which is set at 25 cases for public reporting (75 FR 50185 and 76 FR 51609). For the HCAHPS Survey measure (NQF #0166) we have previously indicated in section III.D.2.c. of this final rule that a minimum of 100 cases is required for the measure which is also consistent with the threshold set for HVBP program (76 FR 26502)

Comment: A commenter recommended beginning the process of vendor certification as soon as possible with respect to patient-reported outcome data collection. Specifically, the commenter recommended CMS use previously established vendor guidelines such as those governing the data submission process for chart-abstracted measures or electronic clinical quality measures (eCQM).

Response: We will consider this recommendation when and if patient-reported outcome data collection is mandatory. The current patient-reported outcome data collection is voluntary, and hospitals can collect the data using whatever mechanisms are available to them.

Comment: A few commenters recommended we use a standardized data collection file template with respect to patient-reported outcome data

collection. A commenter recommended creating a file template for data collection in a web-based platform.

Response: We plan to create a standardized file template to assist hospitals' data collection and submission efforts for the patient-reported outcome data. We will take the commenter's recommendation to create a web-based data collection template into account when we design the template prior to the start date of the CJR model.

Final Decision: After consideration of the public comments we received, we are finalizing our proposals as to the form, manner, and timing of data submissions to CMS by participant hospitals for THA/TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0166) used in the CJR model, the frequency of sharing of measure results with participant hospitals annually, and the proposed performance periods set forth in Table 32. We note that the form, manner, and timing of data submissions to CMS by participant hospitals for THA/TKA Readmissions measure (NQF #1551) is not finalized since the THA/TKA Readmissions measure (NQF #1551) is not being adopted for the CJR model.

5. Display of Quality Measures and Availability of Information for the Public From the CJR Model

In the proposed rule (80 FR 41290), we stated our belief that display of quality data is an important way to educate the public on hospital performance. We have used several methods to report quality data to the public, including posting data on the *Hospital Compare* and *data.medicare.gov* Web sites. We shared that data have been available for viewing on these Web sites and in downloadable databases since 2005, and are well-known mechanisms for providing information to the public. We proposed to post data for measures included in the CJR model for each participant hospital on the *Hospital Compare* Web site in an easily understood format. The proposed applicable time periods for the measures during the CJR model initiative are summarized in Table 17 of the proposed rule (80 FR 41290) and in the following Table 31.

TABLE 31—SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE CJR MODEL

Measure title	Model year				
	1st	2nd	3rd	4th	5th
THA/TKA Complication *	April 1, 2013–March 31, 2016.	April 1, 2014–March 31, 2017.	April 1, 2015–March 31, 2018.	April 1, 2016–March 31, 2019.	April 1, 2017–March 31, 2020.
THA/TKA ** Readmission	July 1, 2013–June 30, 2016.	July 1, 2014–June 30, 2017.	July 1, 2015–June 30, 2018.	July 1, 2016–June 30, 2020.	July 1, 2017–June 30, 2016.
HCAHPS ***	July 1, 2015–June 30, 2016.	July 1, 2016–June 30, 2017.	July 1, 2017–June 30, 2018.	July 1, 2018–June 30, 2019.	July 1, 2019–June 30, 2020.

* Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550).

** Hospital-Level Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551).

*** HCAHPS Survey measure (NQF #0166).

We stated that the proposed time periods for the THA/TKA Complications measure (NQF #1550), and the THA/TKA Readmissions measure (NQF #1551) are consistent with HIQR Program performance periods for July 2017 public reporting. The HCAHPS Survey measure (NQF #0166) results performance periods as previously stated in section III.D.2.c. of this final rule would not align with the HIQR program. We also stated our belief that the public is familiar with the proposed measures, which have been publicly reported in past releases of Hospital Compare as part of the HIQR Program. Finally, we clarified in the propose rule our intent to minimize confusion and facilitate access to the data on the measures included in the CJR model by proposing to post the data on each participant hospital's performance on each of the 3 proposed quality measures in a downloadable format in a section of the *Hospital Compare* and *data.medicare.gov* Web sites specific to the CJR model, similar to what is done for the Hospital Readmissions Reduction Program and the Hospital-Acquired Conditions Reduction Program. We also proposed to post data on whether or not each participant hospital met the proposed threshold (section III.C.5.b. of the proposed rule) for receiving a reconciliation payment in the same downloadable database; we note that section III.C.5. of this final rule provides a detailed discussion on the final decision for indicating which hospitals are eligible for a reconciliation payment.

In addition, we also stated our belief that information about functional status both pre- and post-operatively is important for hip and knee replacements. We are developing a functional status measure that we believe will provide this needed information. The measure, Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (see section III.D.3. of the proposed rule for a detailed description), requires comprehensive testing before it can be used in a CMS program. As part of the effort to collect data on functional status voluntarily from hospitals, we proposed that hospitals that voluntarily submit data for this measure be acknowledged through the use of a symbol on *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*). The data submitted voluntarily for the functional status measure would not be publicly reported along with the other measures in the program.

We also provide clarification for the performance periods proposed for years 4 and 5 in Table 17 (80 FR 41290) in the proposed rule, and in Table 31 of this final rule, for the THA/TKA Readmissions measure (NQF #1551). In Table 17 of the proposed rule we had indicated a year 4 performance period of: July 1, 2016 through June 30, 2020 and for year 5 July 1, 2017 through June 30, 2016. We note that these proposed time frames are not consistent with prior proposals (80 FR 41290) and would like to clarify that the correct proposed performance periods for the THA/TKA Readmissions measure (NQF #1551) for year 4 is: July 1, 2016 through June 20, 2019; and for year 5: July 1, 2017 through June 30, 2020. We also note that the THA/TKA Readmissions measure (NQF #1550) has not been finalized for this model.

We invited public comments on these proposals to post data for mandatorily required measures on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) and to acknowledge hospitals that voluntarily submit data for the functional status measure with an icon on the *Hospital Compare* Web site.

The following is a summary of the comments received and our responses.

Comment: A few commenters supported the public reporting of measure results.

Response: We appreciate the support of our proposal to publicly report measure results implemented in the CJR model.

Comment: A commenter recommended that CMS give participant hospitals a year-long preview of measure performance prior to the public release of data. Another suggested that CMS delay public reporting of performance data for at least one year into the CJR model while allowing participant hospitals to preview their measure results during that time.

Response: We appreciate these two comments, and note our belief that the availability of quality data to the public is an important way to educate the public, including patients, consumers, and their family members and care givers, on hospital performance and that not publicly reporting such quality data as soon as they are available would not be consistent with our policy to be transparent with CMS quality and payment programs. Further, the finalized measures are currently used in the HIQR Program, and hospital performance information is publicly reported for this program on the Hospital Compare Web site. We refer reviewers to section III.C.5.b. of this final rule for further discussion of pay-for-reporting during the first year of the model from a payment perspective.

Comment: A few commenters requested clarification as to whether CMS intends to provide PRO data preview reports for participating hospitals.

Response: To provide further clarification regarding the release of quality measure results information to hospitals prior to public reporting on Hospital Compare Web site, we stated in the proposed rule (80 FR 41290) that we would use existing CMS hospital public reporting processes as in the HIQR Program. We also emphasized in the proposed rules the importance of providing accurate measure results to hospitals and the timely and accurate calculation of measure results that are consistently produced to determine annual reconciliation payments (80 FR 41290). As in the HIQR Program for outcome measures, we will deliver confidential reports and accompanying confidential discharge level information, as applicable to the measure, to participant hospitals on an annual basis. These reports will contain hospital-specific information on the THA/TKA Complications measure (NQF #1550), the HCAHPS Survey measure (NQF #0166), and whether a hospital has successfully submitted the voluntary patient-reported outcome data. The reports will be delivered in participant hospitals' secure QualityNet accounts prior to the information being made available to the public.

We will provide participant hospitals a period of 30 days to review and submit corrections to calculations of measure results and determinations of successful patient-reported outcome data submission using a process that is similar to the process currently used for posting results on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) in programs such as the HIQR, HVBP, HRRP programs and the Hospital-Acquired Condition Reduction Program. Our intent in providing this information is two-fold—(1) To facilitate hospitals' verification of their measure results calculations; and (2) to facilitate hospitals' quality improvement efforts with respect to the care provided to LEJR patients. More specifically, this 30-day period will begin when the participant hospitals' confidential reports and accompanying discharge-level information are posted to their QualityNet accounts. This time period will enable us to evaluate correction requests in a timely manner in order to provide accurately calculated measure results for the determination of annual reconciliation payments. We believe that this review and corrections process will ensure that hospitals are able to fully and fairly review their measure results as they will be used in the CJR model and publicly reported on the Hospital Compare Web site (*http://www.hospitalcompare.hhs.gov/*).

We note that with respect to the claims based THA/TKA Complications measure (NQF #1550), the review and correction process will not include submitting additional corrections related to the underlying claims data we used to calculate the measure result, nor adding new claims to the data extract we used to calculate the measure result. This is because it is necessary to take a static ''snapshot'' of the claims in order to perform the calculations. For purposes of the CJR model, we would calculate the THA/TKA Complications measure (NQF #1550) result using a static snapshot (that is, data extract) taken at the conclusion of the 90-day period following the last date of discharge used in the applicable performance period. This is consistent with our policy for all claims-based measures used in the HIQR, HVBP, HRRP programs, and the Hospital-Acquired Condition Reduction Program (for example, see 77 FR 53399 through 53401 as this policy is applied for HRRP and 78 FR 50725 through 50727 as this policy is applied in the Hospital-Acquired Condition Reduction Program). We recognize that under our current timely claims filing policy, hospitals have up to 1 year from the date of discharge to submit a claim to us. However, in using claims data to calculate quality measure results for the CJR model, we will create claims data extracts approximately 90 days after the last discharge date in the applicable performance period. For example, for model year one of the CJR model, the last discharge date in the performance period for the THA/TKA Complications measure (NQF #1550) is March 31, 2016, so we would create the data extract on or around June 30, 2016 and use that data to calculate the measure result for the April 1, 2013 to March 31, 2016 performance period. Participant hospitals are already familiar with this 90-day claims ''run-out'' period, which we apply when creating data extracts for all of our claims-based outcome measures used in the HIQR, HVBP, HRRP Programs, and the Hospital-Acquired Condition Reduction Program (for example, see 77 FR 53399 through 53401 as this policy is applied for HRRP and 78 FR 50725 through 50727 as this policy is applied in the Hospital-Acquired Condition Reduction Program).

Comment: A commenter requested clarification regarding the 1-year difference in performance periods for FY 2016's HIQR Program and the proposed performance periods for the CJR model (80 FR 41290, Table 17). The clarification request was specific to the THA/TKA Complications measure (NQF #1550) where they indicated that the FY 2016 HIQR Program THA/TKA Complications measure (NQF #1550) is April 2012 through March 2015 and for the CJR model THA/TKA Complications measure (NQF #1550) performance period is April 2013 through March 2016.

Response: Table 17 of the proposed rule (80 FR 41290), had set forth the performance periods for each of the proposed quality measures for the 5 performance years of the CJR model. As we state in section III.D.5. of this final rule, we are finalizing Table 32 with respect to the THA/TKA Complications

measure (NQF #1550) and the HCAHPS Survey measure (NQF #0166) with the performance periods as previously set forth, but we are not finalizing the THA/TKA Readmissions measure (NQF #1550). In addition, we want to provide further clarification on the CJR model performance periods for the THA/TKA Complications measure (NQF #1550) as compared to the performance periods that will be used in the HIQR Program. As we stated in the proposed rule (80 FR 41290), the performance periods are intended to align with the public reporting timeline for this measure in the HIQR Program. For example, for the first performance year of the CJR model, the performance period of the THA/TKA Complications measure (NQF #1550) is April 1, 2013 through March 31, 2016. When we are calculating reconciliation payment determinations for model year one (that is, CY 2016) during the spring of 2017, we will be using quality measure data that are the most currently available, which will be from the April 1, 2013 through March 31, 2016 performance period for the THA/TKA Complications measure (NQF #1550). The HIQR Program will be using data from the same period to prepare for public reporting on *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) in July 2017. When information on each participant hospital's performance in the CJR model will be publicly reported on *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) in July 2017, the performance period for the THA/TKA Complications measure (NQF #1550) will align with the performance period used for the same measure in the HIQR Program. We believe that aligning the performance periods for the THA/TKA Complications measure (NQF #1550) in this manner will reduce the potential for confusion among users of the Hospital Compare Web site (*http://www.hospitalcompare.hhs.gov/*) and also ensure that the CJR model uses the most currently available measure results for calculating participant hospital reconciliation payment determinations. The CJR model will not use measure results data from the HIQR Program's July 2016 public reporting, which will be April 1, 2012 through March 31, 2015 for the THA/TKA Complications measure (NQF #1550), for the reasons previously described.

Comment: A commenter urged CMS to rapidly disclose hospitals' results on the THA/TKA PRO–PM to the public.

Response: We will not publicly report the voluntary patient-reported outcomes and limited risk variable data during or after this model. We note that the data will be used to complete measure development of the THA/TKA patient reported performance based outcome measure. We intend to acknowledge those hospitals that are voluntarily submitting PRO and limited risk variable data via an icon or symbol by the hospital's name on the *Hospital Compare* Web site. If we consider adopting such a measure for the CJR model, we would do so through rulemaking.

Final Decision: After consideration of the public comments we received, we are finalizing our proposals to publicly report quality measure results each year on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*), including acknowledgment of hospitals that voluntarily submit data for the functional status measure with an icon on the *Hospital Compare* Web site. We are finalizing the public reporting of measure results each year for the THA/TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0166). Measure results for the THA/TKA Readmissions measure (NQF #1551) will not be publicly reported each year since we are not finalizing this measure. We have also provided further clarification as to the sharing of quality measure results with participant hospitals, the use of confidential reports that participant hospitals will receive, and the opportunity they will have to review and submit correction requests for their measure result calculations prior to public reporting on *Hospital Compare* Web site.

TABLE 32—SUMMARY OF FINALIZED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE CJR MODEL

Measure title	CJR Model year				
	1st	2nd	3rd	4th	5th
THA/TKA Complications*	April 1, 2013–March 31, 2016.	April 1, 2014–March 31, 2017.	April 1, 2015–March 31, 2018.	April 1, 2016–March 31, 2019.	April 1, 2017–March 31, 2020.
HCAHPS**	July 1, 2015–June 30, 2016.	July 1, 2016–June 30, 2017.	July 1, 2017–June 30, 2018.	July 1, 2018–June 30, 2019.	July 1, 2019–June 30, 2020.

*Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550).

**Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure (NQF #0166).

This final policy is set forth at § 510.400.

E. Data Sharing

1. Overview

In section III.E. of the proposed rule, we proposed to provide data to the hospital participants of the CJR model. We have experience with a range of efforts designed to improve care coordination for Medicare beneficiaries, including the Medicare Shared Savings Program (Shared Savings Program), Pioneer ACO Model, and BPCI, all of which make certain data available to participants. In section III.C.2. of the proposed rule, we proposed a model to financially incentivize hospitals, through retrospective bundled payments, to engage in care redesign efforts to improve quality of care and reduce spending for the aggregate Part A and B FFS spending for beneficiaries included in the model during the inpatient hospitalization and 90 days post-discharge. Given this, we expressed our belief that it is necessary to provide historical and ongoing claims data representing care furnished during episodes of care for LEJRs to hospitals so that they can, among other things, adequately structure their care pathways, coordinate care for beneficiaries, and estimate acute inpatient and PAC spending within LEJR episodes.

As noted previously, this would not be the first instance in which we have provided claims data to entities participating in a CMS model or program. For example, participants in Shared Savings Program initially receive aggregate information on their historical financial performance as well as quarterly data throughout their tenure in the program. In addition, Shared Savings Program ACOs receive certain beneficiary-identifiable claims information in accordance with our regulations. (For more information, see

the November 2, 2011 final rule titled ''Medicare Program; Medicare Shared Savings Program: ACOs'' (76 FR 67844 through 67849)). The Shared Savings Program final rule noted that while an ACO may have complete information for the services it provides or coordinates on behalf of its FFS beneficiary population, it may not have access to complete information on a FFS beneficiary who chose to receive services, medications or supplies from non-ACO providers and suppliers. Thus, we decided to provide ACOs participating in the Shared Savings Program with an opportunity to request CMS claims data on the premise that more complete beneficiary-identifiable information would enable practitioners in an ACO to better coordinate and target care strategies. Recently, we noted that the ACOs participating in the Shared Savings Program have reported that the beneficiary identifiable claims data that they receive from us are being used effectively to better understand the FFS beneficiaries that are receiving services from their providers. These data give ACOs valuable insight in to patterns of care for their beneficiary population; enable them to improve care coordination among and across providers and suppliers and sites of care, including providers and suppliers and sites of care not affiliated with the ACO; and allow them to identify and address gaps in patient care. (For more information, see the Medicare Shared Savings Program final rule (80 FR 32733 through 32734.)

Similarly, participants in the Pioneer ACO model can request historical claims data of beneficiaries aligned with the particular Pioneer ACO entity, and the entities continue to receive certain ongoing data regarding the services furnished to those beneficiaries. (For more information, see the CMS Web site *http://innovation.cms.gov/Files/fact-sheet/Pioneer-ACO-Model-Beneficiaries-Rights-Fact-Sheet.pdf*). In addition, we provide BPCI participants with the opportunity to request beneficiary-level claims data regarding their own patients, both for the historical period of 2009 to 2012 that was used to set baseline prices for entities participating in BPCI, as well as ongoing monthly claims feeds containing Medicare FFS claims for beneficiaries that could have initiated an episode of care for that particular BPCI participant. These monthly claims feeds provide BPCI participants with data for both acute and PAC spending for beneficiaries that could have initiated an episode of care at that BPCI participant.

As noted in the proposed rule, based on our experience with these efforts, we believe that providing a similar opportunity for hospitals participating in the CJR model to request data is necessary for participant hospitals to have the relevant information to allow for practice changes supported by CJR and to identify services furnished to beneficiaries receiving LEJRs under the model. Specifically, providing participant hospitals with certain claims and summary information on beneficiaries in accordance with established privacy and security protections would improve their understanding of the totality of care provided during an episode of care. With this greater understanding, we anticipate that hospitals would be better equipped to evaluate their practice patterns and actively manage care delivery so that care for beneficiaries is better coordinated, quality and efficiency are improved, and payments aligned more appropriately to the medically necessary services beneficiaries have a right to receive. We also expect that providing this data to CJR participants will benefit beneficiaries by allowing providers to use the data to improve care coordination activities in areas that may be currently lacking. However, we also noted our expectation that CJR hospitals are able to, or will work toward, independently identifying and producing their own data, through electronic health records, health information exchanges, or other means that they believe are necessary to best evaluate the health needs of their patients, improve health outcomes, and produce efficiencies in the provision and use of services.

Accordingly, we believe that making certain data available to CJR hospitals, as we do with ACOs participating in the Shared Saving Program and Pioneer ACO Model, would help them to monitor trends and make needed adjustments in their practice patterns. In order for CJR participants to understand and track their care patterns, we proposed to provide the participants with beneficiary-level claims data for the historical period used to calculate a CJR hospital's target price as well as ongoing quarterly beneficiary-identifiable claims data in response to their request for such data in accordance with our regulations. Given that the CJR model also proposes to incorporate regional pricing in the calculation of target prices, we also proposed to provide participants with aggregate regional data.

Comment: Some commenters noted that CMS expects that hospitals are able to, or will work toward, independently identifying and producing their own data. These commenters concurred that hospitals were making these efforts, but noted that there were challenges in doing so.

Response: We appreciate hospitals' efforts to independently identify and produce performance data, and believe that our proposal, which makes certain financial performance data available, will be supportive of these efforts.

2. Beneficiary Claims Data

In the proposed rule we noted that, based on our experience with BPCI participants, we recognize that hospitals vary with respect to the kinds of beneficiary claims information that would be most helpful. While many hospitals located in MSAs that are selected for participation in CJR model may have the ability to analyze raw claims data, other hospitals may find it more useful to have a summary of these data. Given this, we proposed to make beneficiary claims information available through two formats.

First, for participant hospitals that lack the capacity to analyze raw claims data, we proposed to provide summary beneficiary claims data reports on beneficiaries' use of health care services during the baseline and performance periods. These reports would allow participant hospitals to assess summary data on their relevant beneficiary population without requiring sophisticated analysis of raw claims data. Such summary reports will provide tools to monitor, understand, and manage utilization and expenditure patterns as well as to develop, target, and implement quality improvement programs and initiatives. For example, if the data provided by CMS to a particular hospital participant reflects that a certain PAC provider admits beneficiaries who then have significantly higher rates of inpatient readmissions than the rates experienced by other beneficiaries with similar care needs at similarly situated PAC providers, that may be evidence that the hospital could consider, among other things, the appropriateness of discharges to that provider, whether other alternatives might be more appropriate, and whether there exist certain care interventions that could be incorporated post-discharge to lower readmission rates.

Therefore, for both the baseline period and on a quarterly basis during a participant hospital's performance period, we proposed to provide participant hospitals with an opportunity to request summary claims data that would encompass the total expenditures and claims for an LEJR episode, including the procedure,

inpatient stay, and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, PAC, and physician services for the hospital's beneficiaries whose anchor diagnosis at discharge was either MS DRG 469 or 470. We proposed that these summary claims aggregate data reports would also contain payment information, utilizing the categories listed for each episode triggered by a beneficiary as follows:

- Inpatient hospital.
- Outpatient hospital.
- Physician.
- Long-term care hospital (LTCH).
- IRF.
- SNF.
- HHA.
- Hospice.
- ASC.
- Part–B drug.
- Durable medical equipment (DME).
- Clinical laboratory.
- Ambulance.

These reports would likely include the following:

- Information such as admission and discharge date from the anchor hospitalization.
- The physician for the primary procedure, Medicare payments during the anchor hospitalization.
- Medicare payments during the PAC phase.
- Medicare payments for physician services would likely be included in these reports.

These summary claims data would reflect all Medicare Part A and Part B expenditures during the 90-day episodes, except for those claim types noted later in this section, as well as excluding expenditures related to those MS–DRGs that we proposed to be specifically excluded from the episode of care, as set forth in section III.B.2. of the proposed rule.

Alternatively, for hospitals with a capacity to analyze raw claims data, we would make more detailed beneficiary-level information available in accordance with established privacy and security protections. These data would enable hospitals to better coordinate and target care strategies for beneficiaries included in CJR episodes. For example, in the BPCI initiative, we provide participants with beneficiary-level claims data for all Part A and Part B services furnished to a beneficiary treated by that BPCI participant for all MS–DRGs included in an episode that the participant has selected for participation (See BPCI: Background on Model 2 for Prospective Participants, page 3 at *http://innovation.cms.gov/Files/x/BPCI_Model2Background.pdf.*)

These data include services furnished by the participant, as well as services furnished by other entities during the 30-, 60- or 90-day episode. For example, where the entity participating in BPCI is an acute care hospital, we provide beneficiary-level claims data for all Medicare Part A and B services and supplies furnished by the hospital during the inpatient admission, as well as all PAC services furnished to the beneficiary by the hospital or any other providers or suppliers.

The response from entities participating in BPCI has indicated that the availability of these data is necessary to monitor trends and pinpoint areas where care practice changes are appropriate, as well as assess the cost drivers during the acute and PAC periods of the episode. Thus, for the baseline period and on a quarterly basis during a hospital's performance period, we proposed to provide participant hospitals with an opportunity to request line-level claims data for each episode that is included in the relevant performance year, as described in section III.C. of the proposed rule.

For both the proposed summary claims data and the more detailed claims data formats, we proposed that the sets of these files would be packaged and sent to a portal in a ''flat'' or binary format for the individual participant hospitals to retrieve. Furthermore, the files would contain information on all claims triggered by a beneficiary in a participating CJR hospital.

Finally, we note that beneficiary information that is subject to the regulations governing the confidentiality of alcohol and drug abuse patient records (42 CFR part 2) would not be included in any beneficiary identifiable claims data shared with a hospital under our proposal.

We requested comments on these proposals as well as the kinds of data and frequency of reports that would be most helpful to the hospitals' efforts in coordinating care, improving health, and producing efficiencies.

The following is a summary of the comments received and our responses.

Comment: Commenters supported CMS's proposal to make both historical baseline and updated beneficiary claims information available to hospitals participating in CJR both on a detailed line level and a summary basis. Commenters noted the importance of these data for such purposes as formulating processes and protocols to redesign care, developing networks with physicians, physician groups and PAC providers, establishing necessary clinical and administrative infrastructure during the pre-implementation period, and estimating potential savings associated with better care delivery.

Response: We appreciate and concur with these comments that support our proposal.

Comment: A commenter stated that participants should be provided both line-level and summary beneficiary claims information rather than just one data type or the other.

Response: We appreciate this suggestion and wish to clarify that we will make both line-level and summary beneficiary claims data available to participating hospitals upon request in accordance with established privacy and security protections.

Comment: Commenters opposed the proposal to exclude beneficiary information that is subject to the regulations governing the confidentiality of alcohol and drug abuse patient records (42 CFR part 2) from any beneficiary identifiable claims data shared with a hospital. Commenters noted that this information was vital for hospitals to understand the full risk associated with beneficiaries and was needed to identify appropriate care management methods. Some commenters expressed the view that hospitals should not be required to assume risk for beneficiaries where these data are not made available. Other commenters requested that CMS make available de-identified cost and claims data or aggregate payment data for these services. Moreover, some commenters recommended that CMS apply its waiver authority to make beneficiary-specific claims level substance abuse data available to hospitals or work with the Congress to create an exception to 42 CFR part 2 to provide claims level, identifiable data.

Response: Section 1115A of the Act does not authorize the waiver of the requirements under 42 CFR part 2. Moreover, our proposal to exclude this information is consistent with our usual treatment of these data with other similar CMS programs and models where providers must take on risk in managing the care of their beneficiaries, such as the Shared Savings Program and BPCI model. We would note that, based on our experience to date, we are unaware of this policy being a significant impediment to the operations of these efforts. We also appreciate the suggestions to make these data available in a de-identified manner. We have considered this option and are not currently aware of a means to make de-identified beneficiary-specific data available in a way that would provide useful information to participating hospitals without potentially making it

possible to identify beneficiaries. Similarly, we have also not identified a way in which to make meaningful aggregate data available on a limited basis without potentially compromising beneficiary confidentiality. However, we will continue to consider these comments and the feasibility of making such data available in a way that is both meaningful to participating hospitals and in compliance with 42 CFR part 2.

Comment: Commenters questioned the frequency, mechanisms, and content of the information we propose to make available to participant hospitals.

Response: These comments and our responses will be discussed in their respective sections, which follow.

Final Decision: After considering the public comments we received, we are finalizing the proposal at § 510.300(d) to make available to participant hospitals, through the most appropriate means, data that CMS determines may be useful to participant hospitals. We are also finalizing our proposal to exclude information that is subject to the regulations governing the confidentiality of alcohol and drug abuse patient records (42 CFR part 2) from any beneficiary identifiable claims data shared with a hospital at this time.

3. Aggregate Regional Data

Because we proposed to incorporate regional pricing data in the creation of prices for CJR, as set forth in section III.C.4. of the proposed rule, we noted our belief that it will also be necessary to provide comparable aggregate expenditure data available for all claims associated with MS–DRGs 469 and 470 for the census region in which the participant hospital is located. As noted in section III.C.4.b.(5) of the proposed rule, we proposed that a hospital's target price will be determined based on a blend of its own historical expenditures as well as regional pricing data of all other hospitals in its region. Thus, we also proposed to provide CJR hospitals with aggregate data on the total expenditures during an acute inpatient stay and 90-day post-discharge period for all Medicare FFS beneficiaries whose anchor diagnosis at discharge was either MS–DRG 469 or 470 (and would have initiated a CJR episode if discharged from a CJR hospital) in their census region. These data would not include beneficiary-identifiable claims data, but would provide high-level information on the average episode spending for MS–DRGs 469 and 470 in the region in which the participant hospital is located. We requested comments on these proposals as well as the kinds of aggregate data and frequency of data reports that would be most helpful to the hospitals' efforts in coordinating care, improving health, and producing efficiencies.

The following is a summary of the comments received and our responses.

Comment: Commenters supported the proposal to make expenditure data available for claims associated with MS–DRGs 469 and 470 for the census region in which the participant hospital is located, for example, that these data would be critical to hospitals in tracking their performance relative to benchmarks over time or would allow them to anticipate future changes in target pricing. A commenter noted that the proposal to provide 3 years of historical claim-level data is sufficient for purposes of this program and expressed support for CMS' proposal to include both Part A and Part B spending data. However, another commenter expressed reservations about the usefulness of high-level aggregate spending data by spending census region.

Response: We concur with the comments supporting our proposal to make aggregate regional data available to hospitals. We recognize that some hospitals might prefer to have more detailed data rather than aggregated data. However, we believe the data we will be making available should be helpful both as a performance benchmark for participating hospitals relative to their peers as well as to better understand their financial performance expectations, particularly given that regional pricing data will be incorporated for purposes of determining their target prices.

Comment: The comments we received on the frequency with which aggregate regional data would be made available to hospitals were often requests for us to make these data available more frequently, such as on a monthly basis.

Response: Our response to these comments is discussed later in section III.E.5. of this final rule.

Comment: With respect to data content, we received a suggestion that these data contain enough detail to identify potential opportunities for improvement. A commenter suggested that CMS use the BPCI data extracts as a starting point for CJR, since they were satisfactory to BPCI participants. Specific requests included proposals that the data reflect a rolling 18-month period, include separate subsets for outpatient physical and occupational therapy and for comprehensive outpatient rehabilitation facility (CORF) services, and that CMS provide a detailed description of the calculations needed to derive the regional target prices. Several comments requested that the data be broken down by MS–DRG as follows:

- Total normalized episode expenditures.
- Normalized episode expenditures within cost categories (anchor inpatient, SNF, HHA, IRF, LTCH readmissions, professional services, other).
- Variability metrics related to the total normalized episode expenditures (standard deviation, 95th percentile, 99th percentile, etc.).
- Episode counts.
- Variability metrics surrounding episode counts (what is the mean number of episodes at a hospital in the region, the standard deviation, the 95th or 99th percentile, etc.).
- Utilization percentages for key services (what percentage of episodes had SNF utilization, IRF, LTCH, HHA, readmissions).
- Percentage of episodes that were non-elective (for example, using the quality metric specification exclusions methodology).

Response: We appreciate the comments we received on the kinds of data that might be helpful to participating hospitals, and agree with the comment that the regional data we provide should contain enough detail to identify potential opportunities for improvement.

Final Decision: We are finalizing our proposal to provide CJR hospitals with aggregate data on the total expenditures during an acute inpatient stay and 90-day post-discharge period for all Medicare FFS beneficiaries whose anchor diagnosis at discharge was either MS–DRG 469 or 470 (and would have initiated a CJR episode if discharged from a CJR hospital) in their census region. We will also consider the range of comments we received on the additional kinds of data elements and formats that would be most useful to participating hospitals. In the event we consider adopting additional elements or formats for these data, we will provide further guidance, potentially through rulemaking if warranted.

4. Timing and Period of Baseline Data

As stated in the proposed rule, we considered various options for the timing of providing baseline data to CJR participant hospitals. We considered provision of data prior to the proposed start date of the model as well as providing data to participants at the point of the first payment reconciliation (described in section III.C.6. of the proposed rule). We proposed to make baseline data available to hospitals participating in CJR no sooner than 60 days after the proposed start date of the model. We noted our recognition that

these data are important to the abilities of CJR participant hospitals to estimate costs, coordinate care, and identify areas for practice transformation, and that early release of this data can facilitate their efforts to do so. We also noted our view that hospitals will view the CJR effort as one involving continuous improvement. As a result, changes initially contemplated by a hospital could be subsequently revised based on updated information and experiences. We also indicated that while we would like to be able to make data available as soon as possible once the model had begun, we did not believe that these baseline data must be immediately available upon the start date of the model as hospitals can begin considering improvements that would enhance their ability to better coordinate care and increase efficiencies in the absence of these data. Therefore, we proposed to begin making baseline data available to CJR hospitals within 60 days of CMS' receipt of the request by the participant hospital for such data, in a form, time, and manner of such requests to be determined by CMS and announced at a later date. Further requests would not be accepted until the model had begun. We sought comments on this proposal.

In the proposed rule, we also discussed which period of baseline data should be shared with hospitals, for example, whether the data should represent a single year, or some longer period such as a 3-year period or more. We expressed our belief that to be most useful, the baseline information should be recent enough to reflect current practices yet of a sufficient duration to reflect trends in those recent practices. For example, 1 year of data would likely reflect a hospital's most current practices, but would not be helpful for purposes of identifying trends. In contrast, 3 years of data could both reflect a hospital's most recent performance and recent performance trends. Moreover, we noted that making data available for a 3-year period aligned with our proposal to set a target price based on a 3-year period of baseline data, which is a factor in assessing CJR hospitals' performance (see section III.C. of this final rule). That is, if a hospital has access to baseline data for the 3-year period used to set its target price, then it would be able to assess its practice patterns, identify cost drivers, and ultimately redesign its care practices to improve efficiency and quality.

We alternatively considered making data available for an even longer historical period—for example, 4 or 5 years. However, we questioned the usefulness of information that is older than 3 years for purposes of changes contemplated for current operations. Accordingly, in our proposed rule, we proposed to make available baseline data for up to a 3-year period. We indicated that we would limit the content of this data set to the minimum data necessary for the participant hospital to conduct quality assessment and improvement activities and effectively coordinate care of its patient population. This period would encompass up to the 3 most recent years for which claims data are available for the hospital and would align with the baseline period we proposed to utilize to establish target prices, as noted previously. We sought comments on our proposal and invited comments on alternative time periods that could better help hospitals evaluate their practice patterns and actively manage care delivery so that care is better coordinated, quality and efficiency are improved, and costs are better controlled.

The following is a summary of the comments received and our responses.

Comment: The comments we received supported our proposal to make 3 years of baseline data available to participating hospitals.

Response: We appreciate and concur with those comments.

Comment: Many commenters opposed the proposal to make baseline data available to hospitals participating in CJR no sooner than 60 days after the proposed start date of the model. Commenters expressed concern that this proposal would allow insufficient time to prepare and that hospitals should be provided with historical claims data in advance of the start data; typically, 3 to 6 months prior to implementation with some commenters recommending up to 1 year prior to implementation.

Commenters indicated that data would be needed sooner than was proposed for reasons such as participating hospitals would need the data and time to analyze claims for purposes of identifying opportunities for care redesign, formulate processes and protocols to redesign care, assess the performance of potential partners, develop networks with physicians and PAC providers, and establish necessary clinical and administrative infrastructure. Further, hospitals might not have the in-house resources to analyze the data and thus need to use consulting resources for these purposes. Commenters noted that activities such as these could take several months to complete once the data were made available.

Some commenters also noted that the absence of downside risk does not diminish the need for access to data in advance of the CJR performance period. Moreover, commenters pointed to other CMS/CMMI efforts where data were made available prior to implementation. For example, under the BPCI model, participants received historical claims data feeds prior to the start of the program, and had approximately 12 months from receiving the data prior to enrollment in the program.

Commenters expressed concerns that insufficient time for preparation and lack of data for preparatory analysis, prior to start, could hinder a hospital's ability to effectively coordinate and ensure smooth transitions across the continuum of care for beneficiaries undergoing LEJR procedures. As discussed elsewhere in this final rule, several commenters recommended that the program be delayed so that data could be made available in advance of implementation.

Response: We appreciate the concerns and reasons expressed by commenters for opposing our proposal to make baseline data available to hospitals participating in CJR no sooner than 60 days after the initially proposed start date of the model, as well as suggestions for when these data should be made available. We have carefully considered the timeframes for making these data available, and have made other modifications to our proposed rule that should assist in mitigating the concerns commenters have raised on this issue. First, as discussed in section III.C.2.a. of this final rule, we are delaying the start date of the model to April 1, 2016, which is, in part, in response to when data could be made available. Second, as discussed in III.C.8. of this final rule, we are also reducing the potential risk to participating hospitals by lowering the stop-loss limit from 10 percent to 5 percent.

Final Decision: After considering the public comments we received, we are finalizing our proposal to make 3 years of baseline data available to hospitals and intend to make these data available, upon request, before the April 1, 2016 start date.

5. Frequency and Period of Claims Data Updates for Sharing Beneficiary-Identifiable Claims Data During the Performance Period

As indicated in our proposed rule, we believe that the availability of periodically updated beneficiary-identifiable claims data will assist hospitals participating in CJR to identify areas where they might wish to change their care practice patterns, as well as

monitor the effects of any such changes. With respect to these purposes, we have considered what would be the most appropriate period for making updated claims information available to hospitals, while complying with the HIPAA Privacy Rule's ''minimum necessary'' provisions standard. We stated our belief that quarterly claims data updates align with a 90-day episode window. Moreover, as a larger episode window would be included, the claims data would be more representative of total costs and hence more useful to hospitals as they consider long-term practice changes. Accordingly, in our proposed rule, we proposed to make updated claims data available to hospitals upon receipt of a request for such information that meets CMS's requirements to ensure the applicable HIPAA conditions for disclosure have been met, as frequently as on a quarterly basis. We sought comments on this proposal.

Related to this is the period of claims that would be represented in each update. For example, as stated in our proposed rule, we considered limiting this period to 3 months of data, which aligns with the frequency with which we would make updated claims data available. However, other than this alignment, we did not see additional reasons for artificially limiting the period to this extent. Alternatively, we considered providing an updated dataset as frequently as each quarter that would include data from up to the previous 6 quarters. We noted our belief that this level of cumulative data would offer more complete information and allow better trend comparisons.

Accordingly, we proposed to make beneficiary-identifiable and aggregate claims data available that would represent up to 6 quarters of information upon receipt of a request for such information that meets the requirements of the HIPAA Privacy Rule. We noted that we intended for the data for this model to be consistent with our proposed performance year of (January 1 through December 31). To accomplish this for the first year of CJR (2016), we proposed to provide, upon request and in accordance with the HIPAA Privacy Rule, claims data from January 1, 2016 to June 30, 2017 on as frequently as a running quarterly basis, as claims were available. For each quarter and extending through June 30, 2017, we proposed that participants during that first year would receive data for up to the current quarter and all of the previous quarters going back to January 1, 2016. These datasets would contain all claims for all potential episodes that were initiated in 2016 and capture a sufficient amount of time for relevant claims to have been processed. We noted in our proposed rule that we would limit the content of this data set to the minimum data necessary for the participating hospital to conduct quality assessment and improvement activities and effectively coordinate care of its patient population. We sought comment on our proposal.

The following is a summary of the comments received and our responses.

Comment: Commenters noted the importance of hospitals being provided timely data. Some commenters requested real time data to enable hospitals to quickly identify and appropriately intervene to manage cost and quality or to achieve the goals of the program. Another commenter noted that having data from the most recent quarters would enable them to understand their current performance.

While some commenters supported the proposal to make data available on a quarterly basis, most of the comments we received on this topic indicated that data would be needed on a more frequent basis—specifically, on a monthly basis. Commenters suggested that monthly data would be needed for hospitals to react more quickly and to make course changes in response to changes in cost, quality, and utilization. A commenter noted that monthly updates would be needed for tracking patients whose highest utilization is in the first 30 days after their surgery. Another commenter suggested that in addition to facilitating hospitals' ability to implement the model, having more frequent data updates would encourage provider engagement in the program. Several comments also noted and requested that we make data available on a monthly basis as is done with the BPCI model.

Response: We appreciate and concur with comments on the importance of being provided timely data, such as claims data during the most recent quarters, and the usefulness of these data to hospitals' ability to understand, monitor, and adjust their performance. We also appreciate commenter's requests for more frequent data updates, but are not persuaded that access to real-time data is needed for hospitals to monitor and understand trends in their practice patterns. We would also note that making these data available on a real-time basis would not be feasible for CMS. Accordingly, we are modifying our proposal from making these data available on a quarterly basis to making these data available ''no less frequently'' than on a quarterly basis with the goal of making these data available on as frequently as a monthly basis if practicable. Thus, we are revising § 510.300 (d) to state ''The minimum data necessary to achieve the goals of the CJR model, as determined by CMS, may be provided under this section for a participant hospital's baseline period and no less frequently than on a quarterly basis throughout the hospital's participation in the CJR model.'' We would note that this modification would apply to both beneficiary-identifiable claims data (line- and summary-level) and aggregate regional data that was discussed earlier in section III.C.4. of this final rule. We would also note that, because we are delaying our start date from January 1 to April 1, 2016, we will be providing upon request and in accordance with the HIPAA Privacy Rule, claims data for episodes that began on or after April 1, 2016 (rather than January 1, 2016) and ended on or before December 31. In subsequent years, data for each performance year would reflect episodes that began on or after January 1 of that year and ended on or before December 31 of that year. Further, in our proposed rule, we had proposed to make up to six quarters of data available to participating hospital. We wish to clarify that, in order to make these data most meaningful to participating hospitals, we plan to synchronize the availability of these data with the annual payment reconciliation process, which will occur in the second quarter of the year following the performance year. For example, these data could then represent four quarters for the first year and five quarters thereafter.

Comment: Commenters requested that data be made available automatically without a specific request for the data. These commenters typically pointed to the potential for additional administrative burden associated with requesting the data. As an alternative, commenters suggested that hospitals receive data upon acceptance or subscribe to receive data for the duration of the model. A commenter suggested that CMS establish a data delivery sign-up process under which hospitals can elect to receive beneficiary claims data only, summary data only, or both beneficiary claims and summary data on an ongoing basis. Under this system, hospitals could change their election at any point during the model as they develop data handling and analytical capability. Another commenter suggested that CMS make data available through secure portals for providers (or their designees) to access.

Response: We wish to limit administrative burden for hospitals participating in the model and wish to clarify that while we will make data

available to hospitals only upon request, hospitals would be able to make a single request for these data at the start of the model that would make data available to them for the duration of their participation or until they notify CMS that they no longer wish to receive these data. To be consistent with the HIPAA Privacy Rule's ''minimum necessary'' standard, we will continue to make data available only in response to a request.

Final Decision: After consideration of the public comments we received, we are modifying our proposal at § 510.300 (d) to no longer limit the availability of updated data to a frequency ''no more often than once a quarter'' to instead ''no less frequently than on a quarterly basis'' with the goal of making these data available as frequently as on a monthly basis if practicable. We also clarify that in order to receive data during their participation in the model, a hospital need only make a single initial request rather than multiple periodic requests.

6. Legal Permission To Share Beneficiary-Identifiable Data

As stated in our proposed rule, we recognize that there are a number of issues and sensitivities surrounding the disclosure of beneficiary-identifiable health information, and note that a number of laws place constraints on sharing individually identifiable health information. For example, section 1106 of the Act bars the disclosure of information collected under the Act without consent unless a law (statute or regulation) permits for the disclosure. In this instance, the HIPAA Privacy Rule permits this proposed disclosure of individually identifiable health information by us.

We proposed to make participant hospitals financially responsible for services that may have occurred outside of the hospital during the 90-day post-discharge period. Although we expect hospitals to be actively engaged in post-discharge planning and other care during the 90-day post-discharge period for beneficiaries receiving LEJRs, as discussed in section III.A. of the proposed rule, we stated our belief that it was necessary for the purposes of the CJR model to provide participant hospitals with beneficiary-level claims data, either in summary or line-level claim formats for a 3-year historical period as well as on a quarterly basis during the performance period. We believe that these data constitute the minimum information necessary to enable the participant hospital to understand spending patterns during the episode, appropriately coordinate care, and target care strategies toward individual beneficiaries furnished care by the participant hospital and other providers and suppliers.

Under the HIPAA Privacy Rule, covered entities (defined as health care plans, providers that conduct covered transactions, including hospitals, and health care clearinghouses) are barred from using or disclosing individually identifiable health information (called ''protected health information'' or PHI) in a manner that is not explicitly permitted or required under the HIPAA Privacy Rule. The Medicare FFS program, a ''health plan'' function of the Department, is subject to the HIPAA Privacy Rule limitations on the disclosure of PHI. The hospitals and other Medicare providers and suppliers are also covered entities, provided they are health care providers as defined by 45 CFR 160.103 and they conduct (or someone on their behalf conducts) one or more HIPAA standard transactions electronically, such as for claims transactions. In light of these relationships, we believe that the proposed disclosure of the beneficiary claims data for an acute inpatient stay plus 90-day post-discharge episode where the anchor diagnosis at discharge was MS–DRG 469 or 470 would be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI for ''health care operations'' purposes. Under those provisions, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operations purposes if both covered entities have or had a relationship with the subject of the PHI to be disclosed, the PHI pertains to that relationship, and the recipient will use the PHI for a ''health care operations'' function that falls within the first two paragraphs of the definition of ''health care operations'' in the HIPAA Privacy Rule (45 CFR 164.506(c)(4)).

The first paragraph of the definition of health care operations includes ''conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines,'' and ''population-based activities relating to improving health or reducing health costs, protocol development, case management and care coordination'' (45 CFR 164.501).

Under our proposal, hospitals would be using the data on their patients to evaluate the performance of the hospital and other providers and suppliers that furnished services to the patient, conduct quality assessment and improvement activities, and conduct population-based activities relating to improved health for their patients. When done by or on behalf of a covered entity, these are covered functions and activities that would qualify as ''health care operations'' under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. Hence, as previously discussed, we believe that this provision is extensive enough to cover the uses we would expect a participant hospital to make of the beneficiary-identifiable data and would be permissible under the HIPAA Privacy Rule. Moreover, our proposed disclosures would be made only to HIPAA covered entities that have (or had) a relationship with the subject of the information, the information we would disclose would pertain to such relationship, and those disclosures would be for purposes listed in the first two paragraphs of the definition of ''health care operations.''

When using or disclosing PHI, or when requesting this information from another covered entity, covered entities must make ''reasonable efforts to limit'' the information that is used, disclosed or requested the ''minimum necessary'' to accomplish the intended purpose of the use, disclosure or request (45 CFR 164.502(b)). We believe that the provision of the proposed data elements listed previously would constitute the minimum data necessary to accomplish the CJR model goals of the participant hospital.

The Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act applies when the federal government maintains a system of records by which information about individuals is retrieved by use of the individual's personal identifiers (names, Social Security numbers, or any other codes or identifiers that are assigned to the individual). The Privacy Act prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply (5 U.S.C. 552a(b)).

''Routine uses'' are an exception to this general principle. A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the **Federal Register** about the applicable system of records describing to whom the disclosure will be made and the purpose for the disclosure. We believe that the proposed data disclosures are consistent with the purpose for which the data discussed in the proposed rule was collected and may be disclosed in accordance with the routine uses applicable to those records.

Notwithstanding these exceptions, in the proposed rule, we stated our belief

that it would be appropriate to provide some form of notice to Medicare beneficiaries about sharing these data. Based on our experiences with data sharing in other CMS programs and models, we proposed a strategy for notifying beneficiaries of claims data sharing in the proposed rule, and in order to provide meaningful beneficiary choice over claims data sharing with the participant hospitals in CJR. We considered both ''opt-in'' and ''opt-out'' options for beneficiaries with respect to data sharing in CJR. In our proposed rule, we noted that an advantage of an opt-in method was that consumers have consistently expressed a desire that their consent should be sought before their health information may be shared (Schneider, S. et al. ''Consumer Engagement in Developing Electronic Health Information System.'' Prepared for: Agency for Healthcare Research and Quality, July 2009, at 16. Available at: *http://healthit.ahrq.gov/ahrq-funded-projects/consumer-engagement-developing-electronic-health-information-systems*).

In the proposed rule, we also noted that an opt-out method has been used successfully in most systems of electronic exchange of information because it is significantly less burdensome on patients and providers while still providing an opportunity for patients to exercise control over their data. Thus, in our proposed rule, we proposed to use an ''opt-out'' approach to provide beneficiaries with the opportunity to decline claims data sharing directly through 1–800-Medicare, rather than through the participant hospital. We also proposed to provide advance notification to all Medicare beneficiaries about the opportunity to decline claims data sharing with entities participating in CMS programs and models through CMS materials such as the Medicare & You Handbook. The Handbook would include information about the purpose of the model, describe the opportunity for participants to request beneficiary identifiable claims data for health care operations purposes, and provide instructions on how beneficiaries may decline claims data sharing by contacting CMS directly through 1–800–MEDICARE. The Handbook would also contain instructions on how a beneficiary may reverse his or her preference to decline claims data sharing by contacting 1–800–MEDICARE.

In the proposed rule, we noted one advantage of these strategies was that 1–800–MEDICARE is a communication method to which beneficiaries have familiarity and broad exposure. It also has the capability for beneficiaries to use accessible alternative or appropriate assistive technology, if needed. Also, while many procedures in MS–DRGs 469 and 470 are planned in advance, some are emergent or unplanned procedures. Thus, asking the participant hospital to provide advance notification to the beneficiary, prior to the provision of services, may be inappropriate or impossible in certain circumstances. We indicated that we would continue to maintain a list of beneficiaries who have declined data sharing and ensure that their claims information is not included in the claims files shared with participants. Further, hospitals with patient portals or Blue Button® may have capability to garner patient input prior to discharge through a hospital intervention specific to patient and caregiver education, while also aiding the hospital to meet reporting requirements for other CMS programs, such as Meaningful Use under the EHR Incentive Program for Medicare Hospitals.

Finally, we proposed that participant hospitals in CJR would only be allowed to request beneficiary-identifiable claims data for beneficiaries who: (1) Have been furnished a billable service by the participant hospital corresponding to the episode definitions for CJR; and (2) have not chosen to opt-out of claims data sharing. A beneficiary that chose to opt-out of claims data sharing would only be opting out of the data sharing portion of the model. The decision to opt-out would not otherwise limit CMS' use of the beneficiaries' data, whether the beneficiary can initiate an episode, inclusion in quality measures, or inclusion in reconciliation calculations. Where a beneficiary chose to opt-out of claims data sharing, our data contractor would maintain a list of all HICNs that choose to opt-out of data sharing. We would monitor whether participant hospitals continue to request data on beneficiaries who have opted out of having their data shared and do not intend to make such data available in response to CJR such a hospital's request.

We requested comments on our proposals related to the provision of both aggregate and beneficiary-identifiable data to participant hospitals in CJR. We indicated that we were particularly interested in comments on the kinds and frequency of data that would be useful to hospitals, potential privacy and security issues, the implications for sharing protected health information with hospitals, and the use of a beneficiary opt-out, as opposed to an opt-in, to obtain beneficiary consent to the sharing of their information. We also requested comments on whether it would be helpful to provide any such system of notices, since Medicare claims information and other electronic information is already routinely shared for many other purposes among health care providers and insurers, and generally is subject to HIPAA protections. We also proposed where available, the exchange of CMS beneficiary data with the local electronic health information exchange, a system that allows doctors, nurses, pharmacists, other health care providers and patients to appropriately access and securely share a patient's vital medical information electronically in order to facilitate the hospitals ability to share timely patient data supporting improved patient referral, access, and care coordination across varied service settings.

The following is a summary of the comments received and our responses.

Comment: Several commenters requested that the range of providers with whom CMS shares data be expanded beyond participating hospitals, for example, to all CJR collaborators including physicians and PAC providers. A commenter suggested that hospitals should receive data, even if they were not in a participating MSA, in order to begin making improvements. Another commenter requested that researchers, entrepreneurs and/or health care consumers be provided data or a subset of these data. A commenter requested that a state be provided with the data provided to participating hospitals. This commenter noted that making these data available would assist the state in determining how such a payment model would work under their state Model. This commenter noted that the data would facilitate data-driven conversations with stakeholders around the state and assist in determining opportunities for improvement in their health care environment.

Commenters expressed views that expanding the availability of data would enable collaborators to be in a better position to improve their performance and management of patient care as well as ensure that care decisions are driven by patient needs rather than the potential financial risk of the hospital.

Response: We understand commenters' desire for us to expand the scope of entities that would receive beneficiary-identifiable claims data. However, we believe it is neither appropriate nor do we have the authority to expand the availability of these data beyond what we proposed. As indicated earlier, there are significant sensitivities and constraints

on our ability to make beneficiary-identifiable data available. We proposed to make these data available to hospitals participating in the model in recognition of and in compliance with these sensitivities and constraints. For example, we proposed to make these data available to hospitals as ''covered entities'' that had a relationship with a beneficiary under the HIPAA Privacy Rule provision that permits the disclosure of this information for ''health care operations'' purposes. Accordingly, requests for data from entities that are not participating in the model would not meet the required standards to receive these data. Thus, we do not believe that we can make data available under the model to outside entities such as researchers or states that might wish access to these data.

In the case of providers and suppliers (for example, physicians, PAC providers, etc.) that are collaborators with hospitals participating in the model, those providers and suppliers might be eligible to receive data under HIPAA provided that they had a relationship with the beneficiary. However, we do not believe it is appropriate for CMS to provide collaborators these data because hospitals are the entities designated under the model to assume risk and responsibility for a beneficiary's episode of care under the model. Accordingly, as the responsible entity (and as a covered entity under HIPAA), we believe that hospitals should decide what data they need to manage care and care processes with their collaborators and what data they may or may not wish to make available to those collaborators provided they are in compliance with the HIPAA Privacy Rule.

Comment: Commenters opposed our proposal to allow beneficiaries to opt out of having their data shared. Commenters pointed to difficulty in effectively managing care and improving outcomes for these beneficiaries in the absence of data. A commenter noted that when a hospital's episode volume is small, the impact of a single episode can have more significant financial consequences. Further, they expressed the view that access to complete data is important during the reconciliation process in order to validate changes in savings and gainsharing payments. A commenter noted that while beneficiaries can decline to have their data shared under the Shared Savings Program, few have elected this option. (We would note that in our December 2014 proposed rule for the Shared Savings Program (79 FR 72788), we indicated that approximately two percent of beneficiaries had declined to have their data shared.) The commenter also expressed the view that CMS was under no legal obligation to offer a data sharing opt out to beneficiaries and that the conditions for receiving data and potential criminal penalties should suffice to discourage misuse of the data. Some commenters pointed to other CMS programs and models where beneficiaries cannot opt out of having their data shared, for example, BPCI and the Hospital Readmissions Reduction Program (HRRP).

Some commenters suggested that CMS exclude from the model those beneficiaries who elect not to have their data shared. Another commenter recommended that CMS monitor the frequency with which beneficiaries opt out of sharing data and, if it reaches a certain threshold for a CJR participant, exclude those beneficiaries from payment calculations. Further, they requested that CMS seek stakeholder input on how to prevent providers from being disadvantaged by lack of data as well as the appropriate thresholds for excluding beneficiaries when data opt out has reached a certain level.

Response: We appreciate the desire among hospitals and other providers to have complete information on their assigned beneficiaries included in the CJR model. While in our proposed rule (80 FR41198), we stated our belief that it would be appropriate to provide some form of notice to Medicare beneficiaries about sharing their data, we agree with comments noting that we are not required by law to offer beneficiaries the choice to opt out of having their personal information shared with hospitals participating in the CJR model. Rather, the HIPAA Privacy Rule provides beneficiaries a right to request restrictions on the use of their data, but a covered entity, which includes the Medicare FFS program or a hospital participating in the model, may or may not choose to grant the requested restriction. We also concur with the comment that CMS does not offer beneficiaries the choice to opt out of having their data shared under either BPCI (see *https://innovation.cms.gov/Files/x/BPCI_Model2Background.pdf*, or *https://innovation.cms.gov/Files/slides/BPCI-Overview2-4.pdf*) or HRRP (see § 412.154(f)).

In consideration of the comments we received and our experience with programs and models such as BPCI, we have decided to provide participating hospitals with as complete data on their beneficiaries as is possible under the law. We believe that making these data available will enhance hospitals' ability to identify existing care patterns that need to be changed or strengthened as well as the kinds of strategies needed to improve their care practices so that they can be most successful under the model. Thus, we have decided to not finalize our initial proposal to allow beneficiaries the choice to opt out of having their data shared at this time. We would note, however, that this does not preclude beneficiaries from exercising their right to request restrictions on the use of their data either with the participant hospital or with CMS, which administers the Medicare FFS program, by contacting 1–800–Medicare, through which they can speak with a customer service representative who can address their concern.

Final Decision: We are not finalizing our proposal permitting beneficiaries the choice to opt out of having their beneficiary-identifiable data shared. We will make these data available to participant hospitals, upon request and in accordance with the HIPAA Privacy Rule. We will not, however, be providing beneficiary-identifiable data under this model to collaborators within the model or entities that are not participating in the model.

Comment: Commenters encouraged CMS to ensure its contractors that are responsible for making data available to participants provide accurate and complete data within acceptable timeframes. A commenter suggested the creation of an ombudsman to serve as a conduit for complaints and determining whether a contractor should be subject to a penalty. Another commenter suggested that if data were not delivered to a participant within a given period (for example, 90 days after the end of a calendar quarter), then payments to the participant should be increased by some percentage (for example, 5 percent) during the following quarter. Similarly, we also received a number of comments related to data sharing but not with respect to the CJR model. For example, some commenters expressed concerns with the quality and challenges of using data provided under the BPCI model.

Response: We appreciate the need for accurate, complete, and timely data and will work with our contractors to ensure they are achieving these goals according to the terms of their contracts. Likewise, consistent with the terms of their contracts, we will take appropriate corrective actions with contractors where performance falls short of expectations. While the model has not yet been implemented, we have no reason to expect that contractor performance should fall short of expectations and thus do not anticipate a need for a special ombudsman to address data complaints and assess

penalties. Moreover, given that the model is intended to encourage and reward participants for improving the efficiency and quality of care provided to beneficiaries undergoing LEJR procedures, we do not believe that it would be appropriate to increase payments to participants in response to less than satisfactory performance by administrative contractors, should it occur. Comments on data sharing under BPCI or other models or programs are outside the scope of this rule and we will not be addressing them.

Final Decision: In summary, we are finalizing our proposal at § 510.300(d) to make available to participant hospitals, through the most appropriate means, data that CMS determines may be useful to participant hospitals. We are finalizing our proposal to exclude information that is subject to the regulations governing the confidentiality of alcohol and drug abuse patient records (42 CFR part 2) from any beneficiary identifiable claims data shared with a hospital. We are finalizing our proposal to make 3 years of baseline data available to hospitals and note our intent to make these data available prior to the April 1, 2016 start date. We are modifying our proposal at § 510.300 (d) to no longer limit the availability of updated data to a frequency no more often than once a quarter to ''no less frequently than on a quarterly basis''. We also clarify that in order to receive data during their participation in the model, a hospital need only make a single rather than multiple periodic requests. We are not finalizing our proposal permitting beneficiaries the opportunity to decline having their beneficiary-identifiable data shared. We will make these data available to participant hospitals, upon request and in accordance with the HIPAA Privacy Rule. However, under the CJR model, we will not be providing these data to collaborators within the model or entities that are not participating in the model.

F. Monitoring and Beneficiary Protection

1. Introduction and Summary

We proposed the CJR model as we believe it is an opportunity to improve the quality of care and that the policies of the model support making care more easily accessible to consumers when and where they need it, increasing consumer engagement and thereby informing consumer choices. For example, under this model we proposed certain waivers that would offer participant hospitals or their collaborators additional flexibilities with respect to furnishing telehealth services, post-discharge home visits, and care in SNFs, as discussed in section III.C.11. of this final rule. We believe that this model will improve beneficiary access and outcomes. Conversely, we do note that these same opportunities could be used to try to steer beneficiaries into lower cost services without an appropriate emphasis on maintaining or increasing quality. We direct readers to sections III.C.5. and III.D. of this final rule for discussion of the methodology for incorporating quality into the payment structure and the measures utilized for this model.

We believe that existing Medicare provisions can be effective in protecting beneficiary freedom of choice and access to appropriate care under the CJR model. However, because the CJR model is designed to promote efficiencies in the delivery of all care associated with LEJR procedures, providers may seek greater control over the continuum of care and, in some cases, could attempt to direct beneficiaries into care pathways that save money at the expense of beneficiary choice or even beneficiary outcomes. As such, we acknowledge that some additional safeguards may be necessary under the CJR model as providers and suppliers are simultaneously seeking opportunities to decrease costs and utilization. We believe that it is important to consider any possibility of adverse consequences to patients and to ensure that sufficient controls are in place to protect Medicare beneficiaries receiving LEJR related services under the CJR model.

2. Beneficiary Choice and Beneficiary Notification

We have proposed that hospitals in selected geographic areas will be required to participate in the model, and that individual beneficiaries will not be able to opt out of the CJR model when they receive care from a participant hospital in the model. We stated our belief that it is not appropriate or consistent with other Medicare programs to allow patients to opt out of a payment system that is unique to a particular geographic area. For example, the state of Maryland has a unique payment system under Medicare, but that payment system does not create an alternative care delivery system, nor does it in any way impact beneficiary decisions. We also stated our belief that an inability to opt out of a payment system does not limit beneficiary choice as all covered Medicare services remain available under the model. We stated that we did not believe that an ability to opt out of the payment system was germane to beneficiary decisions because this model does not change beneficiary cost-sharing. We also stated our belief that full notification and disclosure of the payment model and its possible implications is critical for beneficiary understanding and protection, given that under all payment systems it is important to create safeguards for beneficiaries to ensure that care recommendations are based on clinical needs and not inappropriate cost savings. It is also important for beneficiaries to know that they can raise any concerns with their physicians, with 1–800–MEDICARE, or with their local QIOs.

This model does not limit the ability to choose among Medicare providers or the range of services available to the beneficiary. Beneficiaries may continue to choose any Medicare participating provider, or any physician or practitioner who has opted out of Medicare, with the same costs, copayments and responsibilities as they have with other Medicare services regardless of whether the provider or supplier is a participant hospital or has entered into a sharing arrangement with a participant hospital. Physicians and hospitals may identify and recommend ''preferred providers,'' a term used to include both providers and suppliers, which may include but are not limited to CJR collaborators with sharing arrangements with the participating hospital, as long as such recommendations do not result in violations of current laws or regulations. However, participant hospitals may not restrict beneficiaries to any such list of preferred or recommended providers/suppliers and must clearly advise beneficiaries that their choices are not constrained. Moreover, hospitals may not charge any CJR collaborator a fee to be included on any list of preferred providers or suppliers, nor may the hospital accept such payments, which would be considered to be outside the realm of risk-sharing agreements. Thus, this proposed payment model does not create any restriction of beneficiary freedom to choose providers and suppliers, including surgeons, hospitals, PAC or any other providers or suppliers.

As participant hospitals redesign care pathways, it may be difficult for providers and suppliers to sort individuals based on health care insurance and to treat them differently. We anticipate that care pathway redesign occurring in response to the model will increase coordination of care, improve the quality of care, and decrease cost for all patients, not just for Medicare beneficiaries. This anticipated

change in the delivery of care to all patients may further promote consistent treatment of all beneficiaries.

We stated our belief that beneficiary notification and engagement is essential because there will be a change in the way participating hospitals are paid. We stated our belief that appropriate beneficiary notification should explain the model, advise patients of both their clinical needs and their care delivery choices, and should clearly specify that any non-hospital provider or supplier holding a risk-sharing agreement with the hospital should be identified to the beneficiary as a ''financial partner of the hospital for the purposes of LEJR services.'' These policies seek to enhance beneficiaries' understanding of their care, improve their ability to share in the decision making, and ensure that they have the opportunity to consider competing benefits even as they are stated with cost-saving recommendations. We stated our belief that appropriate beneficiary notification should do all of the following:

- Explain the model and how it will or will not impact their care.
- Inform patients that they retain freedom of choice to choose providers and services.
- Explain how patients can access care records and claims data through an available patient portal and through sharing access to caregivers to their Blue Button® electronic health information.
- Advise patients that all standard Medicare beneficiary protections remain in place. These include the ability to report concerns of substandard care to QIOs and 1–800–MEDICARE.

After carefully considering the appropriate timing and circumstances for the necessary beneficiary notification, we proposed in the preamble that participating hospitals must require all providers and suppliers who execute a sharing arrangement with a participant hospital to share certain notification materials, to be developed or approved by CMS, that detail this proposed payment model before they order an admission for joint replacement for a Medicare FFS patient who would be included under the model. Participant hospitals must require this notification as a condition of any sharing arrangement. We also proposed in the preamble that where a participant hospital does not have sharing arrangements with providers or suppliers that furnish services to beneficiaries during a CJR episode of care, or where the admission for joint replacement for a Medicare FFS patient who would be included under the model was ordered by a physician who does not have a sharing arrangement, the beneficiary notification materials must be provided to the beneficiary by the participant hospital. However, we proposed text regulations that would require this notification by the hospital in all instances, a requirement we will keep in this final rule. The purpose of this proposed policy is to ensure that all beneficiaries that initiate a CJR episode receive the beneficiary notification materials, and that they receive such materials as early as possible. We stated our belief that this proposal targets beneficiaries for whom information is relevant, and increases the likelihood that patients will become engaged and seek to understand the model and its potential impact on their care.

We noted that beneficiaries are accustomed to receiving similar notices of rights and obligations from healthcare providers prior to the start of inpatient care. However, we also considered that this information might be best provided by hospitals at the point of admission for all beneficiaries, as hospitals provide other information concerning patient rights and responsibilities at that time. We invited comment on ways in which the timing and source of beneficiary notification could best serve the needs of beneficiaries without creating unnecessary administrative work for providers. We stated our belief that this notification is an important safeguard to help ensure that beneficiaries in the model receive all medically necessary services, but it is also an important clinical opportunity to better engage beneficiaries in defining their goals and preferences as they share in the planning of their care.

The following is a summary of the comments received and our responses.

Comment: Some commenters requested clarification as to the meaning of our statement in the proposed rule that beneficiaries could not ''opt out'' of the model. Others were concerned that this could restrict beneficiary choice. Several commenters expressed an opinion that beneficiaries should be able to opt out of the CJR model if they believed that it might result in a less than optimum outcome.

Response: In proposing that beneficiaries are not able to ''opt out'' of the CJR model, we meant that beneficiaries are not able to ''opt out'' of having their care—when furnished in a CJR episode—paid for under the bundled payment methodology. This does not mean that their right to choose or decline otherwise covered Medicare items and services is limited. CJR is a test of a new payment methodology, and as such, it is similar in many respects to other payment methodologies that already exist in Medicare, such as the hospital IPPS. For example, payment under the IPPS is a bundled payment but does not create new coverage limits for services contained within the bundle. This model will test changes to how we pay for care, but like Medicare payment systems, it neither defines nor limits coverage, nor limits beneficiary choices to any specific covered services. Providers may be influenced by the CJR payment model, but in our view this would be similar to how they may be influenced by other payment methodologies in Medicare. In both cases, providers are expected not to treat Medicare beneficiaries differently from other patients based on differences in Medicare payment. Moreover, the safeguards discussed in this final rule exist to ensure that the payment structure does not disadvantage Medicare beneficiaries. We note that within traditional FFS Medicare we do not allow beneficiaries to opt out of any Medicare payment systems as payment systems exist to ensure appropriate payments for similar services across beneficiaries and across providers. Furthermore, because beneficiary cost sharing will be unchanged under this model, it will not have a direct financial effect on beneficiaries and therefore minimizes any impacts on beneficiary freedom of choice.

Comment: Commenters questioned whether hospitals should be allowed to maintain lists of preferred providers and suppliers. They expressed many concerns about the tradeoffs between beneficiary choice and the ability of the participant hospital to steer, direct, or compel beneficiaries into certain paths or to certain providers and suppliers. The more common sentiment was that CMS should allow hospitals to clearly identify their clinically integrated, preferred partners and promote these relationships to patients as a way of promoting their care redesign efforts. Commenters expressing this view stated that CMS should allow hospitals to differentiate between preferred and non-preferred PAC providers and suppliers, with hospitals determining the providers and suppliers who were in each category. This situation was described as a ''network'' of preferred providers.

Other commenters believed that hospitals should be required to define criteria for inclusion in a ''preferred network'' based in whole or in part on non-financial criteria such as quality metrics, or that hospitals should define and publish the criteria that they use. Other commenters believed that hospitals should be required to offer the same gainsharing contracts to all willing providers or suppliers. Other

commenters pointed to section 1861(ee)(2)(H) of the Act, which states that hospitals must ''not specify or otherwise limit the qualified provider which may provide post-hospital home health services, and identify any entity to whom the individual is referred in which the hospital has a disclosable financial interest or which has such an interest in the hospital.'' These commenters believe that the Act precludes hospitals from establishing and promoting networks under any circumstances.

Commenters recommended that the Secretary establish minimum criteria such as quality of care, health outcomes, price, accessibility, willingness to work together on evidence-based protocols, and patient experience of care, and that CMS should exercise caution if it permits the recommendation of specific providers, given concerns that the hospital may not have an adequate understanding of the difference between providers or provider types or that the hospital may drive patients to ''low cost'' providers in order to retain a greater share of the savings while putting beneficiaries at clinical risk by potentially stinting on care. However, commenters noted that hospitals must be able to limit the options stated to patients because the hospital will be financially responsible for costs in the episode.

Response: We agree that hospitals should be allowed to identify preferred providers and suppliers. We believe, as we stated in our proposed rule, that there are ways to balance beneficiary freedom of choice with the ability of hospitals to leverage efficiencies and cost savings that may occur through the use of certain providers/suppliers. On the one hand, we proposed that hospitals could recommend certain providers/suppliers, including providers/suppliers who are CJR collaborators. On the other hand, we proposed that hospitals could not limit beneficiary choice, must inform beneficiaries of all available providers/suppliers, must inform beneficiaries that their choices are not limited to preferred providers/suppliers, and must inform beneficiaries of the mechanisms by which they may file concerns, complaints or grievances. We do not believe that it is necessary to require hospitals to publicize or standardize their preferred provider/supplier selection criteria or release details of their sharing arrangements, as we believe that our proposal, which we are finalizing in this final rule, sufficiently protects beneficiary access while providing the necessary flexibility to hospitals to leverage their relationships with efficient providers and suppliers.

We believe that allowing hospitals to disclose those providers and suppliers who best contribute to improved efficiency and better outcomes does not limit beneficiary choice, provided that beneficiaries are fully informed of any financial dealings that could create a conflict of interest. We therefore believe that identifying these preferred providers/suppliers is consistent with section 1861(ee)(2)(H) of the Act, as it does not specify or limit qualified providers/suppliers that may provide PAC, and we believe that our requirement that beneficiaries must be notified of financial arrangements is both consistent with and required by that section. We further believe that the proposed requirement to notify beneficiaries of all preferred and non-preferred PAC providers/suppliers, coupled with the requirement to identify CJR collaborators that we are finalizing in this rule, provides beneficiaries with sufficient information to allow them to avoid improper steering or referral.

Comment: Commenters expressed concern that if hospitals were allowed to maintain and promote a network of preferred providers/suppliers, additional steps were needed to ensure that beneficiaries had access to the entire spectrum of PAC providers. Some commenters suggested that hospitals should be required to ensure that they have an adequate network of PAC providers and have partnerships with a full range of PAC providers. Some commenters also believed that hospitals should be required to document that the full range of PAC providers was offered, documenting conversations with patients about all treatment options, and requiring that discussions between the patient and unbiased care team members should all be on record.

Response: We do not agree with these recommendations from commenters. With respect to the extent of the network, we note that different communities have different assortments of PAC providers/suppliers that meet the unique needs of that community. Requiring a full range of PAC providers/suppliers in a network could disrupt established patterns of care in a manner that we do not intend and is not necessary for success under the model, and thus we decline to adopt such a requirement. With respect to specific documentation requirements suggested by commenters, although we agree with the intent of ensuring that hospitals provide full disclosures to beneficiaries, we do not believe that additional regulatory requirements are necessary as hospitals are best positioned to determine the ways in which they can use their existing medical records and discharge planning to document compliance with all applicable Medicare beneficiary notification requirements, including the requirements we are finalizing in this rule, without creating a new administrative burden, which could be extensive if specific conversations were required to be documented.

Comment: Many commenters commented on the timing, content and form of the initial beneficiary notification of the model. Most commenters believed that notification at the point of admission was too late and was not occurring at a time when beneficiaries could process and act on the information. They recommended that notification should be provided at least a week prior to admission or during the individual's consultation with their physician, prior to surgery. A commenter suggested that basic fact sheets should be made available to beneficiaries in physician offices. Another commenter believed that we should require CJR hospitals to meet with prospective beneficiaries prior to admission so that this notification could be delivered and discussed.

With respect to content, some commenters believed that the notification should be highly standardized, based on a standard or model notice created by CMS, or even that CMS should create and provide a single notice to all beneficiaries. Other commenters believed that the notice should reflect specifics of the PAC specific network or of the patient, informing beneficiaries of differences in capacity and patient incurred costs among the various settings or explaining the patient's ability to choose their own PAC provider/supplier, even if the hospital is not satisfied with the quality of the provider/supplier that is chosen. Finally, a commenter believed that the model should be considered to be human experimentation and should follow human subject notice requirements.

With respect to form, several commenters opined that beneficiary notification should be permitted on an electronic basis, with proof of receipt by the beneficiary rather than a paper process that requires a beneficiary's signature.

Response: We believed that we had identified the essential elements in our proposed rule, and that any notice that was compliant with those elements would provide sufficient notice to the beneficiary. We acknowledge that this model will be collecting information

about humans as we monitor the impact of this payment model on the quality and efficiency of the delivery of patient care, but we further note that, under the public benefit exemption at 45 CFR 46.101(b)(5), this would qualify for exemption from the HHS human subjects regulatory requirements, and is therefore not required to comply with those requirements. However, we agree with commenters that additional specific details regarding the notice requirements and a model notice will improve the consistency of the notification. We discuss those additional requirements in the following paragraphs and we will incorporate them in a model notice or model notices which we will produce. We will produce a model notice or model notices, or versions of a model notice, that will satisfy our notice requirements for physicians who are CJR collaborators, for PAC providers and suppliers who are involved in a sharing arrangement, and for participant hospitals, who are required to provide beneficiaries with general notice of the CJR model.

With respect to timing, we proposed that beneficiaries should be notified at the point of admission because it is hospitals that are participants in the model, not physicians. We do not agree that the point of admission is too late, noting that the point of admission is when notice of other patient rights regarding the hospital stay are required by Medicare. However, we acknowledge that earlier notification of the beneficiary is desirable. We concur that a beneficiary fact sheet and/or a standard notification form for voluntary distribution in the physician's office would be helpful, and that physicians should be encouraged to explain the model to prospective patients as early as possible. In addition to the model notification forms for hospitals, physicians, and PAC providers/suppliers that we will develop and publish prior to the start of the model, we will consider developing a model fact sheet as we develop educational materials, and we note that participant hospitals are not precluded from developing such fact sheets for the use of their medical staff. Furthermore, we agree that, in the limited case of physicians who have sharing arrangements with hospitals, we are modifying the regulations text from what we proposed to specify that hospitals must include in any physician sharing arrangement a condition under which the collaborating physician—(1) Agrees to notify the patient of the structure of the CJR model; (2) agrees to inform the patient that the physician is participating in a sharing arrangement; and (3) agrees to deliver that information at the time that a decision for surgery is made. We also will modify our proposal in response to concerns that more PAC-specific notice is necessary. In addition to this physician notification requirement, we will require notification of involvement in a sharing arrangement from any other providers and suppliers engaged in a sharing arrangement with a participant hospital, with that notice of involvement to be delivered before the first time a service related to the joint replacement, such as a PAC SNF stay, is furnished to the beneficiary by that entity. However, in response to comments to preserve participant hospitals' flexibility, as we previously discussed we are not finalizing our proposal that these notices would be approved by CMS, but we will instead develop one or more model notices that participant hospitals and others can use.

With respect to form, we agree with commenters that written communication is not limited to paper, and we note that we did not propose a written signature requirement in regulation. We agree that electronic health records may be used to maintain documentary evidence of written communications, and we have not specified a specific mechanism by which proof of beneficiary notification must be maintained.

Comment: Commenters were varied in their opinions regarding the requirements for the hospital to identify PAC providers/suppliers at the point of admission and/or the point of discharge planning. Many commenters believed that the hospital should be required to provide a list of all PAC providers. There was a concern that the CJR model may function like ACO networks, where it will be mandatory to tell beneficiaries which providers are in network, but it will not be mandatory to disclose out-of-network options. It was common, but not universal, for commenters to believe that the list could distinguish the providers included within a CJR participant hospital's provider network (preferred) from those not participating in the CJR model (not preferred), that is, which PAC providers are ''collaborators.'' Some commenters believed that financial arrangements should be disclosed, while others believed that non-financial arrangements should also be disclosed. Focusing on the list of collaborators, commenters suggested that the hospital identify all CJR collaborators and should further identify differences between CJR collaborators that may be important to beneficiaries, including such things as their geographic proximity.

Response: Noting the wide range of comments, we believe that our proposed rule represents a middle position that adequately balances transparency and beneficiaries' need to know their full range of options with hospitals' desire to inform beneficiaries to which PAC providers/suppliers are most efficient and provide the highest quality care. We believe this is best accomplished by requiring hospitals to provide beneficiaries with a complete list of all PAC providers/suppliers in the area but allowing them to identify ''preferred providers,'' that is, high-quality, efficient providers whom a participant hospital would prefer patients choose, on the basis of internal assessments of quality and cost. Because we recognize that there may be many high quality and efficient PAC providers/suppliers who do not enter into sharing arrangements, we do not believe that a hospital's list of preferred providers/suppliers must include only CJR Collaborators, nor do we believe that all CJR Collaborators must be considered to be preferred providers/suppliers. We do not believe that the details of sharing arrangements need to be disclosed, as those arrangements may be business-sensitive, but we do believe that the existence of any CJR gainsharing or other financial relationship with any physician or PAC provider must be disclosed. We recommend that hospitals be transparent in how preferred providers/suppliers are generally selected, and we note that policies that define the relationships between the participant hospital and the physicians and PAC providers/suppliers in its region must be consistent with applicable law, but we do not believe that the details of hospitals' internal business processes must be disclosed. However we do agree that additional notification as part of discharge planning is important. We will also modify our proposal in response to comments to add a patient-specific financial notification at the point of discharge planning. We will require that a supplementary notification should be made available to beneficiaries, requiring that hospitals must, at the point of discussing PAC options, provide written notification to beneficiaries if the hospital makes any referrals for non-covered services during discharge planning. Specifically, hospitals shall be required to notify beneficiaries of any transfers to a SNF under circumstances in which the SNF stay will not be covered, and also notify the beneficiary of any other referral for PAC that the hospital knows or should

have known will not be covered by Medicare.

Comment: Commenters requested that CMS provide additional information about what details must be included in the beneficiary notices, and stated that significant education of hospitals will be required. To promote facility compliance and avoid improper interpretations or incorrect assessments at audit, some commenters urged CMS to completely waive hospital discharge planning requirements that prohibit hospitals from specifying or otherwise limiting the information provided on post-hospital services. Other commenters recommended that we provide specific guidance on how to facilitate and operate within partnerships with PAC collaborators (whether a financial or simply a clinical partnership exists) while also complying with existing patient choice requirements. A commenter suggested that hospitals could continue to be required to—(1) Inform the patient or the patient's family of their freedom to choose among participating Medicare providers of post-hospital care services; (2) respect patient and family preferences when they are expressed; (3) present a complete list of qualified providers that are available to the patient; and (4) recommend high quality PAC providers with whom they have relationships (either financial and/or clinical) for the purpose of improving quality, efficiency or continuity of care.

Response: We agree that additional guidance may be helpful and believe that, in addition to the discussions we have included in this preamble to our final rule, such information may best be provided as additional detail in the regulation text governing beneficiary notification and supplemented by published guidance and educational materials. We agree with commenters' suggestions of additional details that they believe should be specified in order to promote understanding, consistency and compliance. Therefore, we will modify the beneficiary notice requirements as recommended in comments, to require participant hospitals to—(1) Inform the patient or the patient's family of their freedom to choose among participating Medicare providers/suppliers of post-hospital care services; (2) respect patient and family preferences when they are expressed; and (3) present a complete list of qualified providers/suppliers that are available to the patient. We believe that these requirements were inherent in our proposal to require notice of all qualified providers/suppliers but we acknowledge that the additional details may be helpful.

We do not agree that a waiver of existing discharge planning requirements is necessary, and we discuss the specification of allowable and non-allowable financial arrangements in section III.C.10. of this proposed rule. However, we will also add additional details concerning financial arrangements to our notice requirements in order to protect beneficiaries while ensuring that hospitals, if desired, may recommend ''preferred providers,'' that is, high quality PAC providers/suppliers with whom they have relationships (either financial and/or clinical) for the purpose of improving quality, efficiency, or continuity of care. Specifically, in order to address financial concerns deriving from potential conflicts of interest, we will specify that hospitals and collaborators must disclose the existence of sharing arrangements. In order to protect against situations which might expose beneficiaries to unexpected liability, we will also specify that hospitals must provide written notification of any non-covered services which are recommended or considered as part of discharge planning whenever a hospital knows or should have known that such services are non-covered.

Comment: Commenters were concerned that it could be confusing to inform beneficiaries that any participating SNF could provide covered services if the 3-day stay rule was met, but that SNFs meriting 2 stars or less would not be covered under the 3-day waiver provisions. This was believed to be particularly problematic because individual star ratings can change frequently, making it difficult for hospitals to keep up with all current ratings. Commenters inquired whether they could limit the list of PAC providers stated to beneficiaries.

Response: We do not agree that this is overly confusing as beneficiaries already understand that there are statutes and regulations that define the circumstances under which SNF stays are covered, for example, following a 3-day hospital stay. Moreover, we have stated that it is essential for beneficiary choice to ensure that beneficiaries are informed of all covered opportunities available to them, including PAC providers/suppliers considered by the hospital to be preferred as well as non-preferred. Since stays in SNFs that do not meet the conditions of the 3-day waiver would be covered by Medicare if they met the existing conditions for coverage (that is, the beneficiary has a qualifying 3-day hospital stay), these SNFs still must be included in any complete list of PAC providers. Providing the complete list is necessary to meet the requirements of section 1861(ee)(2)(H) of the Act, a requirement which we believe promotes beneficiary choice. However we do note that the star rating may be critical for the beneficiary to determine liability in the event that a beneficiary is discharged with less than a 3-day stay. We had proposed that cost-sharing and quality information must be provided to beneficiaries where applicable and we agree with commenters who recommended that additional information about beneficiary liability could be provided. Therefore, we are modifying our requirement to notify the beneficiary of all covered PAC options by adding that this list of PAC options stated as part of discharge planning must be accompanied by a written statement that identifies any non-covered services to which the beneficiary may be referred. Specifically, in the event that the patient is discharged prior to completing a 3-day stay, the hospital will be required to clearly identify, in writing, any 1 or 2 star SNFs on the complete list of PAC providers provided to the beneficiary. In the event of a discharge prior to a 3-day stay, the list must also include a statement that the named beneficiary, having not completed a 3-day stay in the acute care hospital, would be entirely financially responsible for a stay at any of those 1 or 2 star SNFs.

Final Decision: After consideration of the public comments received, we are finalizing our proposal to require that hospitals in the CJR model notify beneficiaries of the requirements surrounding the model at the point of admission to the hospital and we are modifying our proposal to add additional detail to the content, timing and form of our notification requirements in response to comments, as specified in this paragraph. We will continue to require participant hospitals to provide beneficiaries on admission with a general notice of the existence of the model and of certain beneficiary rights. We are requiring that, as discussed in the preamble to the proposed rule, participant hospitals must require as a condition of any sharing arrangement that the collaborators must notify beneficiaries of the existence of a sharing arrangement. We are modifying our regulations to specify that, in the case of physicians, this notification must occur at the point of the decision to proceed to surgery, or, in the case of other collaborators, prior to the furnishing of the first service provided by the

collaborator that is related to the joint replacement. We additionally are finalizing with modification our PAC notification requirements, specifying that participant hospitals as part of discharge planning must inform beneficiaries of all Medicare participating PAC providers/suppliers in an area but may identify those providers/suppliers that the hospital considers to be preferred. To increase beneficiary awareness we are specifying that the participant hospital must also as part of this specific second notice inform the beneficiary of providers/suppliers with whom a sharing arrangement exists. We are further modifying the notification requirements to require participant hospitals to reference the most recently published CMS list of SNFs which qualify for the waiver of the 3-day rule. This modification is to specifically notify beneficiaries of their liability should they be discharged upon a less-than-3-day stay to a SNF that does not qualify for the waiver that we are finalizing for this model, and to notify the beneficiary of possible beneficiary liability if the hospital recommends or refers the beneficiary to any other services, which it knows or should have known to be non-covered services under Medicare. This latter notice is in addition to any ABN or other hospital notice of noncoverage that may be required under existing regulations.

3. Monitoring for Access to Care

Given that participant hospitals would receive a reconciliation payment when they are able to reduce average costs per case and meet quality thresholds, they could have an incentive to avoid complex, high cost cases by referring them to nearby facilities or specialty referral centers. We intend to monitor the claims data from participant hospitals—for example, to compare a hospital's case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded. We will publish these data as part of the model evaluation to promote transparency and an understanding of the model's effects. We also proposed to continue to review and audit hospitals if we had reason to believe that they are compromising beneficiary access to care. For example, where claims analysis indicates an unusual pattern of referral to regional hospitals located outside of the model catchment area or a clinically unexplained increase or decrease in joint replacement surgery rates.

The following is a summary of the comments received on monitoring for access to care, and our responses.

Comment: Many commenters reported concerns related to ways in which the payment structure might adversely impact the services that were available to beneficiaries. Commenters also suggested a number of approaches to mitigate those general risks, such as increased risk adjustment, and increased quality measures in order to improve beneficiary protections. These comments are addressed in the preamble sections most closely concerned with the individual topics.

Commenters raised a number of questions about determinations of medical necessity and their effect on access to care. A commenter, quoting our proposed rule in which we stated that gainsharing payments and alignment of payments must not induce collaborators to limit medically necessary services, requested that we articulate who will decide what is medically necessary and how this determination would be made. That commenter recommended that we encourage the use of treatment protocols based on objective criteria. Other commenters urged us to require CJR participant hospitals to demonstrate that they have appropriateness criteria in place to assess beneficiary need for joint replacement.

Commenters had two competing concerns. First, they were concerned that the bundled payment created a risk of patient ''dumping,'' or inappropriately referring patients to other providers based on financial considerations. They were concerned that surgeons/hospitals will avoid complex/sicker patients not only to avoid the losses associated with expensive cases but also to avoid cases at risk for readmission. Similarly, they stated that hospitals will avoid lower socioeconomic patients unless there is a socioeconomic risk adjustment. Commenters suggested that these risks could be mitigated by adding specific, separate penalties for withholding care or steering patients inappropriately or rejecting patients entirely. These penalties should progress up to and include termination from Medicare.

Second, commenters identified a risk of overutilization. These commenters believed that some physicians and hospitals will provide services to healthier patients who could benefit from less invasive treatments in order to improve their metrics, or increase volume to account for lost revenue, or treat healthier patients, which will result in adjustments to a hospital's patient mix. A commenter asserted that both influences are already in effect, with considerable overutilization of LEJR (based on regional variation) and also with some studies suggesting that ''only 1 in 10 patients needing LEJR are getting it.''

Commenters also recommended other steps in addition to a general recommendation for an appropriateness (medical necessity) measure to gauge the appropriateness of care at the beginning of the episode. It was for this reason that commenters urged us to require CJR participant hospitals to demonstrate that they have appropriateness criteria in place to assess beneficiary need for joint replacement. Commenters urged CMS to monitor changes in utilization patterns and case mix as part of the evaluation, and to generally monitor whether barriers to patient access develop in MSAs participating in the CJR program, and to make necessary alterations to the model if complicated hip/knee replacement cases are found to be underserved.

Response: We acknowledge that overutilization and underutilization are both potential issues related to access. We note that the usual tools employed by CMS to monitor and prevent overutilization all apply to the services delivered within the CJR model. These tools include data analysis, the process of tracking patterns of utilization and trends in the delivery of care, and medical review, a clinical audit process by which we verify that services paid by Medicare were reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act. We believe that these tools as employed by the MACs and by the QIOs will be sufficient to check for the medical necessity of CJR services. We do not believe that it is necessary to impose a requirement that hospitals maintain specific appropriateness criteria. We note that there are a wide variety of criteria developed by national healthcare organizations, including providers and payers, and that a process that is appropriate for a large facility with many community physicians might not be workable in a smaller facility with a single LEJR surgeon. With respect to underutilization, we agree that it is important for us to monitor changes in utilization patterns and case mix, and to generally monitor whether barriers to patient access develop in MSAs participating in the CJR model. We note that this is encompassed by the evaluation process for the model, so we will be able to make necessary alterations to the model if complicated cases are found to be underserved. However, we do not at this time believe that specific requirements for medical necessity or utilization review are necessary, beyond those broad requirements which are set by the CoPs,

such as those at § 482.30. We believe that the existing influences of reputation, care guidelines, QIO review, Joint Commission review, quality metrics, and our retrospective model evaluation are sufficient to ensure that beneficiary access to care is not impeded.

We also agree with commenters that additional specific regulatory detail should be added to address the consequences of systemic underutilization. We proposed that participant hospitals would not be eligible for reconciliation payments if those payments are associated with actions that threaten beneficiary health, and we note that systemic instances of under-delivery of care threaten that health and therefore constitute a reason to withhold reconciliation payments. We also note that we have the authority to revoke provider enrollment in the Medicare program for cause, such as providing substandard care that places beneficiaries at risk that, is, by under-delivering care. As an intermediate step, we further note that we have additional options, such as requiring additional actions under a corrective action plan in order to avoid revocation. However, we reiterate that we do not believe such aggressive measures are necessary, as we believe that such concerns as reputation and patient outcomes provide sufficient motivation for most providers/suppliers.

Comment: Commenters also identified concerns about inappropriate limitations of access to certain services due to network restrictions for beneficiaries who are appropriately undergoing a joint replacement. Some commenters believed that the current CJR proposal has the potential consequence of encouraging hospitals to select only the most ''efficient'' or ''cost effective'' orthopedic surgeon to enter into sharing arrangements or to continue having admitting privileges. Hospitals might de-credential or restrict surgeons who treat expensive patients. Similar concerns exist for PAC providers; the model might encourage hospitals to limit access to small providers/suppliers, or encourage hospitals to buy small PAC providers and even physician practices. While integrated systems may lead to more coordinated care, consolidation may also lead to price increases and diminished quality as competition is reduced. Commenters believed that CMS should introduce a prohibition of any practice of excluding ''less efficient'' or ''less cost effective'' surgeons or PACs. Other commenters suggested that we should monitor activities involving distribution of payments to guard against unfair business practices and to promote a fair and equitable distribution of savings for all providers who are involved as collaborators.

Response: While we recognize the concerns that higher quality is sometimes at odds with lower cost, we note that the purpose of this model is to encourage more efficient delivery of high quality care, that is, to reduce cost while maintaining or increasing quality. We believe that such factors as reputation and peer-reviewed practice guidelines work to ensure that hospitals and physicians will continue to provide quality services. We also believe that the antitrust laws help to prevent anti-competitive practices in the maintenance of hospital networks, allowing competition between network providers to promote high quality outcomes. While we believe that antitrust laws, anti-kickback provisions and other existing laws and regulations may help deter the business practices which concerned commenters, we agree that additional monitoring is prudent and will therefore monitor sharing arrangements and beneficiary and provider/supplier comments for any evidence of anticompetitive behavior.

Comment: In addition to the previous commenters' concerns about opportunities for participant hospitals to restrict beneficiary access to specific providers, commenters were also concerned about opportunities for the under-delivery of care by providers the beneficiary did access, that is, underdelivery of care by the participant hospitals and their collaborators. This practice is often referred to as ''stinting.'' Commenters were concerned that the CJR model does not represent a balanced approach to improve quality while reducing cost. Overall, they believed that the use of Medicare spending per beneficiary scores as a key indicator will drive hospitals to low cost care at the expense of quality. Specific concerns were that patients may be directed away from more expensive PAC options (IRFs or SNFs, for example), it will discourage extensive therapy in the PAC environment even when warranted, less attention will be paid to such positive factors as prevention (for example, falls), pain management and overall outcomes, and readmissions may be avoided even when necessary. A commenter was also concerned that beneficiaries may be forced to attend in-network facilities rather than out-of-network facilities near their homes. To mitigate these concerns, commenters recommended that controls be put in place to ensure that sicker patients receive LEJR and appropriate higher intensity PAC, to ensure that collaborators do not reduce or limit medically necessary services to any beneficiary, and to ensure that physicians continue to select the devices, supplies and treatments that are in the best interest of the patients. They recommended a pre-model hospital review, that hospitals have the ability to deliver, or contract for, evidence-based care for the entire bundle of services, including the capacity to provide all levels of rehabilitation services, including people with disabilities or who may need intensive rehabilitation services and/or community supports. Finally, several commenters recommended that alternative payment options should be considered for otherwise expensive environments such as the IRF, SNF, and, in the case of outpatient surgery, the outpatient hospital or ambulatory surgical center.

Response: We agree that commenters have accurately described possible risks, and we note that similar risks are inherent in all bundled payment models and systems. For example, commenters expressed similar concerns when DRGs were introduced in 1985, yet DRGs are now used in the established IPPS. After 30 years of use, we have not reported any evaluations establishing that the economic pressures to create efficiencies have compromised beneficiary care, so we do not expect different results with this model. Nonetheless, we agree that monitoring is necessary in order to further reduce these potential risks. However, we have consistently found that those traditional authorities available to the Secretary, previously discussed in their role to prevent the use of limited networks to avoid the delivery of necessary services, are adequate to provide a counterbalance to the economic incentives that could drive underdelivery of care. Therefore, we believe that we must use our existing oversight authority to monitor the risks of this payment model, just as we monitor the various risks inherent in all payment models and systems, but we do not believe that new controls are necessary which require specific incorporation into regulation, other than those which we proposed and we have now modified in response to comments.

We do not believe that the additional controls are necessary because we have a number of established mechanisms by which we will monitor for evidence of the underdelivery of care, and by which we can react to and mitigate any identified problems. We will be monitoring data in the process of calculating quality metrics, and we have several reporting mechanisms, such as

1–800–MEDICARE. We monitor the quality of hospitals stays and surgical procedures through the QIO, we routinely review medical records in our claims audits, and we specifically investigate outcomes as part of our evaluations of demonstrations and payment and service delivery models. All of these processes create opportunities to identify potentially non-compliant providers/suppliers. Providers/suppliers who are investigated and found to be inappropriately denying care or diverting patients may be sanctioned using our existing authority, with penalties that may include participant hospital ineligibility for reconciliation payments, revocation from the Medicare program if patients are placed at risk by substandard care, or other applicable administrative actions.

Final Decision: After consideration of the public comments we received, we are finalizing the proposal to apply our existing authority to monitor for overutilization and underutilization of care under the CJR model. We are modifying our proposed policies for reconciliation payments at § 510.410 to allow us to determine that a participant hospital is ineligible to receive or retain a reconciliation payment if the payment is found to be based in part on savings resulting from an inappropriate and systemic underdelivery of care.

4. Monitoring for Quality of Care

Monitoring General Quality of Care: As we noted previously, in any payment system that promotes efficiencies of care delivery there may be opportunities to direct patients away from more expensive services at the expense of outcomes and quality. We believed that professionalism, the quality measures in the model, and clinical standards can be effective in preventing beneficiaries from being denied medically necessary care in the inpatient setting and in PAC settings during the 90 days post-discharge. Accordingly, the potential for the denial of medically necessary care within the CJR model will not be greater than that which currently exists under IPPS. However, we also believe that we have the authority and responsibility to audit the medical records and claims of participating hospitals and their CJR collaborators in order to ensure that beneficiaries receive medically necessary services. We may also monitor agreements between participant hospitals and their CJR collaborators to ensure that such agreements do not result in the denial of medically necessary care or other program or patient abuse. We invited public comment on whether there are elements of the CJR model that would require additional beneficiary protection for the appropriate delivery of inpatient care, and if so, what types of monitoring or safeguards would be most appropriate.

The following is a summary of the comments received on monitoring for quality of care, and our responses.

Comment: Several commenters stated that CMS should ensure the safety and cost effectiveness of surgical implants used in the CJR model and that CMS should require that evidence-based purchasing be required in the CJR model. As these commenters were concerned that hospitals will avoid high cost devices, they urged CMS to put controls in place that protect patients against wholesale changes in device offerings of providers. A commenter suggested that we should consider prohibiting gainsharing altogether when tied to the use of less expensive and lower-utility devices but in any event that participating hospitals should be carefully monitored for the appropriateness of device choice for individual patients and surgeons.

Response: We note that the CJR model is built around an inpatient admission. Under the IPPS, the cost of the device is already bundled into the payment for the hospital admission. Therefore, hospitals have long had incentives to use less expensive and lower utility devices as a way of maximizing their profit under IPPS. However, we have not identified any problems with the inappropriate use of inexpensive devices, so we believe that existing considerations, such as hospital and physician reputation, clinical standards, and incentives to maintain high quality outcomes, have been successful in driving the appropriate selection of devices. We do not believe that there are any significant new incentives to inappropriately use lower quality devices as the device remains packaged in the IPPS payment bundle. We believe that ongoing monitoring of the quality of devices and the selection of specific devices for specific beneficiaries is appropriate, but, given the success of our over 30 year experience with IPPS, we do not believe that additional programs need to be defined in regulation. However, we do expect that the focus on shared decision making and physician leadership, described in the following discussions, will further reduce any beneficiary risk.

Comment: Commenters provided their views about the role of quality metrics in ensuring the quality of care as a counter to economic pressures. They expressed concerns about the design of the metrics, concerns that are discussed in the quality section of this rule, but they also expressed concerns that the quality metrics were not adequate protection against the delivery of poor quality care. Commenters were concerned that the proposed model does not include enough safeguards to substantially improve the care experience, and that reference to quality and outcomes were inadequately defined. Some commenters were also concerned that measurements were hospital-centric, with inadequate consideration of tools that assess such measures as patient functional status, a component that they believed tied closely to protections that promote improved beneficiary care. Commenters proposed that quality metrics should include functional requirements, pain management and patient experience, patient reported outcomes and other measures of the outcomes of the post-acute care treatment. They also opined that the public reporting of quality measures would help empower consumers to make informed decisions.

Response: We agree that there are opportunities to better employ quality metrics. However, we note that obstacles exist not only in defining new measures but in implementing mechanisms to report and asses those metrics without creating undue administrative burdens or provider technological challenges. For example, we note that it will take time to collect and validate data required under the IMPACT Act but once that has occurred it will create opportunities for potentially better metrics. Therefore, we thank commenters for their suggestions and note that while we are finalizing a set of quality metrics for this year, the methodology by which this model is being phased in, with gradually increasing economic incentives, gives us an opportunity to continue to evaluate the use of quality metrics and modify them through future rulemaking if better metrics emerge.

Final Decision: After consideration of the public comments we received, we are finalizing the proposal to use our existing authority to audit claims and services, to use the QIO to assess for quality issues, to use our authority to investigate allegations of patient harm, and to monitor the impact of the quality metrics that we are finalizing.

Monitoring PAC Quality of Care. With respect to PAC, we believed that requiring participating hospitals to engage patients in shared decision making is the most important safeguard to prevent inappropriate recommendations of lower cost care, and we stated in the preamble that such a requirement can be best effected by requiring hospitals to make this a

condition of any sharing arrangements with practitioners who perform these procedures, although we did not propose any regulations text. Additional deterrents are created by the financial accountability of the 90-day bundle, which is sufficiently long that it encourages the provision of high-quality care to avoid the risk of complications and readmissions, which would typically occur within that time period. Physician patterns of practice are also constrained by clinical standards of care, and we believe that the risk associated with deviations from those standards provides further deterrence to compromising care.

We believe that these safeguards are all enhanced by beneficiary knowledge and engagement. As we discussed in the section on beneficiary notification, we proposed to require that participant hospitals must, as part of discharge planning, account for potential financial bias by providing patients with a complete list of all available PAC options in the service area consistent with medical need, including beneficiary cost-sharing and quality information (where available and when applicable). We expect that the treating surgeons or other treating practitioners, such as physiatrists, will continue to identify and discuss all medically appropriate options with the beneficiary and that hospitals will discuss the various facilities and providers who are available to meet the clinically identified needs. These proposed requirements for CJR participant hospitals would supplement the existing discharge planning requirements under the hospital CoPs. We also specifically note that neither the CoPs nor this proposed transparency requirement preclude hospitals from recommending preferred providers within the constraints created by current law, as coordination of care and optimization of care are important factors for successful participation in this model. We invited comment on this proposal, including additional opportunities to ensure high quality care.

The following is a summary of the comments received regarding provisions to ensure quality during the delivery of PAC services, and our accompanying responses.

Comment: Commenters strongly advocated for the need to encourage shared decision making as a methodology for ensuring that beneficiaries are provided PAC options of the highest quality. The comments consistently followed several themes. Numerous commenters were concerned about the role of the physician/surgeon in the CJR. Some commenters were concerned that physicians are marginalized by placing all economic power with the hospital, and that this will disrupt the physician-patient relationship. These commenters were also concerned that the model fails to recognize the vital importance of the physician's role in healthcare, that the episode is in fact generated because of the orthopedic physician's care for the beneficiary months and sometimes years prior to the LEJR surgical event. These commenters believe that it is the physician/surgeon who drives the care and that this should be incorporated into the model. Conversely, commenters were concerned that hospitals should not be allowed to coordinate and manage care as that represents a conflict of interest since they are the entity that is financially responsible for excess spending during the episode.

Response: We agree that the physician/surgeon is critical to the CJR model and that this is incorporated into the concept of shared decision making. As a practical matter, patients place considerable trust in the advice of their physicians, such that almost all medical care is physician-directed even when it is delivered by many coordinated entities. This physician direction is fundamental to the design of most Medicare programs and models, including the CJR model. Although the economic effects of the CJR model are borne by the hospital, considerable economic power resides with the beneficiary and the physician due to the strength of the established doctor-patient relationship. In our proposed rule we repeatedly emphasized the principle of beneficiary freedom of choice, the right to choose any care options and for the fact that Medicare continues to covers all medically necessary Medicare benefits. It is the beneficiary's selection of specific medically necessary options that determines the composition of the episode, because the episode is composed only of services the beneficiary consents to receive and is not impacted by the services that the beneficiary declines. Under the concept of shared decision making, the beneficiary retains that ultimate right to accept or request desired services and refuse services that are not desired. This is a significant economic power. Meanwhile, the physician is responsible for advising the beneficiary as to whether a particular choice is medically necessary and, as a corollary, for advising the patient as to the most medically appropriate and medically beneficial options. This also gives the physician considerable economic power and places him or her in the position, together with the beneficiary, of driving the actual care. The hospital, although it is the participant in the CJR model that is directly tied to the economic incentives, is therefore limited by the additional economic power held by the beneficiary, who holds the final choice with respect to all care, and the economic power held by the physician, who is the primary driver of care through his recommendations to the beneficiary in accordance with the special doctor-patient relationship. These checks and balances are a major mechanism to mitigate against any potential hospital conflict of interest created by the payment bundle.

Comment: Commenters proposed numerous and diverse requirements that they wanted us to consider imposing on the CJR decision making process that steers patients into specific PAC settings and services. On the one hand there were some requests for general guidance of what is and is not acceptable in discussions with the beneficiary. A commenter stated that our current proposal does not address the role of the patient in the process, and does not propose methods to empower patients to seek out the highest quality joint care. On the other hand there were numerous recommendations to require certain specific elements in the decision making process. A commenter suggested that we require shared care planning, a concept that includes collaborative provider-patient goal-setting, decision making, and monitoring through the use of documented, completed individualized care plans. Another commenter suggested the inclusion of advance care planning, an opportunity for thorough discussion of patients' desires relative to care options if, following the procedure, they are unable to convey those desires. A commenter recommended a requirement that hospitals create patient family advisory councils or other similar organizations in order to promote the patient perspective in discussions of episode design and care coordination, and suggested that this should include family members if desired by the patient. Commenters advised CMS to ensure that planning is initiated with the primary care physician or surgeon before admission and is coordinated with the pre-admission process conducted by the hospital, and that appropriate standards of care should be a key characteristic of these processes.

Response: We recognize that the concept of shared decision making is a complex process, with many permutations based on the needs of the

patient, the availability of resources, and the nature of the individual doctor-patient relationship for each specific case. Therefore, we recognize the importance of shared decision making as previously described, but we defer from specifying other elements that must be included as components of the decision making process. We believe there are many acceptable ways to engage the beneficiary and that, just as different commenters offered different techniques that they have found to be helpful, different hospitals with their unique characteristics will similarly identify and implement the programs that best serve to engage their patient population.

Comment: Commenters proposed modifications to the decision making process, as well as recommending different technical systems that they believed should be required by participant hospitals. Some commenters recommended that the hospital should document the use of evidence-based clinical practice guidelines and evidence-based decision aids for shared decision making, and that hospitals should be required to have specific systems in place to coordinate all providers involved in the episode of care, track quality measures, manage medical complications, coordinate with community services to foster the patient's independence and implement evidence-based shared decision making with patients. However, other commenters emphasized the need for technical inclusiveness. A commenter encouraged us to enable providers to participate in these models as collaborators without requiring major investments in infrastructure and electronic health records. Another commenter proposed that patients should not select providers but should select physician-led teams in which a pre-organized slate of providers would collaborate to deliver the necessary portfolio of care.

Response: We do not believe that pre-formed teams of PAC providers linked to a single physician would be consistent with beneficiary free choice if beneficiaries were restricted to providers in that specific team. Beyond that, we note that there are many modes of decision making and that different modes may be preferred by different provider groups under different circumstances. We do not believe that a single approach or a single technical solution will meet the needs of the diversity of participant hospitals and patient and provider populations who will be engaged in providing services under this model. For this reason we do not elect to further define mandatory approaches to decision making.

Comment: Similar to commenters' concerns regarding additional monitoring to ensure that providers did not limit access to PAC services (''stinting''), commenters also expressed concerns that specific monitoring would be necessary to ensure that those PAC services provided to beneficiaries were not subject to restrictions that adversely impacted their quality. Some commenters recommended that we establish basic requirements for care coordination and competencies that must be met, independent of payment and measurement. Their rationale was that certain functions, such as discharge planning, are so integral to care coordination that requiring them should be routine for entities that aspire to coordinate care well. Specifically, participating hospitals should be required to have clearly documented clinical care models, care and transition plans including shared decision making tools and coordination with community supports, and protocols for documenting discharge planning and PAC coordination and supports.

Other recommended controls included a requirement that any and all documents used by the hospital during discharge planning must be submitted to (not approved by) CMS, a requirement that any agreement between hospitals and PAC providers should be submitted to (not approved by) CMS, and that CMS should do a random sample audit of these agreements to ensure they comply with current regulations. A commenter recommended that CMS make available to the public the amount hospitals earn from reconciliation payments for a performance year, while another recommended that we should do random face to face interviews post discharge to determine if the patient was steered to a particular provider if such interviews warranted based on changes in utilization rates or if we identify inappropriate or concerning sharing arrangements between a hospital and a PAC provider.

Other commenters wanted us to underscore in the final rule that hospital utilization review committees and physicians who sign discharge orders remain fully accountable to make the determination that a patient discharge is medically appropriate. A commenter believed that part of the discharge process should include an independent determination that medical resources and care required by each beneficiary are available in an available PAC setting.

Response: We agree with commenters that monitoring is essential to protect against practices that might reduce the quality of PAC services. We believe that monitoring for quality is accomplished at the population level through the monitoring for access to the appropriate level and quantity of PAC services, a process that we discussed earlier with respect to underutilization of services. We also believe that the practice of shared decision making, the reliance on the medical direction of the physician, the monitoring of quality metrics, the complaint and oversight opportunities through 1–800–MEDICARE and the QIO, and the use of care coordination all cooperate to ensure the quality of individual services delivered to individual beneficiaries.

With respect to comments that we establish basic requirements for care coordination or require specific documentation of care coordination procedures, we agree with commenters that activities such as discharge planning are integral to care coordination. However, we note that it is one function of state agencies and accrediting organizations to ensure that discharge planning is effectively addressed, and that their applications of the CoPs are updated as necessary to establish appropriate standards. We note that CMS has recently proposed updated discharge planning requirements for hospitals through proposed changes to the hospital CoPs.

We do not believe that new requirements, such as CMS receipt of discharge planning documents or public posting of amounts involved in gainsharing, are necessary to ensure appropriate post discharge care. We note that, with the exception of waivers discussed in section III.C.11. of this final rule, all other Medicare rules for coverage and payment continue to apply. However, as discussed elsewhere in this section of this final rule, we have modified proposed § 510.500 to require additional disclosure of CJR sharing arrangements with PAC providers to CMS. Therefore, we believe that sufficient controls are in place to allow us to ensure the quality of the PAC services without requiring additional public disclosure or CMS approval.

We also note that whereas both utilization review activities and discharge planning are required by the hospital CoPs, a review of the appropriateness of post-discharge services is not an activity currently undertaken by hospitals. We agree that the ultimate direction for the care of the patient lies with the physician and patient, and claims for services are subject to appropriate validation and

review for coverage and medical necessity. We do not believe that at this time it is necessary or appropriate to require a medical necessity review of every PAC decision under the model. First, we note that such a requirement would create a significant administrative burden that would need to be balanced against the potential benefits. Second, we believe that the hospital and its PAC providers must already comply with existing federal and state requirements to respect beneficiary wishes and follow physician direction. Third, we have noted the opportunities available to the beneficiary, such as the 1–800–MEDICARE line, to raise quality concerns associated with the episode of care.

Comment: Commenters offered other suggestions and observations on opportunities to improve beneficiary protections that ensure the delivery of quality care. Several commenters suggested that CMS should require a ''second opinion'' process whereby a concerned consumer can seek an independent medical opinion concerning a PAC plan. Other commenters opined that we should provide appeal rights to any Medicare beneficiary subject to the CJR model, comparable to those appeal rights available to Medicare Advantage enrollees, in order to protect against ''adverse care'' decisions. Still other commenters encouraged us to inform beneficiaries of the hotlines available to convey grievances on care at each level of service during the episode, to develop training for 1–800–MEDICARE call center staff to identify and flag potential care reductions or inappropriate steering in this model, to ensure that the State Health Insurance Assistance Programs (SHIPs) are appropriately trained and engaged as the final model is implemented, and to highly publicize outlets where consumers can provide positive or negative feedback, such as 1–800–MEDICARE and the contact information for the local QIO. A commenter proposed that we consider establishing an independent ombudsman program.

Response: We do not believe that a second opinion program or special appeal rights are necessary. First, as we have previously discussed, there are numerous processes in place to protect beneficiary choice. The beneficiary retains all rights to choose the provider/supplier for medically necessary covered services. The beneficiary retains the benefits of the doctor-patient relationship, with additional notification of any sharing arrangement that could create a potential conflict of interest. In the event that the beneficiary is stated with a notice of non-coverage for continuing services, such as a continued stay in a participant hospital or a SNF, the beneficiary has access to the existing expedited review process. The beneficiary may also voice concerns or grievances, such as to the QIO or through 1–800–MEDICARE. We also do not agree with the need to establish a dedicated ombudsman, given the existence not only of the appeal process but also of the existing office of the Ombudsman. However, we agree that it would be beneficial to distribute educational materials to ensure that beneficiaries can take advantage of the support available at 1–800–MEDICARE, at the SHIP, and especially at the QIO, and we will consider developing such materials in the future.

Final Decision: After consideration of the public comments we received, we are finalizing our regulations as proposed and are not creating additional requirements for discharge planning or care coordination specific to the CJR model, beyond the previously identified requirements that hospitals must provide a complete list of PAC providers and that CJR collaborators must provide notice that they are participating in a CJR sharing arrangement with the hospital.

5. Monitoring for Delayed Care

This model is based in part on an incentive for hospitals to create efficiencies in the delivery of care within a 90-day episode following the joint replacement surgery. Theoretically this could create incentives for hospitals and other CJR collaborators involved in any CJR sharing arrangements to delay services until after that window has closed.

We believe that existing Medicare safeguards are sufficient to protect beneficiaries. First, our experience with other bundled payments such as the BPCI initiative has shown that providers focus on appropriate care first and efficiencies only when those efficiencies can be obtained in the setting of appropriate care. We believe that a 90-day post-discharge episode will sufficiently minimize the risk that services furnished in relation to the beneficiary's LEJR procedure will be necessary beyond the end of the episode duration. To ensure that the length of the episode duration sufficiently minimizes the risk that any LEJR related care will not exceed the time established for the episode, we proposed to establish a 90-day post-discharge duration. We believe that participant hospitals would be unlikely to postpone services beyond a 90-day period because the consequences of delaying care beyond this long episode duration would be contrary to usual standards of care.

However, we also note that additional monitoring would occur as a function of the payment model. We have proposed as part of the payment definition (see section III.C. of the proposed rule) that certain post-episode payments occurring in the 30-day window subsequent to the end of the 90-day episode would be counted as an adjustment against savings. We believe that the inclusion of this payment adjustment would create an additional deterrent to delaying care beyond the episode duration. In addition, the data collection and calculations used to determine this adjustment provide a mechanism to check if providers are inappropriately delaying care. Finally, we note that the proposed quality measures create additional safeguards as they are used to monitor and influence hospital clinical care at the institutional level. We invited public comment on our proposed requirements for notification of beneficiaries and our proposed methods for monitoring participants' actions and ensuring compliance as well as- on other methods to ensure that beneficiaries receive high quality, clinically appropriate care.

The following is a summary of the comments received and our responses.

Comment: Commenters provided numerous suggestions and observations on the processes by which we will monitor the model in order to ensure that the beneficiary is fully protected against unintended consequences. Commenters were in agreement with our intent to monitor for unexpected changes in the delivery of care, but several commenters believed that additional explanation would be helpful. A commenter believes that it was not clear what would constitute an inappropriate change in delivered services, particularly in light of the fact that the intent of this model is to promote change. Other commenters believe that, just as more definition was needed around the concept of inappropriate change, more definition was needed to define the contractors who would audit for those changes. A commenter requested that CMS build into the CJR model checks and balances to assess the CJR patient's care throughout the duration of the episode and extending for four months beyond the end of the episode. Another commenter suggested that a similarly structured auditing system should be established to monitor CJR participants' care management processes and compliance with the patient-centered

care planning expected in the model, with audits conducted by an outside party in the early stages of the new model and periodically thereafter.

Response: We understand that commenters would like additional definition surrounding inappropriate changes. We consider changes in patterns of care to be inappropriate when they do not improve the quality and efficiency of care delivered to Medicare beneficiaries, or when they occur in violation of statute, regulation, or guidance. This would include, for example, practices that prevent potentially higher-cost patients from receiving services, reduce the delivery of medically necessary services, limit beneficiary choices between equally valued options, increase or fail to reduce waste, or maximize reimbursement at the expense of the beneficiary. However we do not believe that specific examples must be identified in regulation. Rather we believe that the regulation should define the general principles under which the beneficiary must be protected and the authorities under which monitoring will take place, and we have so defined these principles in § 510.410. For example, we stated that action that threatens the health or safety of patients and actions to avoid at risk Medicare beneficiaries are prohibited actions, so we would consider changes that result from ''stinting'' (threatening the health of patients) and ''patient dumping'' (avoiding at risk beneficiaries) to represent inappropriate change. We also expect to interact with both providers and our contractors over the course of this model, to refine and clarify our educational materials and, when necessary, our regulations or guidance. We note that although we defined the types of inappropriate changes in § 510.410, we do not believe that it is necessary to define through regulation the specific contractors who will be responsible for monitoring this aspect of the program. We have numerous contractors who have the authority and scope to perform this work, and we will use our usual contracting authorities to assign any necessary tasks during the life of the model. We also note that we previously discussed that we did not believe that additional auditing of providers' discharge planning and care coordination activities was necessary. Given that we do not believe that special audits are necessary to ensure the quality of PAC services to a specific beneficiary, we similarly do not believe that audits of care coordination are necessary to monitor the quality of care delivered to the population as a whole. We believe that the financial incentives of the model promote increased care coordination, a process that will increase the timeliness of interventions and reduce opportunities for delays in care.

Comment: Commenters had specific comments about the extent of post-episode monitoring and about monitoring in general, which is necessary to track for the occurrence of instances of delays in the delivery of care.

Commenters suggested that post-episode monitoring should be extended for at least 3 to 6 months after the end of the bundle period or even 5 or more years in order to include the late effects of suboptimal implant selection. As part of PAC monitoring, commenters acknowledged that CMS proposed to look at changes in referral patterns as a result of the model, but also believed that we should evaluate the impact that the model may have on the availability of services in a market.

With respect to monitoring in general, commenters requested that we should be more transparent about monitoring. Specific recommendations were that we should track readmission rates, complication rates, ER visits, observation stays, length-of-stay, changes in patient function, and patient experience, gap between discharge and first PAC use and between discharge and physician follow-up visit, days lapsed between discharge from the hospital to the first PAC use, and days lapsed between hospital discharge and the first physician visit. Some providers also requested that we should incorporate information from/related to reporting requirements of the IMPACT Act into functional monitoring. Commenters also believed that we should perform some baseline monitoring, looking at case mix before and after CJR implementation as well as the rates of joint replacement in MSAs included in the CJR model and MSAs excluded from the model.

Response: We acknowledge the validity of these recommendations and thank commenters for their suggestions. With respect to prolonged monitoring for long-term consequences related to device selection, we agree that monitoring of this sort is of interest in optimizing long-term outcomes. However, we note that devices have long been included in IPPS inpatient bundles. Thus any risks associated with low cost device selection are not specific to the CJR. We also do not believe that the policy changes necessary to respond to any findings based on sub-optimal device selection would be limited to this model. Furthermore, we note that we would not expect on a clinical basis for any effects of low-cost low-quality devices to become apparent for many years. Therefore monitoring for this impact would require (1) additional years that are at least equally as long as the model duration itself in order to detect quality and cost effects; and (2) similar analysis of the impact of devices provided under IPPS but outside the model. This further underscores the difficulty of including this analysis as a component of the model and suggests that, if such a study is undertaken, it should be a separate study of the impact of device selection both within and outside of the CJR model. On the other hand, we believe that the other measures suggested are all reasonable metrics by which program effects can be monitored. We will consider whether we should incorporate some of all of these approaches in our arrangements with our monitoring and evaluation contractors.

Comment: Some commenters questioned the manner in which existing or potential medical review and audit programs would interact with the CJR, given that such programs are necessary to ensure access and quality in all services but are particularly important and potentially burdensome when used to monitor both the entire episode of care as well as the post-episode period in which delayed care would appear. Commenters believe that CMS should implement those evaluation processes that are least disruptive to participants. Several commenters opined that any cases reimbursed under a ''shared accountability payment'' methodology such as CJR should not be subjected to claim denials as part of Medicare contractors' medical review activities. Other commenters requested that we explain the relative roles of RACs, QIOs, and other review contractors.

Other commenters believe that special controls and audits should be implemented to further protect beneficiaries. A commenter believes that CMS should require providers to submit annual reports that detail original care redesign objectives they agreed to implement, the progress they made in achieving those objectives and how achieving those objectives has been linked to gainsharing rewards. Another believed that we should institute a structured monitoring program to ensure compliance with the patient notice requirements, using a contractor such as a state survey agency, a QIO, or a hospital private accrediting body. Recommended elements of monitoring and control included the submission of any model notice in advance of its use,

certification of assurances of compliance by the hospital/physician auditing of compliance within the first 30 to 60 days of implementation of CJR and annual auditing of compliance thereafter.

CJR

Response: With respect to existing auditing programs, we agree that it is important to minimize the disruption of provider activity and to minimize the cost and burden of audits to the extent possible. We do not agree that services furnished to beneficiaries included in the CJR model should be excluded from MAC, RAC, ZPIC or other medical review or audit activity because CJR does not contain a substitute for these existing program integrity measures. Considerable financial risk is still retained by Medicare in that the direct payments to the hospital and PAC providers are still borne by Medicare. For example, if the participant hospital provided joint replacements on relatively healthy beneficiaries for whom the replacements were considered to be not medically necessary in accordance with a coverage decision or clinical guidelines, that overpayment could not be identified and corrected except through audit. Conversely, those lower cost procedures would reduce average cost and increase a participant hospital's reconciliation payment, benefitting the hospital while increasing costs borne by Medicare. Moreover, under the model the beneficiary remains responsible for the deductible for the hospital admission covered under Part A as well as copayments for many PAC services. We believe that ensuring that beneficiaries pay the correct deductibles and copayments is a function that is consistent with commenters' concerns for beneficiary protection as well as our obligation to enforce the statutory provisions that define Medicare benefits and beneficiary and provider obligations pursuant to those benefits.

We agree that contractors conducting audits or medical review to assess for delays in care or for other purposes may find and deny claims that were incorrectly billed. We also agree that there is a complex interaction between the denial of a service on a claim and its impact on the reconciliation process for the performance year under the CJR model, depending on the provider whose claim is denied, the timing of the adjustment relative to the model reconciliation, the limits of upside and downside risk, and other factors. For example, if a PAC claim is denied after final reconciliation, the hospital will still have incurred a cost approximately equal to the amount that was denied to the PAC provider because those costs would still be included in the calculation of the positive or negative NPRA as calculated in accordance with § 510.305. On the other hand, if the denial occurs prior to reconciliation, the hospital will have lower costs attributed to it as the cost of the service would be removed from the claims history. This will affect the NPRA as if the denied service had never been delivered and benefit the hospital by an amount that is approximately equal to the amount that was denied to the PAC provider. Given this complex interaction that can create diverse and opposing impacts but only in the setting of inappropriate (denied) claims, we do not believe that it is necessary or desirable to exclude services from medical review because they are delivered under the CJR model.

G. Coordination With Other Agencies

Impacts created by payment changes under this model are entirely internal to HHS operations; coordination with other agencies is not required outside of the usual coordination involved in the publication of all HHS regulatory changes.

IV. Evaluation Approach

A. Background

The CJR model is intended to enable CMS to better understand the effects of bundled payments models on a broader range of Medicare providers than what is currently being tested under BPCI. Obtaining information that is representative of a wide and diverse group of hospitals will best inform us on how such a payment model might function were it to be more fully integrated within the Medicare program. All CMS models, which would include the CJR model, are rigorously evaluated on their ability to improve quality and reduce costs. In addition, we routinely monitor CMS models for potential unintended consequences of the model that run counter to the stated objective of lowering costs without adversely affecting quality of care. We outlined the proposed design and evaluation methods, data collection methods, key evaluation research questions, and the evaluation period and anticipated reports for the CJR model in the 2016 Comprehensive Care for Joint Replacement proposed rule (80 FR 4198).

B. Design and Evaluation Methods

Our evaluation approach for the CJR model will have elements in common with the standard Innovation Center evaluation approaches we have taken in other projects such as the BPCI initiative, ACE Demonstration, Pioneer ACO model, and other Innovation Center models. Specifically, the evaluation design and methodology for the CJR model would be designed to compare patterns of care among the CJR providers to patterns of care among non-CJR providers, potentially contrasted with historical differences in care between these two groups of providers.

Our evaluation methodology for this model builds upon the fact that MSAs were selected for participation in the model based on a stratified random assignment. In this approach, researchers evaluate the effects of the model on outcomes of interest by directly comparing MSAs that are randomly selected to participate in the model to a comparison group of MSAs that were not randomly selected for the model (but could have been). Randomized evaluation designs of this kind are widely considered the ''gold standard'' for social science and medical research because they ensure that the systematic differences are reduced between units that do and do not experience an intervention, which ensures that (on average) differences in outcomes between participating and non-participating units reflect the effect of the intervention.

The removal of the 8 MSAs that were previously selected but are now considered not eligible due the revision to the MSA exclusion rules does not compromise our proposed evaluation approach. The relative ranking of MSAs with respect to episode payments is unchanged by the new exclusions. The selected MSAs remain randomly selected and also remain distributed throughout the payment and population size dimensions. As with other evaluation issues, the methodological approach to examining and drawing conclusions about the impact of the model will be finalized in the Evaluation Contract.

We plan to use a range of analytic methods, including regression and other multivariate methods appropriate to the analysis of stratified randomized experiments to examine each of our measures of interest. Measures of interest could include, for example, quality of and access to care, utilization patterns, expenditures, and beneficiary experience. The evaluation would also include rigorous qualitative analyses in order to capture the evolving nature of the care model interventions.

In our design, we plan to take into account the impact of the CJR model at the geographic unit level, the hospital level, and the patient level. We are also considering various statistical methods

to address factors that could confound or bias our results. For example, we anticipate using statistical techniques to account for clustering of patients within hospitals and markets. Clustering allows our evaluation to compensate for commonalities in beneficiary outcomes by hospitals and by markets. Accounting for clustering ensures that we do not overstate our effective sample size by failing to account for the fact that performance of hospitals in a given market may not be fully independent of one another. Alternatively, accounting for clustering may improve statistical precision or allow us to better examine how patterns of performance vary across hospitals. For example, in cases where a large hospital consistently has poor performance, clustering would allow us to still be able to detect improved performance in the other, smaller hospitals in a market rather than place too much weight on the results of one hospital and potentially lead to mistaken inferences. Finally, we plan to use various statistical techniques to examine the effects of the CJR model while also taking into account the effects of other ongoing interventions such as BPCI, Pioneer ACOs, and Medicare Shared Savings Program. For example, we will consider additional regression techniques to help identify and evaluate the incremental effects of adding the CJR model in areas where patients and market areas are already subject to these other interventions as well as potential interactions among these efforts.

C. Data Collection Methods

We are considering multiple sources of data to evaluate the effects of the CJR model. We expect to base much of our analysis on secondary data sources such as Medicare FFS claims and required patient assessment instruments such as the Minimum Data Set (MDS) collected for SNF stays, the Patient Assessment Instrument for Inpatient Rehabilitation Facility (IRF–PAI) collected for IRF stays, and the Outcome and Assessment Information Set (OASIS) collected for home health episodes of care. The beneficiary claims data would provide information such as expenditures in total and by type of provider and service as well as whether or not there was an inpatient hospital readmission. The assessment tools would provide information on a beneficiary's functioning (for example, physical, psychological and psychosocial functioning).

In conjunction with the previously stated secondary data sources, we are considering a CMS-administered survey of beneficiaries who received an LEJR during the performance period. This survey would be administered to beneficiaries who either had received an LEJR under the CJR model or were selected as part of a control group. The primary focus of this survey would be to obtain information on the beneficiary's perception of their functional status before and after the LEJR as well as information on their pain and LE joint symptoms, and perceptions on access to care. The administration of this beneficiary survey would be coordinated with administration of the HCAHPS Survey so as to not conflict with or compromise the HCAHPS efforts. Likewise, we are considering a survey administered by CMS and guided interviews conducted by CMS with providers and suppliers including, but not limited to, orthopedic surgeons, initiating hospitals, and PAC providers participating furnishing services to beneficiaries included in the CJR model. These surveys would provide insight on beneficiaries' experience under the model and additional information on the care redesign strategies undertaken by health care providers.

In addition, we are considering CMS evaluation contractor-administered site visits with selected hospitals and PAC providers as well as focus groups with a range of populations such as PAC providers and orthopedic surgeons. We believe that these qualitative methods would provide contextual information that would help us better understand the dynamics and interactions occurring among CJR providers furnishing services included within a CJR episode. For example, these data could help us better understand hospitals' intervention plans as well as how they were implemented and what they achieved. Moreover, in contrast to relying on quantitative methods alone, qualitative approaches would enable us to view model nuances as well as identify factors that are associated with successful interventions and distinguish the effects of multiple interventions that may be occurring within participating providers, such as simultaneous ACO and bundled payment participation.

D. Key Evaluation Research Questions

Our evaluation would assess the impact of the CJR model on the aims of improved care quality and efficiency as well as reduced health care costs. This would include assessments of patient experience of care, utilization, outcomes, Medicare expenditures, provider costs, quality, and access. Our key evaluation questions would include, but are not limited to, the following:

- *Payment.* Is there a reduction in total Medicare expenditures in absolute terms or for subcategories of providers (for example, acute versus PAC providers, providers in certain geographic areas, providers within concentrated vs non-concentrated market areas or in urban vs rural areas)? Do the participants reduce or eliminate variations in utilization and expenditures or both that are not attributable to differences in health status? If so, how have they accomplished these changes?
- *Utilization.* Are there changes in Medicare utilization patterns overall or for specific types of providers or services? How do these patterns compare to historic patterns, regional variations, and national patterns of care? How are these patterns of changing utilization associated with Medicare payments, patient outcomes and general clinical judgment of appropriate care?
- *Outcomes/Quality.* Is there either a negative or positive impact on quality of care and patient experiences of care or both? Did the incidence of complications remain constant or decrease? Was there a change in beneficiaries' level of pain reduction, functional outcomes or return to independence under the model than relative to appropriate comparison groups? If so, how and for which beneficiaries?
- *Referral Patterns and Market Impact.* How, if at all, has the behavior in the selected geographic areas changed under the model? How have the referral patterns changed and for which type(s) of providers? Similarly, does the model have an impact on the number of patients with LEJR procedures and what types of patients are undergoing the procedure? To what extent, if any, is this related to gainsharing activities?
- *Unintended Consequences.* Did the CJR model result in any unintended consequences, including adverse selection of patients, access problems, cost shifting beyond the agreed upon episode, evidence of stinting on appropriate care, anti-competitive effects on local health care markets, evidence of inappropriate referrals practices? If so, how, to what extent, and for which beneficiaries or providers?
- *Potential for Extrapolation of Results.* What was the typical patient case mix in the participating practices and how did this compare to regional and national patient populations? What were the characteristics of participating practices and to what extent were they representative of practices treating Medicare FFS beneficiaries? Was the model more successful in certain types

of markets? To what extent would the results be able to be extrapolated to similar markets and nationally or both?

• *Explanations for Variations in Impact.* What factors are associated with the patterns of results? Specifically, are the results related to the following?

++ Characteristics of the models including variations by year and factors such as presence of downside risk?

++ The participating hospital's specific features and ability to carry out their proposed intervention?

++ Characteristics and nature of interaction with partner providers and suppliers including orthopedic surgeons and PAC provider community?

++ Characteristics of the geographic area, such as market concentration or size of city and availability of PAC providers?

++ Characteristics associated with the patient populations served?

E. Evaluation Period and Anticipated Reports

As discussed in section III.C.2.a. of this final rule, each of the selected participants in the CJR model would have 5 performance years. The evaluation period would encompass all 5 performance years and up to 2 years after. We plan to evaluate the CJR model on an annual basis. However, we recognize that interim results are subject to issues such as sample size and random fluctuations in practice patterns. Hence, while we intend to have internal periodic summaries to offer useful insight during the course of the effort, a final analysis after the end of the 5 performance years will be important for ultimately synthesizing and validating results.

We sought comments on our design, evaluation, data collection methods, and research questions.

The following is a summary of the comments received and our responses.

Comment: A variety of commenters detailed evaluation topics in which they were particularly interested as follows:

• In the category of ''utilization,'' the following topics were highlighted as of interest to commenters: (1) An examination of utilization shifts between sites of care as well as an examination of the types of patients for which this occurs and if there was an impact on quality, health outcomes, and total spending; and (2) an examination of changes in types of devices being used in total joint replacement procedures compared to historical trends and other markets.

• In the category of ''outcomes and quality,'' the following topics were highlighted: an examination of the impact of the model on certain vulnerable subpopulations, including low-income individuals, individuals residing in low-access areas, and racial and ethnic minorities.

• In the category of ''market impact,'' the following topics were highlighted: an assessment of whether hospitals redesign or eliminate service lines; an assessment on the impact of the availability of services in a market; an assessment of the impact, if any, on the financial viability of PAC providers in impacted markets; the shifting of increased costs to other payers; and an exploration of the use of the gainsharing waiver, including the criteria hospitals use to identify preferred partner relationships and an examination of to whom gains are distributed.

• In the area of ''patient access,'' the following topics were mentioned: an examination of the extent to which beneficiary choice is preserved and whether or not hospitals steer patients towards certain providers; an assessment on the impact of the model on patient access to services including patient travel time; an assessment of the extent to which use of lower cost alternatives or lack of other enhancements to the patient experience led to changes in patient outcomes and satisfaction; and an evaluation of device offerings and patient access to various technologies for joint replacement.

• Within the category of exploring which factors are associated with ''variations'' in success, the following topics were mentioned: examining whether higher risk candidates for surgery are avoided or lower risk patients are inappropriately targeted for inclusion; an assessment of the impact of simultaneous incentives and participation in other models and programs that may impact the same patients or providers; an assessment of the variation in implementation by hospitals and the extent to which hospitals make a financial commitment to prepare staff and to undertake other activities to improve coordination; and an assessment of the use and impact of telehealth services and related efforts.

Response: The commenters' list of topics are in alignment with our stated areas of interest and will be considered in the development of the final evaluation plan in coordination with the contractor chosen to develop and carry out the model evaluation.

Comment: A variety of commenters, including MedPAC, presented measures and metrics that they believed would be important to include in the evaluation. In addition, a commenter suggested CMS make participation in a data registry a requirement for all participants in the model. Other suggested measures include the following:

• Readmission rates, complication rates, use of emergency room visits and observation stays, length of stay, changes in patient function, and patient experience in the assessment of the stinting of care.

• Number of days between discharge from the hospital to first PAC use, and number of days between hospital discharge and first physician visit to assess timely care coordination.

• Comparison of utilization rates for joint replacement procedures in markets included and excluded to monitor any increase.

• The development and implementation of true longitudinal outcome metrics.

Response: Commenters' measurement suggestions will be considered for inclusion in the development of the final evaluation plan. At this time, we do not plan to mandate participation in data registries for this model, given the significant implementation and administrative requirements this would require of providers.

Comment: A commenter suggested a particular methodological consideration relevant to the evaluation. Specifically, this commenter noted that the approach of excluding BPCI participating hospitals in an MSA has its own form of selection bias in that the new model will only include hospitals that have chosen not to participate in the BPCI initiative, and therefore is not necessarily a representative sample.

Response: We recognize the importance of this issue and agree that the model evaluation must account for any limitations on our ability to extrapolate the results achieved under this model. We will take this into consideration during the development of the final evaluation plan in coordination with the Evaluation Contractor.

Comment: While many commenters expressed support for a vigorous evaluation, commenters brought up specific concerns related to the anticipated burden associated with the evaluation. The commenters requested that CMS should implement an evaluation process that is least disruptive to participants (providers and beneficiaries) and incorporate lessons learned from BPCI participants into the development process. One area of concern was the patient survey. A commenter noted that for the BPCI evaluation, participants were requested to refrain from non-patient care-related survey efforts while the CMS BPCI survey was in the field. The commenter wrote that this hampered the bundlers'

ability to seek real-time feedback to improve care. Another commenter recommended minimizing as much as possible the use of site visits and noted a desire for CMS to consider compensating hospitals for the time associated with this effort. In addition, the commenter noted concern that CMS is requiring collaborators to participate in site visits.

Response: We acknowledge the concern related to the administrative burden associated with the evaluation and will endeavor to minimize it to the extent possible, while still ensuring a thorough assessment of the model and its impacts. With regard to the specific concerns, the survey of patients is considered to be a key component of the evaluation intended to address the issues of patient functional performance, pain reduction, and reductions in access. It is likely that we will continue the practice of asking for non-mandated and non-patient care-related surveys to be suspended for brief periods of time so as to not overburden patients. Hospitals' survey efforts are otherwise unaffected. We believe that the temporary disruption in provider efforts is worth gaining the detailed information on patient function, pain, and access that the surveys provide. With regards to site visits, we intend to use this data collection approach judiciously and will be mindful of the impact on providers.

Regarding collaborator agreements, we are requiring that participant hospitals include provisions that require all CJR collaborators to comply with any evaluation, monitoring, compliance, and enforcement activities performed by HHS or its designees for the purposes of operating the CJR model. We intend to be prudent in exercising this requirement but we believe that it is necessary to include, particularly related to the need to assess compliance with model requirements and patient quality of care. We do not anticipate that this will be a significant barrier to CJR collaborators signing agreements.

Final Decision: After consideration of the public comments received, we are finalizing the proposed approach to the evaluation without modification.

V. Collection of Information Requirements

As stated in section1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this final rule need not be reviewed by the Office of Management and Budget.

VI. Regulatory Impact Analysis

We have examined the impact of this rule as required by Executive Order 12866 and other laws and Executive Orders requiring economic analysis of the effects of final rules.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking.

A. Statement of Need

This final rule is necessary in order to implement and test a new payment and service delivery model under the authority of section 1115A of the Act, which allows the Innovation Center to test innovative payment and service delivery models in order to reduce program expenditures while preserving or enhancing the quality of care furnished to individuals. The underlying issue addressed by the CJR model is that under FFS, Medicare makes separate payments to providers and suppliers for items and services furnished to a beneficiary over the course of a treatment (an episode of care). Because the amount of payment is dependent on the volume of services delivered, this creates incentives for care that is fragmented, unnecessary or duplicative, while impeding the investment in quality improvement or care coordination that will maximize patient benefit. We anticipate the CJR model may reduce costs while maintaining or improving quality where the provision of ''bundled services'' in which all the services needed for a given episode of care are included in a single payment arrangement that provides incentives to promote high quality and efficient care.

This final rule will create and test the first bundled payment model under the Innovation Center authority in which providers will be required to participate, building on the experience of the current voluntary BPCI and previous ACE efforts. Testing the model in this manner will also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize improvement in quality for common LEJR procedure episodes. This learning could inform future Medicare payment policy.

Under the CJR model, acute care hospitals in certain selected locations will receive retrospective bundled payments for episodes of care for LEJR or reattachment of a lower extremity. The proposed rule was developed based on the experiences we gained from the implementation of the Bundled Payments and Care Improvement Initiative and the ACE Demonstration to test bundled payments. We believe the model may benefit Medicare beneficiaries through improving the coordination and transition of care, improving the coordination of items and services paid for through Medicare FFS payments, encouraging provider investment in infrastructure and redesigned care processes for high quality and efficient service delivery, and incentivizing higher value care across the inpatient and PAC spectrum spanning the episode of care. It will also provide an opportunity to evaluate the nature and extent of reductions in the cost of treatment by providing financial incentives for providers to coordinate their efforts to provide services to meet patient needs and prevent future costs.

As detailed in Table 33, we estimate a total aggregate impact of $343 million in net Medicare savings over the duration of the model, CYs 2016 through 2020, from the implementation of the CJR model. This reflects the policies finalized in this rule, as well as updates to the data used for the impact analysis. We note that in the impact estimate in the proposed rule we had identified participant hospitals in the proposed selected 75 MSAs, though we inadvertently excluded some of those hospitals in our estimates presented in the proposed rule. For the impact analysis provided in this final rule, we revised our list of participant hospitals to include hospitals in the 67 MSAs selected for CJR and made the identification of hospitals consistent with how we identify hospitals in the selected MSAs in section III.A.3. of this final rule.

We note that we are posting the list of the participant hospitals in the selected MSAs on the CJR final rule Web site at *http://innovation.cms.gov/initiatives/CJR/* which generally reflects the hospitals used to estimate the impacts presented in this rule. Additionally, we note that this list will be updated throughout the model, to account for circumstances such as hospital mergers, BPCI termination, and new hospitals in the selected MSAs.

We note that we are finalizing the start date of this model to begin April 1, 2016 where the first performance year is 9 months and all other performance years begin January 1 and last 12 months. The estimates presented in this final rule reflect the changed start date

and the 9 month period for the first year of the model. These estimated impacts represent the estimated net effect of federal transfers under this model. Furthermore, the CJR model may benefit beneficiaries since the model requires participant hospitals to be accountable for 90-day episodes of care for Medicare beneficiaries with a LEJR, which may incentivize providers to improve the coordination of FFS items and services, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

Our analysis of the model's effects shows that this final rule will trigger the threshold of ''an annual effect on the economy of $100 million or more'' under E.O. 12866. Accordingly it will also be a major rule under the Congressional Review Act, and we are required to prepare an analysis that presents the costs and benefits of this final rule. We have prepared an analysis that address benefits and costs that applies to ''economically significant'' or ''major'' rules. We solicited comment on the assumptions and analysis presented throughout this regulatory impact section.

The following is a summary of the comments received and our responses.

Comment: A commenter found our savings estimates to be overly optimistic where our assumptions were based on other models launched by CMMI. The commenter found that because those models were voluntary and participants would withdraw from those models at any time based on their performance under the model that we could not apply those assumptions for this model where we have selected participants and those participants are not able to withdraw from this model. As a result, the commenter found our savings estimates to be overly optimistic and aggressive. Another commenter found the savings estimate to be surprisingly small given the scope of the proposed model affecting providers in 75 MSAs. The commenter requested additional information regarding how much savings has been estimated for reduced complications and for reduced use of SNF, IRF, imaging studies, and other specific components.

Response: We acknowledge that many of our assumptions used for these estimates are based on our experience with other voluntary bundled payment models and demonstrations as that is the most recent information that we have regarding how we expect hospitals to perform under a bundled payment model. For this model, we have not assumed any changes in utilization, which is, in part, informed by on our experience in other bundled payment models. However, we expect significant variation among hospitals and among metropolitan areas, but we are unable to predict these. Additionally, we believe the CJR model has been designed to provide additional safeguards considering that we have selected the hospitals to participate in the model. Those safeguards for hospitals to be able to manage risk include a transition to regional pricing, delaying the start date from January 1, 2016 to April 1, 2016 and providing for more incremental stop-loss limits where hospitals are subject to a maximum 20 percent stop-loss limit for performance years 4 and 5. As described earlier, for this final rule, we are updating the data used for the impact analysis to participant hospitals in the now 67 MSAs for the final rule and we are including participant hospitals identified in the proposed rule but that had been inadvertently excluded from the estimates presented in the proposed rule. As a result, the estimates have changed for this final rule, not only to reflect the policy changes finalized in this rule, but also to reflect the additional hospitals included in the estimates. As previously noted, we are posting the list of the participant hospitals in the selected MSAs on the CJR model Web site at *http://innovation.cms.gov/initiatives/CJR/*.

B. Overall Impact

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 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) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). 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. As previously stated, this final rule triggers these criteria.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, pre-empts state law, or otherwise has federalism implications. We do not believe that there is anything in this final rule that either explicitly or implicitly pre-empts any state law, and furthermore we do not believe that this final rule will have a substantial direct effect on state or local governments, preempt states law, or otherwise have a federalism implication.

C. Anticipated Effects

1. Overall Magnitude of the Model and Its Effects on the Market

According to Medicare FFS claims data in 2014, there were approximately 478,000 discharges for MS–DRGs 469 and 470 nationally. Based on the same data for 2014, we estimate that the participant hospitals had approximately 86,000 LEJR episodes (as defined in this model). The number of such procedures has grown in recent years, due both to the aging of the American population and to advances in medical technology and care that have made these operations less physically burdensome on patients and led to faster recovery times.

More uncertain are the total costs of these procedures. The mean estimated 90-day episode payment for LEJR procedures (defined as discharges for MS–DRG 469 and MS–DRG 470) is about $26,000 based on Medicare claims data for FY 2014 where approximately 55 percent of the spending is attributed to hospital inpatient services, 25 percent of spending is attributed to PAC services such as physical therapy (either ambulatory and in a facility) and 20 percent to physician, outpatient hospital and other spending.

We are testing the model in 67 MSAs out of the 196 MSAs initially deemed eligible for selection, as described previously in this final rule. We note that this is a change from the proposed rule where we had selected a proposed 75 MSAs but in this final rule, we are removing 8 MSAs from selection because they did not meet the updated eligibility criteria. Based on the selection methodology finalized in this rule, we estimate that the model will include about 23 percent of all LEJR episodes nationally. We estimate the model will apply to about $1.247 billion in episode spending in 2016 and $2.980 billion in episode spending in 2020 as displayed in Table 33 later in this section. As discussed subsequently in this analysis, this is likely to generate approximately a net amount of $343 million in savings to Medicare over the entire duration of the model. Annual reconciliation payments for each performance year may be greater than or less than the net change as detailed in Table 33 later in this section. In years 2019 and 2020 of the CJR model, we estimate a net change that is greater than the $100 million dollar threshold for economic significance.

There may also be spillover effects in the non-Medicare market, or even in the Medicare market in other areas as a result of this model. Recent research suggests that permanent changes in Medicare payment policy often have substantial effects on non-Medicare payers.[106] Because it is unclear whether and how this evidence applies to a test of a new payment model (as opposed to a change in permanent policy), our analyses assume that spillovers effects on non-Medicare payers will not occur, although this assumption is subject to considerable uncertainty. We welcomed comments on our assumptions and calculations.

2. Effects on the Medicare Program

The CJR model is a model involving an innovative mix of financial incentives for quality of care and efficiency gains within FFS Medicare for LEJR episodes. This model represents a new approach for the Medicare FFS program because it applies bundled payments to hospitals that might not otherwise participate in Innovation Center models or Medicare demonstrations and tests bundled payment models for episodes of care for LEJR procedures in multiple geographic areas. As such, we are interested in testing and evaluating the impact of a bundled payment approach for LEJR procedures in a variety of circumstances, especially among those providers that may not have decided to engage in programs or models in which Medicare makes payments differently than Medicare FFS.

As described earlier in this final rule in section III.B. of this final rule, episodes will begin with admission to an acute care hospital for an LEJR procedure that is paid under the IPPS through MS–DRG 469 or 470 and extend 90 days following discharge from the acute care hospital. The episode will include the LEJR procedure, inpatient stay, and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, PAC, and physician services. Furthermore, we have designated participant hospitals as the episode initiators and to be financially responsible for episode cost under the CJR model. We will require all hospitals paid under the IPPS and physically located in selected geographic areas to participate in the CJR model, with limited exceptions. Eligible beneficiaries who receive care at these hospitals will automatically be included in the model. Geographic areas, based on MSAs, were selected for the model through a stratified random sampling methodology based on the following criteria: historical episode wage-adjusted payment quartiles and population size halves. We anticipate the CJR model may have financial and quality of care effects on non-hospital providers and suppliers that are involved in the care of Medicare beneficiaries with an LEJR episode, improving the coordination of items and services paid for through Medicare FFS, encouraging more provider investment in infrastructure and redesigned care processes for higher quality and more efficient service delivery, and incentivizing higher value care across the inpatient and PAC spectrum spanning the episode of care. However, the CJR model attributes episode spending and makes the retrospective reconciliation payment to or repayment from the participant hospital. Accordingly, our analysis examines the effects on participant hospitals, as they are the providers accountable for the episode payment under this model. Additionally, we will test the CJR model for a performance period beginning April 1, 2016 and ending December 31, 2020 and our estimates cover the duration of the model. We note that in this final rule, we are changing the start date of the model such that the first year of the model will begin April 1, 2016 and have a performance period of 9 months. All other performance years of the model will begin January 1 and have a performance period of 12 months.

As described earlier in this final rule, we will continue paying hospitals and other providers and suppliers according to the usual Medicare FFS payment systems during all performance years. After the completion of a performance year, the Medicare claims payments for services furnished to the beneficiary during the episode, based on claims data, will be combined to calculate an actual episode payment. The actual episode payment is the sum of Medicare Part A and B claims payments for all related items and services furnished to a beneficiary during a CJR episode. The actual episode payment will then be reconciled against an established CJR target price, with consideration of additional payment adjustments based on quality performance and post episode spending. The amount of this calculation, if positive, will be paid to the participant hospital if the hospital has met the quality thresholds finalized in this rule. This payment is the reconciliation payment. If negative, the participant hospital will be required to make repayment to Medicare. We are phasing in the requirement that hospitals whose actual episode payments exceed their CJR target price to pay the difference back to Medicare beginning in performance year 2. Under this requirement, Medicare will not require repayment from hospitals for CJR episode spending above their target price in performance year 1. Lastly, we finalized to limit how much a hospital can gain or lose based on its reconciliation calculation with additional policies to further limit the risk of high payment cases for all participant hospitals and for special categories of hospitals.

Based on the mix of financial and quality incentives, the CJR model could result in a range of possible outcomes for participant hospitals. The effects on hospitals of potential savings and liabilities will have varying degrees.

Table 33 summarizes the estimated impact for the CJR model. Our model estimates that the Medicare program will save $343 million dollars over the 5 performance years (2016 through 2020). Savings to the Medicare program may be greater if providers are able to improve the coordination of care, invest in infrastructure, and redesign care processes to promote high quality and efficient service delivery. Costs to the Medicare program may increase if providers are able to use waivers provided under the model to increase

[106] See, for example, Jeffrey Clemens and Joshua D. Gottlieb. Forthcoming. ''In the Shadow of a Giant: Medicare'sMedicare's Influence on Private Physician Payments.'' *Journal of Political Economy.*

episode volume among beneficiaries that are expected to be less costly than the hospitals target price without the need for improving the coordination of care, or if there are declines in utilization independent of the model that are not incorporated in the prospective target prices. Our analysis to the best of our ability presents the cost and transfer payment effects of this final rule. We solicited comment on the assumptions and analysis presented.

a. Assumptions and Uncertainties

We used final action Medicare claims data from January 1, 2012 through March 31, 2015 as of October 2015 to simulate the impact that this model will have on Medicare spending for joint replacement episodes. This time period is consistent with the historical period that we are finalizing to use to calculate target prices for performance years 1 and 2 of the model as described in section III.C of this final rule (we note that for performance years 3 and 4, target prices will be calculated based on episodes that start between the period of January 1, 2014 to December 31, 2016. And for performance year 5, target prices will be calculated based on episodes that begin between the period of January 1, 2016 to December 31, 2018.) We applied the methodology provided in this final rule for calculating target prices for all hospitals that will be required to participate in the model, as discussed in section III.A. of this final rule, based on their performance from calendar years 2012 through 2014. Specifically, the estimates in this impact analysis reflect all IPPS hospitals in the selected MSAs and not participating in Model 1 or Phase II of BPCI Models 2 or 4 for the LEJR clinical episode as of October 2015. We identified the anchor hospitalizations based on claims with MS–DRG 469 and MS–DRG 470 and included the related spending that occurred 90 days after discharge. Also as finalized in this rule, we are risk stratifying for episodes with hip fractures for MS–DRG 469 and MS–DRG 470. For the purpose of the risk stratification, we identified anchor hospitalizations for MS–DRG 469 and MS–DRG 470 with hip fractures based on ICD–9–CM diagnosis codes reported on the anchor inpatient hospitalization claim. We removed payments excluded from the episode as not being associated with joint replacement care, as well as removing the IPPS add-on payments including disproportionate share hospital and indirect medical educational payments, new technology payments, uncompensated care payments, hospital value based purchasing payments, and hospital readmission reduction payments associated with the anchor hospitalization. We note that we have other payment exclusions in the calculation of the episode target price, in comparing actual episode payments with target prices, and in determining whether a reconciliation payment should be made to the hospital or repayment from the hospital should be made as described in section III.C. of this final rule. For the purpose of this impact analysis, we have only limited our calculations to remove the IPPS add-on payments reported on the IPPS claims including disproportionate share hospital and indirect medical educational payments, new technology payments, uncompensated care payments, hospital value based purchasing payments, and hospital readmissions reduction payments in calculating estimated target prices and in comparing the target price to actual episode payments. We then excluded episodes where the anchor hospitalization occurred in hospitals that are not paid under the IPPS. As finalized in this rule, we excluded episodes where the patient died during the 90 day episode. With the remaining episodes, we standardized episode payments to remove the variation in spending due to differences in the hospital's wage index. We trended utilization and prices in 2012 and 2013 to match 2014 national performance, and we incorporated the outlier policy to cap spending for high cost outlier episodes such that payments are capped at the MS–DRG anchor value that is two standard deviations above the mean as described in section III.C. of this final rule. After we pooled episodes for MS–DRGs 469 and 470 with and without hip fractures, we calculated average risk-stratified episode prices for each hospital and census region, as well as a hospital-specific weight representing a case mix value for each hospital that is dependent only on episode volume for MS–DRGs 469 and 470 with and without hip fractures, and the national anchor factor. We then calculated blended prices for each hospital, with prices set at two-thirds of the hospital's experience and one-third of the region's average experience for performance years 1 and 2 of the model, as one-third of the hospital's experience and two-thirds of the region's experience as used for performance year 3 of the model, and as the region's average experience for performance years 4 and 5 of the model. We made an exception for hospitals with low historical CJR episode volume defined in this final rule as those with fewer than 20 CJR episodes in total across the 3 historical years, by setting their target price as the region's experience. These average prices were then disaggregated based on the national anchor factor of average episode spending for MS–DRG 470 relative to MS–DRG 469, the computed hospital-specific weight, the hospital's wage index was then applied back to the price, and a Medicare discount was applied.

After calculating risk stratified target prices for MS–DRG 469 and 470 for each hospital appropriate for each performance year, we compared these target prices against actual performance in the 2014 calendar year. We capped actual spending for individual episodes based on the methodology in this final rule for high cost episodes. After incorporating the final policy for high cost episodes, total Medicare FFS spending in the 2014 calendar year for each hospital was reconciled against the target price and total number of episodes for the hospital. The aggregate impacts were then determined by multiplying by the total episodes for each MS–DRG.

As described earlier in this rule, we are finalizing our proposal to rebase the target prices in performance years 3 and 4 based on episodes that start between the period of January 1, 2014 to December 31, 2016 and rebase target prices for performance year 5 based on episodes that start between the period of January 1, 2016 to December 31, 2018.

The difference between each CJR episode's actual payment and the relevant target price (calculated as target price subtracted by CJR episode actual episode payment) will be aggregated for all episodes for a participant hospital within the performance year, creating the NPRA. As finalized in this rule, any positive NPRA amount greater than the stop-gain limit will be capped at the stop-gain limit of 5 percent for performance years 1 and 2 of the model, 10 percent in performance year 3 and 20 percent in performance years 4 and 5. We note this is a change from the proposed rule where we had proposed a stop-gain limit to be capped at 20 percent for each performance year of the model. In addition, any negative NPRA amount exceeding the stop-loss limit will be capped at the stop-loss limit as described in section III.C.8.b. of this final rule. To limit a hospital's overall repayment responsibility under this model, a 5 percent repayment limit in performance year 2, 10 percent repayment limit in performance year 3 and a 20 percent repayment limit in performance years 4 and 5. We note that this is a change from our proposed rule where we had proposed to set a 10

percent repayment limit in performance year 2 and 20 percent repayment limit in performance years 3 and subsequent years. For rural hospitals, MDHS, SCHs and RRCs, we are requiring a 3 percent repayment limit in performance year 2 and a 5 percent repayment limit in performance year 3 and subsequent years. Furthermore, as described earlier in this final rule, we are not finalizing our proposal that in order for a participant hospital to qualify for a reconciliation payment, a hospital must meet or exceed the 30th percentile benchmark for each of the following three quality measures in performance years 1 through 3 and 40th percentile in performance years 4–5:

- Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550).
- Hospital-level 30-day, all-cause risk-standardized readmission rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551).
- HCAHPS survey (NQF #0166).

Additionally, as described earlier in this final rule in section III.C.5., we are not finalizing our proposal that hospitals could qualify for a lower discount from 2 percent to 1.7 percent applied to their target episode price if they voluntarily submit patient-reported outcome measures data. Rather, we are finalizing the use of a composite quality score based on achievement and improvement on the THA/TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0116), as well as submission of THA/TKA voluntary PRO data, that will assign hospitals to be below acceptable, acceptable, good, and excellent. Hospitals assigned as 'below acceptable' would not be eligible for a reconciliation payment and would be subject to a 3 percent discount. Hospitals assigned as 'acceptable' would be eligible for a reconciliation payment and would be subject to a 3 percent discount. Hospitals assigned as 'good' would be eligible for a reconciliation payment and would be subject to a 2 percent discount. Lastly, hospitals assigned as 'excellent' would be eligible for a reconciliation payment and would be subject to a 1.5 percent discount. We note that in performance year 2 and 3, the discount for repayment would be 1 percentage point less than the discount applied for a reconciliation payment. We have used the following data to model the impact of this policy:

- Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results reported on Hospital Compare in July 2015 based on the performance period of April 1, 2011 through March 31, 2014.
- HCAHPS survey (NQF #0166) reported on Hospital Compare in October 2015 based on the performance period of January 1, 2014 through December 31, 2014. To calculate improvement included in the composite quality score, we used the following data:
- Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results reported on Hospital Compare in July 2014 based on the performance period of April 1, 2010 through March 31, 2013.
- HCAHPS survey (NQF #0166) reported on Hospital Compare in December 2014 based on the performance period of January 1, 2013 through December 31, 2013.

For the purpose of this analysis, we assumed that no hospitals voluntarily submitted patient reported outcome measures because we do not have the data to determine which hospitals in the model would submit this data. However, if we assumed that all hospitals in the model voluntarily submitted patient reported outcome measures, we would estimate that over the 5 performance years of the model, we would save $329 million (or 2.7% of total episode spend), as opposed to the projected estimates of $343 million (or 2.8% of total episode spend) in this final rule.. Hospitals located in selected MSAs were assigned to a performance percentile and assigned the corresponding quality performance score points listed in Table 16 of this final rule, based on their performance in the historical performance data described earlier. Hospitals that did not have a reported measure result were assigned to the 50th performance percentile. Hospitals assigned a quality measure performance percentile for the most recent year that improved by at least three deciles from the prior years' time period were quality improvement points. We used HCAHPS survey (NQF #0166) reported on Hospital Compare in October 2015 based on the performance period of January 1, 2014 through December 31, 2014 and Hospital-level (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results reported on Hospital Compare in July 2015 based on the performance period of April 1, 2011 through March 31, 2014 to model the hospital's performance in the most recent year. We used HCAHPS survey (NQF #0166) reported on Hospital Compare in December 2014 based on the performance period of January 1, 2013 through December 31,(RSCR)following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results reported on Hospital Compare in July 2014 based on the performance period of April 1, 2010 through March 31, 2013 to calculate the hospital's performance in the prior year for the purpose of modeling a hospital's quality improvement. Composite quality scores, including quality improvement points on the two measures, were calculated for hospitals in selected MSAs, and hospitals were assigned to a quality category of ''below acceptable'', ''acceptable'', ''good'' or ''excellent'' based on their composite quality scores. As discussed in section III.C.5. of this final rule, composite quality scores will affect hospitals' eligibility for reconciliation payments and determine the amount of quality incentive payment a given hospital earns, which will affect hospitals' effective discount percentages at reconciliation.

In order to model payments in this impacts analysis, hospitals assigned as 'below acceptable' would not be eligible for a reconciliation payment and would be subject to a 3 percent effective discount percentage; hospitals assigned as 'acceptable' would be eligible for a reconciliation payment and would be subject to a 3 percent effective discount percentage; hospitals assigned as 'good' would be eligible for a reconciliation payment and would be subject to a 2 percent effective discount percentage, and hospitals assigned as 'excellent' would be eligible for a reconciliation payment and would be subject to a 1.5 percent effective discount percentage. We note that for performance years 2 and 3 of the model, for the purpose of repayment, the discount percentage is one percentage point lower than the effective discount percentage assigned for reconciliation payment. Due to limited data, for the purpose of modeling these estimates, we assumed that hospitals in the selected MSAs would have the same composite quality score throughout the 5 year performance period of the model.

To simulate the impact for performance year 1 or April 1 2016 through December 31, 2016, we calculated the NPRA assuming no downside risk to hospitals, and using the target price calculated for performance year 1, that is two-thirds hospital experience and one-third region experience. If the estimated NPRA is negative (that is, in the aggregate, the actual episode payments

for all episodes is greater than the target price multiplied by the number of episodes) for performance year 1, Medicare will not require repayment of the NPRA from the hospital because we have finalized no hospital responsibility for repayment for the first performance year. Additionally, as part of this estimate, we accounted for whether a hospital met the minimum composite quality score to be eligible for a reconciliation payment and to meet the quality incentive payment that adjusts the effective discount percentage to 2 percent or 1.5 percent. Lastly, we have applied the 5 percent stop-gain limit on the estimated reconciliation payments made to participant hospitals total reconciliation payments reflect what we will expect Medicare to pay hospitals due to normal claims variation, and due to a blended target price which rewards hospitals that already perform better than their regional average.

To simulate the impact in performance year 2, we calculated the NPRA with the 5 percent stop-loss and stop-gain limits applied, but only requiring repayments from hospitals for total spending that is above a 1 percent discount. Additionally, we accounted for whether hospitals would meet the quality payment incentives based on their performance for the THA/TKA complications rate and HCAHPs survey including eligibility for a reconciliation payment and the quality incentive discount at 2 percent or 1.5 percent. For the simulation in performance year 2, we used the target price calculated for performance year 2 that is two-thirds hospital experience and one-third regional experience. A 5 percent stop-loss limit was applied to repayments, and 3 percent stop-loss limit was applied for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers, and a 5 percent stop-gain limit was applied. We note that this is a change from the proposed rule where we proposed to apply a 10 percent stop-loss limit for all hospitals except for rural hospitals, sole community hospitals, Medicare dependent hospitals and rural referral centers.

To simulate the impact in performance year 3, we calculated the NPRA assuming 10 percent stop-gain and stop-loss limit and met the quality incentive scores for a reduced discount and for reconciliation payments, and requiring repayments from hospitals for total spending that is above the 2 percent discount. For the simulation in year 3, we used the target price calculated as one-third of the hospital's experience and two-thirds of the regional experience. We included a 10 percent stop-loss limit on repayments from acute care hospitals included in this analysis, but used a 5 percent stop-loss limit on reconciliation repayments from rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers. We note that this is a change from the proposed rule where we included a 20 percent stop-gain limit and 20 percent stop-loss limit on repayments for all hospitals with the exception of rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers

For performance years 4 and 5, the impact estimates were calculated in the same way except that the episode target prices are based on 100 percent of the regional experience and the stop-loss and stop-gain limits are set to 20 percent.

In the CJR model, we have finalized to include a total of 67 MSAs from 8 MSA groupings. IPPS hospitals located within the selected MSAs will be required to participate in this model unless they participate in BPCI as discussed earlier in this final rule in section III.A.

Additionally, we note for these estimates, we did not assume that participation in this model would result in in efficiency or utilization over the course of the model. Since the model provides hospitals with strong incentives to improve efficiency, however, it is plausible that improvement in efficiency (and corresponding reductions in utilization) could occur. If such improvements occurred, however, it would have a limited effect on the net savings generated by the model since the resulting reduction in episode savings would be offset approximately one-for-one by higher net reconciliation payments up to the stop-gain limits. Over the 5 performance years of the model, we estimate $343 million dollars in savings to the Medicare program, out of $12.299 billion in total episode spending.

TABLE 33—ESTIMATES OF RECONCILIATION PAYMENTS *

	Performance year of the model					Across all 5 years of the model
	2016	2017	2018	2019	2020	
Total episode spending	$1,247	$2,562	$2,688	$2,821	$2,980	$12,299
Net reconciliation payments**	11	(36)	(71)	(120)	(127)	(343)
Reconciliation amounts	11	23	30	52	55	170
Repayment amounts	–	(58)	(101)	(172)	(182)	(513)
Net reconciliation as a percentage of total episode spend	0.8%	−1.4%	−2.6%	−4.2%	−4.2%	−2.8%

* Impact for 67 selected MSAs. All numbers rounded to closest million.
** Sum of reconciliation amount and repayment amount may not add to net reconciliation payment due to rounding.

These estimates contain a significant amount of uncertainty. As a result, this model could produce more significant Medicare savings or could result in additional costs to the Medicare program. The primary source of uncertainty stems from the normal variation in claim cost trends each year coupled with the cap on the repayment made at reconciliation. In addition, this analysis assumes no change in utilization both for the use of services within the bundled episode, as well as no change in total episodes among hospitals. The prospective prices for the CJR model incorporate price updates from the FFS payment systems, but assume no change in utilization for the performance years. If there is a national increase in utilization within each bundle that is independent of this model, then savings to the Medicare program may increase due to greater repayments paid back to Medicare. If there is a national decrease in utilization within each bundle that is independent of this model, then costs to the Medicare program may increase due to greater reconciliation payments paid by Medicare to hospitals. The results will also depend on the cumulative effects over time and across providers on whether and how the model changes either actual medical procedures or the allocations of payments among service providers. We will expect significant

variation among hospitals and among metropolitan areas, but are unable to predict these.

Additionally, although we project savings to Medicare under this model, as stated earlier, we note that under section 1115A(b)(3)(B) of the Act, the Secretary is required to terminate or modify a model unless certain findings can be made with respect to savings and quality after the model has begun. If during the course of testing the model it is determined that termination or modification is necessary, such actions will be undertaken through rulemaking as necessary.

b. Analyses

The first performance year of the model is expected to cost the Medicare program $11 million in reconciliation payments made by CMS to hospitals. No repayments from hospitals will be assessed because hospitals are not subject to downside risk in performance year 1. Hospitals that will receive reconciliation payments are the hospitals that provide lower cost care relative to their regional average. As stated earlier, we are finalizing that the first performance year will be 9 months beginning April 1, 2016 through December 31, 2016. The estimate reflects reconciliation payments made for a 9 month performance period.

In the second performance year of the model, participant hospitals on net are expected to pay $36 million to CMS. We are stipulating a 5 percent stop-loss and stop-gain limit for acute care hospitals, with exception for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral center hospitals which will be subject to a 3 percent stop-loss limit. These limits will cap the total amount of repayments paid by hospitals to CMS.

In the third performance year of the model, net reconciliation payments are expected to be $71 million in savings to the Medicare program. The additional savings in performance year 3 compared to performance year 2 can be attributed to the increase in the stop-loss and stop-gain limits to 10 percent for acute care hospitals, with exception for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral center hospitals which will be subject to a 5 percent stop-loss limit.

For performance years 4 and 5 of the model, the episode target price will be based on full regional pricing. This creates great variation between the target price and hospitals own experience. Therefore, the stop-gain and stop-loss limits of 20 percent on reconciliation payments are estimated to have a larger impact. As a result, net payments are expected to be $120 million dollars from hospitals to the Medicare program in the fourth year and $127 million in the fifth year. These estimated savings in years 4 and 5 represent 4.2 percent of total episode spending in those years.

The total savings to the Medicare program after 5 years of the model are expected to be $343 million dollars out of $12.299 billion dollars or 2.8 percent in total episode spending. Due to the uncertainty of estimating this model, actual results could be significantly higher or lower than this estimate.

c. Further Consideration

We can use our experience in previous implementation of bundled payment models to help inform our impact analyses. We have previously used our statutory authority to create payment models such as the BPCI initiative and the ACE Demonstration to test bundled payments. Under the authority of section 1866C of the Act, CMS funded a 3-year demonstration, the ACE Demonstration. The demonstration used a prospective global payment for a single episode of care as an alternative approach to payment for service delivery under traditional Medicare FFS. The episode of care was defined as a combination of Parts A and B services furnished to Medicare FFS beneficiaries during an inpatient hospital stay for any one of a specified set of cardiac and orthopedic MS DRGs. The MS DRGs tested included 469 and 470, which are included in the CJR model. The discounted bundled payments generated an average gross savings to Medicare of $585 per episode for a total of $7.3 million across all episodes (12,501 episodes) or 3.1 percent of the total expected costs for these episodes. After netting out the savings produced by the Medicare Parts A and B discounted payments and some increased PAC costs that were observed at two sites, Medicare saved approximately $4 million, or 1.72 percent of the total expected Medicare spending.

Additionally, we are currently testing the BPCI initiative. Under the initiative, entities enter into payment arrangements with CMS that include financial and performance accountability for episodes of care. Episodes of care under the BPCI initiative begin with either an—(1) Inpatient hospital stay; or (2) PAC services following a qualifying inpatient hospital stay and include tests of LEJR episodes. The BPCI initiative is evaluating the effects of episode based payment approaches on patient experience of care, outcomes, and cost of care for Medicare FFS beneficiaries. Although there is some evidence from BPCI and ACE suggesting that providers may improve their performance, both of these initiatives were voluntary, and the participants that volunteered to participate may be in a better position to reduce episode spending relative to the average provider. We believe that our experiences with BPCI support the design of the CJR Model.

3. Effects on Beneficiaries

In 2014, approximately 430,000 Medicare beneficiaries had discharges for LEJRs (MS–DRG 469 and MS–DRG 470) nationally. We anticipate that the CJR model may benefit beneficiaries receiving LEJRs because the intent of the model is to test whether providers under this bundled payment system are able to improve the coordination and transition of care, invest in infrastructure and redesigned care processes for high quality and efficient service delivery, and incentivize higher value care across the inpatient and PAC spectrum spanning the episode of care.

We have finalized several quality of care and patient experience measures to evaluate participant hospitals in the CJR model with the intent that it will encourage the provider community to focus on and deliver improved quality care for the Medicare beneficiary. We are finalizing to adopt and publicly report two hospital level quality of care measures for the CJR model. Those measures include a complication measure and a patient experience survey measure. In addition, we are finalizing to voluntarily collect data to develop a hospital-level measure of patient reported outcomes following an elective primary total hip or total knee arthroplasty to be used in future years of the model. We finalized to use these measures to assess the success of the model and to monitor for beneficiary safety. The accountability of participant hospitals for both quality and cost of care provided for Medicare beneficiaries with an LEJR episode provides the hospitals with new incentives to improve the health and well-being of the Medicare beneficiaries they treat.

Additionally, the model does not affect the beneficiary's freedom of choice to obtain health services from any individual or organization qualified to participate in the Medicare program. Under the CJR model, eligible beneficiaries who choose to receive services from a participant hospital will not have the option to opt out of inclusion in the model. Although the CJR model allows hospitals to enter into risk-sharing arrangements with certain other providers and these hospitals may recommended those providers to the

beneficiary, hospitals may not prevent or restrict beneficiaries to any list of preferred or recommended providers.

Many controls exist under Medicare to ensure beneficiary access and quality and we will use our existing authority, if necessary, to audit participant hospitals if claims analysis indicates an inappropriate change in delivered services. As described earlier in this final rule, given that participant hospitals will receive a reconciliation payment when they are able to reduce average costs per case and meet quality thresholds, they could have an incentive to avoid complex, high cost cases by referring them to nearby facilities or specialty referral centers. We intend to monitor the claims data from participant hospitals—for example, to compare a hospital's case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded. Furthermore, we also will require providers to supply beneficiaries with written information regarding the design and implications of this model as well as their rights under Medicare, including their right to use their provider of choice.

We are implementing several safeguards to ensure that Medicare beneficiaries do not experience a delay in services. We believe that the longer the episode duration, the lower the risk of delaying care beyond the episode duration, and we believe that a 90 day episode is sufficiently long to minimize the risk that any LEJR related care will be delayed beyond the end of the episode. Moreover, we have finalized as part of the payment definition (see section III.C. of this final rule) that certain post-episode payments occurring in the 30 day window subsequent to the end of the 90-day episode will be counted as an adjustment against savings. Importantly, approaches to saving costs will include taking steps that facilitate patient recovery, that shorten recovery duration, and that minimize post-operative problems that might lead to readmissions. Thus, the model itself rewards better patient care.

Lastly, we note that Medicare payments for services will continue to be made for each Medicare FFS payment system under this model, and will include normal beneficiary copayments, deductibles, and coinsurance. We expect and assume that beneficiary payments will not be affected, as only the hospital will be subject to the reconciliation process. Beneficiaries may benefit if providers are able to systematically improve the quality of care while reducing costs. We welcomed public comments on our estimates of the impact of our proposals on Medicare beneficiaries. We did not receive any comments on our estimates of the impact of our policies on Medicare beneficiaries.

4. Effects on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities, either by virtue of their nonprofit status or by qualifying as small businesses under the Small Business Administration's size standards (revenues of less than $7.5 to $38.5 million in any 1 year; NAIC Sector-62 series). States and individuals are not included in the definition of a small entity. For details, see the Small Business Administration's Web site at *http://www.sba.gov/content/small-business-size-standards*.

For purposes of the RFA, we generally consider all hospitals and other providers and suppliers to be small entities. We believe that the provisions of this final rule relating to acute care hospitals will have some effects on a substantial number of other providers involved in these episodes of care including surgeons and other physicians, SNFs, physical therapists, and other providers.

Although we acknowledge that many of the affected entities are small entities, and the analysis discussed throughout this final rule discusses aspects of the model that may or will affect them, we have no reason to assume that these effects will reach the threshold level of 5 percent of revenues used by HHS to identify what are likely to be ''significant'' impacts. Although LEJR procedures (MS–DRGs 469 and 470) are among the most common surgical procedures undergone by Medicare beneficiaries, they are only about 5 percent of all acute hospital discharges.[107] We assume that all or almost all of these entities will continue to serve these patients, and to receive payments commensurate with their cost of care. Such changes occur frequently already (for example, as both hospital affiliations and preferred provider networks change), and we have no reason to assume that this will change significantly under the model.

Accordingly, we have determined that this final rule will not have a significant impact on a substantial number of small entities. We solicited public comments on our estimates and analysis of the impact of our proposals on those small entities.

Comment: We received a comment regarding our determination that this rule would not have a significant impact on a substantial number of small entities. The commenter stated that because LEJRs are among the most common surgical procedures for Medicare beneficiaries, a significant number of Medicare patients are receiving their rehabilitation treatment outside the hospital at independent physical therapy practices. Thus, the commenter stated that the analysis erroneously focused on hospitals and neglected to address the impact that this model would have on small independent physical therapy practices.

Response: We acknowledge that many providers, besides hospitals, are involved in the continuum of care for Medicare beneficiaries in the 90-day post discharge LEJR episodes and will be impacted by this model. However, we have focused this impact analysis on the providers that are directly financially responsible for the episode of care for LEJRs, the IPPS hospitals in the selected MSAs. Many of the policies finalized in this rule are directed towards the IPPS hospitals because they are financially at risk under this model. Accordingly, the estimates in this impact analysis are for the hospitals participating in this model and we are unable to estimate the impacts on non-hospital providers and suppliers that are involved in the care for beneficiaries with LEJR episodes.

5. Effects on Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a proposed rule or final rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, a small rural hospital is defined as a hospital that is located outside of an MSA and has fewer than 100 beds. We note that, according to this definition, the CJR model will not include any rural hospitals given that the CJR model will only include hospitals located in MSAs, as discussed in section III.A of this final rule. However, we also note that as discussed in section III.C.8. of this final rule, for purposes of our policy finalized in this rule to include a more protective stop-loss policy for certain hospitals, we are finalizing to define a rural hospital as an IPPS hospital that is either located

[107] Medicare Inpatient Claims data from January-December 2014, Chronic Conditions Warehouse.

in a rural area in accordance with § 412.64(b) or in a rural census tract within an MSA defined at § 412.103(a)(1) or has reclassified to rural in accordance with § 412.103. Thus, the CJR model will affect some rural hospitals, as discussed previously in section III.C.8. of this final rule.

Because of our concerns that rural hospitals may have lower risk tolerance and less infrastructure and support to achieve efficiencies for high payment episodes, we are implementing additional financial protections for certain categories of hospitals, including rural hospitals. In performance year 2, a hospital could owe Medicare no more than 5 percent of the target price multiplied by the number of the hospital's LEJR episodes in CJR as we phase in repayment responsibility under the model and in performance year 3, a hospital could owe Medicare no more than 10 percent. In performance year 4 and 5 when full repayment responsibility is in place, no more than 20 percent of the target price multiplied by the number of the hospital's LEJR episodes in CJR could be owed by a hospital to Medicare. However, for rural hospitals, Medicare Dependent Hospitals, RRCs and Sole Community Hospitals, we are implementing a lower stop loss limit policy of 3 percent of episode payments for these categories of hospitals. More specifically, in performance year 2, a rural hospital, MDH, RRC, or SCH could owe Medicare no more than 3 percent of the target price multiplied by the number of the hospital's episodes in CJR. In performance years 3 through 5, such a hospital could owe Medicare no more than 5 percent of the target price multiplied by the number of the hospital's episodes. We are finalizing these additional protections, and we estimate that approximately 9 percent of participant hospitals are rural hospitals, MDHs, RRCs and SCHs that will be subject to these protections.

Because LEJR procedures (MS–DRGs 469 and 470) account for only about 5 percent of all discharges, because relatively few of these procedures are performed at small rural hospitals, and because our model is designed to minimize adverse effects on rural hospitals, we do not believe that rural hospitals will experience significant adverse economic impacts. Accordingly, we conclude that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

We solicited public comments on our estimates and analysis of the impact of our proposals on those small rural hospitals.

Comment: A commenter questioned our determination that this rule will not have a significant impact on small rural hospitals. The commenter was concerned that the proposed rule could cause significant harm to rural hospitals, particularly rural hospitals paid under cost reimbursement like CAHs. The commenter believed that because swing beds offered in CAHs are reimbursed at a higher cost based rate than SNFs, hospitals would divert their patients from the CAH to a SNF. This would result in a significant financial impact on the CAHs who would lose their swing bed patients.

Response: We appreciate the comment regarding the impact of this model on rural providers, particularly CAHs. CAHs have been excluded as episode initiators in this model as IPPS hospitals are the selected participants that are financially responsible for the 90-day LEJR episode. However, we anticipate that rural providers such as CAHs, RHCs and FQHCs would be involved in the care provided to Medicare beneficiaries with a 90-day LEJR episode. It is possible that as participant hospitals implement changes to improve efficiencies in episode spending that they may change their care coordination patterns with consideration to costs and quality, and it would affect other provider types involved in the care continuum for LEJR patients. As described earlier in this final rule, we recognize that rural IPPS hospitals, SCHs, MDH and RRCs often serve as the only access of care for beneficiaries living in rural areas and may have fewer resources to contain costs under this model and may have more limited options on providers to coordinate care with, such as CAHs that are reimbursed at a higher cost based rate. As a result, we have provided for more protective stop-loss limits for these groups of IPPS hospitals in order to be able to include them in the model while alleviating some financial risk and we believe that this model will not have a significant impact on the operations of a substantial number of small rural hospitals. Because IPPS hospitals are financially at risk in this model, the estimates in this impact analysis are for the hospitals selected to be in this model and we are unable to estimate the impacts on non-hospital rural providers that are involved in the care for beneficiaries with LEJR episodes.

6. Unfunded Mandates

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 2015, that is approximately $144 million. This final rule does not include any mandate that would result in spending by state, local or tribal governments, in the aggregate, or by the private sector in the amount of $144 million in any 1 year.

D. Alternatives

Throughout this final rule, we have identified our policies and alternatives that we have considered, and provided information as to the effects of these alternatives and the rationale for each of the policies. In the proposed rule we solicited and welcomed comments on our proposals, on the alternatives we identified, and on other alternatives that we should consider, as well as on the costs, benefits, or other effects of these. We note that our estimates are limited to the IPPS hospitals that are selected to participate in this model. This final rule will not directly affect hospitals that are not participating in the model. However, it may encourage innovations in health care delivery in other areas or in care reimbursed through other payers. For example, a hospital and affiliated providers may choose to extend their arrangements to all joint replacement procedures they provide, not just those reimbursed by Medicare. Alternatively, a hospital and affiliated providers in one city may decide to hold themselves forth as ''centers of excellence'' for patients from other cities, both those included and not included in the model. In the proposed rule we welcomed comments that address these or other possibilities. We did not receive any comments on the alternatives considered.

E. Accounting Statement

As required by OMB Circular A–4 under Executive Order 12866 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*) in Table 34, we have prepared an accounting statement showing the classification of transfers, benefits, and costs associated with the provisions in this final rule. The accounting statement is based on estimates provided in this regulatory impact analysis. As described in Table 33, we estimate this final model will result in savings to the federal government of $343 million over the 5 performance years of the model from 2016 to 2020. The following Table 34 shows the annualized change in (A) net federal monetary transfers, and (B) potential reconciliation payments to participating hospitals net of repayments from participant hospitals

that is associated with the provisions of this final rule as compared to baseline. In Table 34, the annualized change in payments based on a 7 percent and 3 percent discount rate, results in net federal monetary transfer from the participant IPPS hospitals to the federal government of $63 million and $65 million respectively.

TABLE 34—ACCOUNTING STATEMENT ESTIMATED IMPACTS

Category	Primary estimate	Source citation (RIA, preamble, etc.)
BENEFITS		
Annualized monetized transfers: Discount rate: 7%	$63 million	Change from baseline to final changes (Table 18).
Annualized monetized transfers: Discount rate: 3%	65 million..	
From whom to whom?	From Participant IPPS Hospitals to Federal Government.	

F. Conclusion

The preceding analysis, together with the remainder of this preamble, provides the Regulatory Impact Analysis of a rule with a significant economic effect. As a result of this final rule, we estimate of the financial impact of the CJR model for CYs 2016 through 2020 will be net federal savings of $343 million over a 5 year period. The annualized change in payments based on a 7 percent and 3 percent discount rate, results in net federal monetary transfer from the participant IPPS hospitals to the federal government of $63 million and $65 million respectively.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

List of Subjects for 42 CFR Part 510

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, under the authority at section 1115A of the Social Security Act, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as follows:

SUBCHAPTER H—HEALTH CARE INFRASTRUCTURE AND MODEL PROGRAMS

■ 1. Revise the heading of subchapter H to read as set forth above.

■ 2. Part 510 is added to subchapter H to read as follows:

PART 510—COMPREHENSIVE CARE FOR JOINT REPLACEMENT MODEL

Sec.

Authority: Secs. 1102, 1115A, and 1871 of the Social Security Act (42 U.S.C. 1302, 1315(a), and 1395hh).

Subpart A—General Provisions

§ 510.1 Basis and scope.

(a) *Basis.* This part implements the test of the Comprehensive Care for Joint Replacement model under section 1115A of the Act. Except as specifically noted in this part, the regulations under this part must not be construed to affect the payment, coverage, program integrity, or other requirements (such as those in parts 412 and 482 of this chapter) that apply to providers and suppliers under this chapter.

(b) *Scope.* This part sets forth the following:

(1) The participants in the Comprehensive Care for Joint Replacement model.

(2) The episodes being tested in the model.

(3) The methodology for pricing and payment under the model.

(4) Quality performance standards and quality reporting requirements.

(5) Safeguards to ensure preservation of beneficiary choice and beneficiary notification.

§ 510.2 Definitions.

For the purposes of this part, the following definitions are applicable unless otherwise stated:

ACO stands for accountable care organization.

Actual episode payment means the sum of Medicare claims payments for items and services that are included in the episode in accordance with § 510.200(b), excluding the items and services described in § 510.200(d).

Alignment payment means a payment from a CJR collaborator to a participant hospital under a sharing arrangement, for only the purpose of sharing the

participant hospital's responsibility for repayments to Medicare.

Anchor hospitalization means the initial hospital stay upon admission for a lower extremity joint replacement.

BPCI stands for the Bundled Payment for Care Improvement initiative.

CEC stands for Comprehensive ESRD Care Initiative.

CCN stands for CMS certification number.

CJR collaborator means one of the following Medicare-enrolled persons or entities that enters into a sharing arrangement:

(1) Skilled nursing facility (SNF).

(2) Home health agency (HHA).

(3) Long-term care hospital (LTCH).

(4) Inpatient rehabilitation facility (IRF).

(5) Physician.

(6) Nonphysician practitioner.

(7) Provider or supplier of outpatient therapy services.

(8) Physician group practice (PGP).

CJR reconciliation report means the report prepared after each reconciliation that CMS provides to each participant hospital notifying the participant hospital of the outcome of the reconciliation.

Collaborator agreement means a written, signed agreement between a CJR collaborator and a participant hospital that meets the requirements of § 510.500(c).

Composite quality score means a score computed for each participant hospital to summarize the hospital's level of quality performance and improvement on specified quality measures as described in § 510.315.

Core-based statistical area (CBSA) means a statistical geographic entity consisting of the county or counties associated with at least one core (urbanized area or urban cluster) of at least 10,000 population, plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties with the counties containing the core.

Critical access hospital (CAH) means a hospital designated under subpart F of part 485 of this chapter.

Distribution arrangement means a financial arrangement between a PGP that is a CJR collaborator and a practice collaboration agent in which the PGP distributes some or all of a gainsharing payment that it received from a participant hospital.

Distribution payment means a payment made by a PGP that is a CJR collaborator to a practice collaboration agent under a distribution arrangement.

DME stands for durable medical equipment.

EFT stands for electronic funds transfer.

Episode of care (or Episode) means all Medicare Part A and B items and services described in § 510.200(b) (and excluding the items and services described in § 510.200(d)) that are furnished to a beneficiary described in § 510.205 during the time period that begins with the beneficiary's admission to an anchor hospitalization and ends on the 90th day after the date of discharge from the anchor hospitalization, with the day of discharge itself being counted as the first day of the 90-day post-discharge period.

Episode target price means the amount determined in accordance with § 510.300 and applied to an episode in determining a net payment reconciliation amount.

ESRD stands for end stage renal disease.

Gainsharing payment means a payment from a participant hospital to a CJR collaborator, under a sharing arrangement, composed of only reconciliation payments or internal cost savings or both.

HHA stands for home health agency.

HCAHPS stands for Hospital Consumer Assessment of Healthcare Providers and Systems.

HCPCS stands for CMS Common Procedure Coding System.

Historical episode payment means the most recent 3 years of expenditures for an episode in a given participant hospital.

ICD–CM stands for International Classification of Diseases, Clinical Modification.

Inpatient prospective payment systems (IPPS) means the payment systems for subsection (d) hospitals as defined in section 1886(d)(1)(B) of the Act.

Internal cost savings means the measurable, actual, and verifiable cost savings realized by the participant hospital resulting from care redesign undertaken by the participant hospital in connection with providing items and services to beneficiaries within specific CJR episodes of care. Internal cost savings does not include savings realized by any individual or entity that is not the participant hospital.

IPF stands for inpatient psychiatric facility.

IPPS hospital (or hospital) means a provider subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

IRF stands for inpatient rehabilitation facility.

Lower-extremity joint replacement (LEJR) means any procedure that is within MS–DRG 469 or 470, including lower-extremity joint replacement procedures or reattachment of a lower extremity.

LTCH stands for long-term care hospital.

Medicare severity diagnosis-related group (MS–DRG) means, for the purposes of this model, the classification of inpatient hospital discharges updated in accordance with § 412.10 of this chapter.

Medicare-dependent, small rural hospital (MDH) means a specific type of hospital that meets the classification criteria specified under § 412.108 of this chapter.

Member of the PGP or *PGP member* means a physician, nonphysician practitioner, or therapist who is an owner or employee of the PGP and who has reassigned to the PGP his or her right to receive Medicare payment.

Metropolitan Statistical Area (MSA) means a core-based statistical area associated with at least one urbanized area that has a population of at least 50,000.

Net payment reconciliation amount (NPRA) means the amount determined in accordance with § 510.305(e).

Nonphysician practitioner means (except for purposes of subpart G of this part) one of the following:

(1) A physician assistant who satisfies the qualifications set forth at § 410.74(a)(2)(i) and (ii) of this chapter.

(2) A nurse practitioner who satisfies the qualifications set forth at § 410.75(b) of this chapter.

(3) A clinical nurse specialist who satisfies the qualifications set forth at § 410.76(b) of this chapter.

(4) A certified registered nurse anesthetist (as defined at § 410.69(b)).

(5) A clinical social worker (as defined at § 410.73(a)).

(6) A registered dietician or nutrition professional (as defined at § 410.134).

NPI stands for National Provider Identifier.

OIG stands for the Department of Health and Human Services Office of the Inspector General.

PAC stands for post-acute care.

Participant hospital means an IPPS hospital (other than those hospitals specifically excepted under § 510.100(b)) with a CCN primary address in one of the geographic areas selected for participation in the CJR model in accordance with § 510.105, as of the date of selection or any time thereafter during any performance period.

PBPM stands for per-beneficiary-per-month.

Performance year means one of the years in which the CJR model is being tested. Performance years for the model correlate to calendar years with the

exception of performance year 1, which is April 1, 2016 through December 31, 2016.

PGP stands for physician group practice.

Physician has the meaning set forth in section 1861(r) of the Act.

Post-episode spending amount means the sum of Medicare Parts A and B payments for items and services that are furnished to a beneficiary within 30 days after the end of the beneficiary's episode.

Practice collaboration agent means a PGP member who has entered into a distribution arrangement with the same PGP of which he or she is a member and who has not entered into a collaborator agreement with a participant hospital.

Provider of outpatient therapy services means a provider or supplier furnishing one or more of the following:

(1) Outpatient physical therapy services as defined in § 410.60 of this chapter.

(2) Outpatient occupational therapy services as defined in § 410.59 of this chapter.

(3) Outpatient speech-language pathology services as defined in § 410.62 of this chapter.

Quality improvement points are points that CMS adds to a participant hospital's composite quality score for a measure if the hospital's performance percentile on an individual quality measure increases from the previous performance year by at least 3 deciles on the performance percentile scale.

Quality performance points are points that CMS adds to a participant hospital's composite quality score for a measure based on the performance percentile scale and for successful data submission of patient-reported outcomes.

Reconciliation payment means a payment made by CMS to a CJR participant hospital as determined in accordance with § 510.305(f).

Region means one of the nine U.S. census divisions, as defined by the U.S. Census Bureau.

Repayment amount means the amount owed by a participant hospital to CMS, as reflected on a reconciliation report.

Rural hospital means an IPPS hospital that meets one of the following definitions:

(1) Is located in a rural area as defined under § 412.64 of this chapter.

(2) Is located in a rural census tract defined under § 412.103(a)(1) of this chapter.

(3) Has reclassified as a rural hospital under § 412.103 of this chapter.

Rural referral center (RRC) has the same meaning given this term under § 412.96 of this chapter.

Sharing arrangement means a financial arrangement between a participant hospital and a CJR collaborator for the sole purpose of making gainsharing payments or alignment payments under the CJR model.

Sole community hospital (SCH) means a hospital that meets the classification criteria specified in § 412.92 of this chapter.

SNF stands for skilled nursing facility.

Therapist means one of the following as defined at § 484.4:

(1) Physical therapist.

(2) Occupational therapist.

(3) Speech-language pathologist.

TKA/THA stands for total knee arthroplasty/total hip arthroplasty.

TIN stands for taxpayer identification number.

Subpart B—Comprehensive Care for Joint Replacement Program Participants

§ 510.100 Episodes being tested.

(a) *Initiation of an episode.* An episode is initiated when a participant hospital admits a Medicare beneficiary described in § 510.205 for an anchor hospitalization.

(b) *Exclusions.* A hospital is excluded from being a participant hospital, but only so long as any of the following conditions apply:

(1) The hospital is an episode initiator for an LEJR episode in the risk-bearing period of Models 2 or 4 of BPCI.

(2) The hospital is participating in Model 1 of BPCI.

(3) These exclusions cease to apply as of the date that the hospital no longer meets any of the conditions specified in this paragraph.

§ 510.105 Geographic areas.

(a) *General.* The geographic areas for inclusion in the CJR model are obtained based on a stratified random sampling of certain MSAs in the United States. All counties within each of the selected MSAs are selected for inclusion in the CJR model.

(b) *Stratification criteria.* Geographic areas in the United States are stratified according to the characteristics that CMS determines are necessary to ensure that the model is tested on a broad range of different types of hospitals that may face different obstacles and incentives for improving quality and controlling costs.

(c) *Exclusions.* CMS excludes from the selection of geographic areas MSAs that met the following criteria:

(1) Had fewer than 400 episodes between July 1, 2013 and June 30, 2014.

(2) Had fewer than 400 non-Model 1, 2, or 4 BPCI episodes as of October 1, 2015.

(3) Failed either or both of the following rules regarding participation in BPCI:

(i) More than 50 percent of eligible episodes initiated in a BPCI Model 2 or 4 initiating hospital.

(ii) More than 50 percent of eligible episodes that included SNF or HHA services, where the SNF or HHA services were furnished by a BPCI Model 3 initiating HHA or SNF.

(4) For MSAs including both Maryland and non-Maryland counties, more than 50 percent of eligible episodes were initiated at a Maryland hospital.

Subpart C—Scope of Episodes

§ 510.200 Time periods, included and excluded services, and attribution.

(a) *Time periods.* All episodes must begin on or after April 1, 2016 and end on or before December 31, 2020.

(b) *Included services.* All Medicare Parts A and B items and services are included in the episode, except as specified in paragraph (d) of this section. These services include, but are not limited to, the following:

(1) Physicians' services.

(2) Inpatient hospital services (including hospital readmissions).

(3) IPF services.

(4) LTCH services.

(5) IRF services.

(6) SNF services.

(7) HHA services.

(8) Hospital outpatient services.

(9) Outpatient therapy services.

(10) Clinical laboratory services.

(11) DME.

(12) Part B drugs and biologicals.

(13) Hospice services.

(14) PBPM payments under models tested under section 1115A of the Act.

(c) *Episode attribution.* All items and services included in the episode are attributed to the participant hospital at which the anchor hospitalization occurs.

(d) *Excluded services.* The following items, services, and payments are excluded from the episode:

(1) Hemophilia clotting factors provided in accordance with § 412.115 of this chapter.

(2) New technology add-on payments, as defined in part 412, subpart F of this chapter.

(3) Transitional pass-through payments for medical devices as defined in § 419.66 of this chapter.

(4) Items and services unrelated to the anchor hospitalization, as determined by CMS. Excluded services include, but are not limited to, the following:

(i) Inpatient hospital admissions for MS–DRGs that group to the following categories of diagnoses:

(A) Oncology.

(B) Trauma medical.

(C) Chronic disease surgical, such as prostatectomy.

(D) Acute disease surgical, such as appendectomy.

(ii) Medicare Part B services, as identified by the principal ICD–CM diagnosis code on the claim (based on the ICD–CM version in use during the performance year) that group to the following categories of diagnoses:

(A) Acute disease diagnoses, such as severe head injury.

(B) Certain chronic disease diagnoses, as specified by CMS on a diagnosis-by-diagnosis basis depending on whether the condition was likely to have been affected by the LEJR procedure and recovery period or whether substantial services were likely to be provided for the chronic condition during the episode. Such chronic disease diagnoses are posted on the CMS Web site and may be revised in accordance with paragraph (e) of this section.

(iii) Certain PBPM payments under models tested under section 1115A of the Act. PBPM model payments that CMS determines to be primarily used for care coordination or care management services for clinical conditions in excluded categories of diagnoses, as described in this paragraph.

(A) The list of excluded PBPM payments is posted on the CMS Web site and are revised in accordance with paragraph (e) of this section.

(B) Notwithstanding the foregoing, all PBPM model payments funded from CMS' Innovation Center appropriation are excluded from the episode.

(5) Certain incentive programs and add on payments under existing Medicare payment systems in accordance with § 510.300(b)(6) of this chapter.

(6) Payments for otherwise included items and services in excess of 2 standard deviations above the mean regional episode payment in accordance with § 510.300(b)(5) of this chapter.

(e) *Updating the lists of excluded services.* (1) The list of excluded MS–DRGs, ICD–CM diagnosis codes, and CMS model PBPM payments are posted on the CMS Web site.

(2) On an annual basis, or more frequently as needed, CMS updates the list of excluded services to reflect annual coding changes or other issues brought to CMS's attention.

(3) CMS applies the following standards when revising the list of excluded services for reasons other than to reflect annual coding changes:

(i) Items or services that are directly related to the LEJR procedure or the quality or safety of LEJR care would be included in the episode.

(ii) Items or services for chronic conditions that may be affected by the LEJR procedure or post-surgical care would be related and included in the episode.

(iii) Items and services for chronic conditions that are generally not affected by the LEJR procedure or post-surgical care would be excluded from the episode.

(iv) Items and services for acute clinical conditions not arising from existing, episode-related chronic clinical conditions or complications of LEJR surgery would be excluded from the episode.

(v) PBPM payments under CMS models determined to be primarily used for care coordination or care management services for clinical conditions in excluded categories of diagnoses, as described in § 510.200(d), would be excluded from the episode.

(4) CMS posts the following to the CMS Web site:

(i) Potential revisions to the exclusion to allow for public comment; and

(ii) An updated exclusions list after consideration of public comment.

§ 510.205 Beneficiary inclusion criteria.

(a) Episodes tested in the CJR model include only those in which care is furnished to beneficiaries who meet all of the following criteria upon admission to the anchor hospitalization:

(1) Are enrolled in Medicare Parts A and Part B.

(2) Eligibility for Medicare is not on the basis of end stage renal disease, as described in § 406.13 of this chapter.

(3) Are not enrolled in any managed care plan (for example, Medicare Advantage, health care prepayment plans, or cost-based health maintenance organizations).

(4) Are not covered under a United Mine Workers of America health care plan.

(5) Have Medicare as their primary payer.

(b) If at any time during the episode a beneficiary no longer meets all of the criteria in this section, the episode is canceled in accordance with § 510.210(b).

§ 510.210 Determination of the episode.

(a) *General.* The episode begins with the admission of a Medicare beneficiary described in § 510.205 to a participant hospital for an anchor hospitalization and ends on the 90th day after the date of discharge, with the day of discharge itself being counted as the first day in the 90-day post-discharge period.

(b) *Cancellation of an episode.* The episode is canceled and is not included in the determination of NPRA as specified in § 510.305 if the beneficiary does any of the following during the episode:

(1) Ceases to meet any criterion listed in § 510.205.

(2) Is readmitted to any participant hospital for another anchor hospitalization.

(3) Initiates an LEJR episode under BPCI.

(4) Dies.

Subpart D—Pricing and Payment

§ 510.300 Determination of episode target prices.

(a) *General.* CMS establishes episode target prices for participant hospitals for each performance year of the model as specified in this section. Episode target prices are established according to the following:

(1) MS–DRG assigned at discharge for anchor hospitalization and presence of hip fracture diagnosis for anchor hospitalization—

(i) MS–DRG 469 with hip fracture;

(ii) MS–DRG 469 without hip fracture;

(iii) MS–DRG 470 with hip fracture; or

(iv) MS–DRG 470 without hip fracture.

(2) *Applicable time period for performance year episode target prices.* Episode target prices are updated to account for Medicare payment updates no less than 2 times per year, for updated episode target prices effective October 1 and January 1, and at other intervals if necessary.

(3) *Episodes that straddle performance years or payment updates.* The episode target price that applies to the type of episode as of the date of admission for the anchor hospitalization is the episode target price that applies to the episode.

(4) Adjustments for quality performance, as specified in § 510.305(g).

(5) *Identifying episodes with hip fracture.* CMS develops a list of ICD–CM hip fracture diagnosis codes that, when reported in the principal diagnosis code files on the claim for the anchor hospitalization, represent a bone fracture for which a hip replacement procedure, either a partial hip arthroplasty or a total hip arthroplasty, could be the primary surgical treatment. The list of ICD–CM hip fracture diagnosis codes used to identify hip fracture episodes is posted on the CMS Web site.

(i) On an annual basis, or more frequently as needed, CMS updates the list of ICD–CM hip fracture diagnosis codes to reflect coding changes or other issues brought to CMS' attention.

(ii) CMS applies the following standards when revising the list of ICD–CM hip fracture diagnosis codes.

(A) The ICD–CM diagnosis code is sufficiently specific that it represents a bone fracture for which a physician could determine that a hip replacement procedure, either a PHA or a THA, could be the primary surgical treatment.

(B) The ICD–CM diagnosis code is the primary reason (that is, principal diagnosis code) for the anchor hospitalization.

(iii) CMS posts the following to the CMS Web site:

(A) Potential ICD–CM hip fracture diagnosis codes for public comment; and

(B) A final ICD–CM hip fracture diagnosis code list after consideration of public comment.

(b) *Episode target price.* (1) CMS calculates episode target prices based on a blend of each participant hospital's hospital-specific and regional episode expenditures. The region corresponds to the U.S. Census Division associated with the primary address of the CCN of the participant hospital and the regional component is based on all hospitals in said region, except as follows. In cases where an MSA selected for participation in CJR spans more than one U.S. Census Division, the entire MSA will be grouped into the U.S. Census Division where the largest city by population in the MSA is located for target price and reconciliation calculations. The calendar years used for historical expenditure calculations are as follows:

(i) Episodes beginning in 2012 through 2014 for performance years 1 and 2.

(ii) Episodes beginning in 2014 through 2016 for performance years 3 and 4.

(iii) Episodes beginning in 2016 through 2018 for performance year 5.

(2) Specifically, the blend consists of the following:

(i) Two-thirds of the participant hospital's own historical episode payments and one-third of the regional historical episode payments for performance years 1 and 2.

(ii) One-third of the hospital's own historical episode payments and two-thirds of the regional historical episode payments for performance year 3.

(iii) Regional historical episode payments for performance years 4 and 5.

(3) *Exception for low-volume hospitals.* Episode target prices for participant hospitals with fewer than 20 CJR episodes in total across the 3 historical years of data used to calculate the episode target price are based on 100 percent regional historical episode payments.

(4) *Exception for recently merged or split hospitals.* Hospital-specific historical episode payments for participant hospitals that have undergone a merger, consolidation, spin off or other reorganization that results in a new hospital entity without 3 full years of historical claims data are determined using the historical episode payments attributed to their predecessor(s).

(5) *Exception for high episode spending.* Episode payments are capped at 2 standard deviations above the mean regional episode payment for both the hospital-specific and regional components of the target price.

(6) *Exclusion of incentive programs and add-on payments under existing Medicare payment systems.* Certain incentive programs and add-on payments are excluded from historical episode payments by using the CMS Price (Payment) Standardization Detailed Methodology used for the Medicare spending per beneficiary measure in the Hospital Value-Based Purchasing Program.

(7) *Communication of episode target prices.* CMS communicates episode target prices to participant hospitals before the performance period in which they apply.

(c) *Discount factor.* A participant hospital's episode target prices incorporate applicable discount factors to reflect Medicare's portion of reduced expenditures from the CJR model as described in this section.

(1) *Discount factor for reconciliation payments.* The applicable discount factor for reconciliation payments in all performance years is 3.0 percent.

(2) *Discount factors for repayment amounts.* The applicable discount factor for repayment amounts are—

(i) Not applicable in performance year 1, as the requirement for hospital repayment under the CJR model is waived in performance year 1;

(ii) In performance years 2 and 3, 2.0 percent; and

(3) *Discount factors affected by the quality incentive payment and composite performance years.* In all performance years, the discount factor may be affected by the quality incentive payment and composite quality score as provided in § 510.315 to create a different effective discount factor used for calculating reconciliation payments and repayment amounts.

(d) *Data sharing.* (1) CMS makes available to participant hospitals, through the most appropriate means, data that CMS determines may be useful to participant hospitals to do the following:

(i) Determine appropriate ways to increase the coordination of care.

(ii) Improve quality.

(iii) Enhance efficiencies in the delivery of care.

(iv) Otherwise achieve the goals of the CJR model described in this section.

(2) *Beneficiary-identifiable data.* (i) CMS makes beneficiary-identifiable data available to a participant hospital in accordance with applicable privacy laws and only in response to the hospital's request for such data for a beneficiary who has been furnished a billable service by the participant hospital corresponding to the episode definitions for CJR.

(ii) The minimum data necessary to achieve the goals of the CJR model, as determined by CMS, may be provided under this section for a participant hospital's baseline period and no less frequently than on a quarterly basis throughout the hospital's participation in the CJR model.

§ 510.305 Determination of the NPRA and reconciliation process.

(a) *General.* Providers and suppliers furnishing items and services included in the episode bill for such items and services in accordance with existing rules and as if this part were not in effect.

(b) *Reconciliation.* CMS uses a series of reconciliation processes, which CMS performs as described in paragraphs (d) and (f) of this section after the end of each performance year, to establish final payment amounts to participant hospitals for CJR episodes for a given performance year. Following the end of each performance year, CMS determines actual episode payments for each episode for the performance year (other than episodes that have been canceled in accordance with § 510.210(b)) and determines the amount of a reconciliation payment or repayment amount.

(c) *Data used.* CMS uses the most recent claims data available to perform each reconciliation calculation.

(d) *Annual reconciliation.* (1) Beginning 2 months after the end of each performance year, CMS performs a reconciliation calculation to establish an NPRA for each participant hospital.

(2) CMS—

(i) Calculates the NPRA for each participant hospital in accordance with paragraph (e) of this section including the adjustments provided for in paragraph (e)(1)(iv) of this section; and

(ii) Assesses whether hospitals meet specified quality requirements under § 510.315.

(e) *Calculation of the NPRA.* By comparing the episode target prices described in § 510.300 and the participant hospital's actual episode spending for the performance year and applying the adjustments in paragraph (e)(1)(v) of this section, CMS establishes an NPRA for each participant hospital for each performance year.

(1) *Initial calculation.* In calculating the NPRA for each participant hospital for each performance year, CMS does the following:

(i) Determines actual episode payments for each episode included in the performance year (other than episodes that have been canceled in accordance with § 510.210(b)) using claims data that is available 2 months after the end of the performance year. Actual episode payments are capped at the amount determined in accordance with § 510.300(b)(5) for the performance year.

(ii) Multiplies each episode target price, after applying any reduction to the discount percentage as provided in § 510.315(f) by the number of episodes included in the performance year (other than episodes that have been canceled in accordance with § 510.210(b)) to which that episode target price applies.

(iii) Aggregates the amounts computed in paragraph (e)(1)(ii) of this section for all episodes included in the performance year (other than episodes that have been canceled in accordance with § 510.210(b)).

(iv) Subtracts the amount determined under paragraph (e)(1)(i) of this section from the amount determined under paragraph (e)(1)(iii) of this section.

(v) Makes the following adjustments:

(A) *Increases in post-episode spending.* If the average post-episode Medicare Parts A and B spending for a participant hospital in any given performance year is greater than 3 standard deviations above the regional average post-episode spending for the same performance year, then the spending amount exceeding three standard deviations above the regional average post-episode spending for the same performance year is applied to the NPRA.

(B) *Limitation on loss.* Except as provided in paragraph (e)(1)(v)(D) of this section, the total amount any participant hospital is responsible for repaying to Medicare for a performance year cannot exceed the following:

(*1*) For performance year 2 only, 5 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(*2*) For performance year 3, 10 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(*3*) For performance years 4, and 5, 20 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(*4*) As provided in paragraph (h)(6)(i) of this section, the subsequent reconciliation calculation reassesses the limitation on loss for a given performance year by applying the limitations on loss to the aggregate of the 2 reconciliation calculations.

(C) *Limitation on gain.* The total amount of any reconciliation payment made to a participant hospital for a performance year cannot exceed the following:

(*1*) For performance years 1 and 2, 5 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(*2*) For performance year 3, 10 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(*3*) For performance years 4, and 5, 20 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(*4*) As provided in paragraph (h)(6)(i) of this section, the subsequent reconciliation calculation reassesses the limitation on gain for a given performance year by applying the limitation on gain limits to the aggregate of the two reconciliation calculations.

(D) *Financial loss limits for rural hospitals, SCHs, MDHs, and RRCs.* If a participant hospital is a rural hospital, SCH, MDH or RRC, then for performance year 2, the total repayment amount for which the participant hospital is responsible cannot exceed 3 percent of the amount calculated in paragraph (e)(1)(iii) of this section. For performance years 3 through 5, the total repayment amount cannot exceed 5 percent of the amount calculated in paragraph (e)(1)(iii) of this section.

(f) *Determination of reconciliation or repayment amount*— (1) *Determination of the reconciliation or repayment amount.* (i) Subject to paragraph (f)(1)(iii) of this section, for performance year 1, the reconciliation payment (if any) is equal to the NPRA.

(ii) Subject to paragraph (f)(1)(iii) of this section, for performance years 2 through 5, results from the subsequent reconciliation calculation for a prior year's reconciliation, as described in paragraph (h)(6)(i) of this section, are applied to the current year's NPRA in order to determine the reconciliation or repayment amount.

(iii) The reconciliation or repayment amount may be adjusted as provided in § 510.410(b)(5).

(2) *Reconciliation payment.* If the amount described in paragraph (f)(1) of this section is positive and the composite quality score described in § 510.315 is acceptable (defined as greater than or equal to 4.00), good (defined as greater than or equal to 6.0 and less than or equal to 13.2), or excellent (defined as greater than 13.2), Medicare pays the participant hospital a reconciliation payment in an amount equal to the amount described in paragraph (f)(1) of this section.

(3) *Repayment amount.* If the amount described in paragraph (f)(1) of this section is negative, the participant hospital pays to Medicare an amount equal to the amount described in paragraph (f)(1) of this section, in accordance with § 405.371 of this chapter. CMS waives this requirement for performance year 1.

(g) *Determination of eligibility for reconciliation based on quality.* (1) CMS assesses each participant hospital's performance on quality metrics, as described in § 510.315, to determine whether the participant hospital is eligible to receive a reconciliation payment for a performance year.

(2) If the hospital's composite quality score described in § 510.315 is acceptable (defined as greater than or equal to 4.00), good (defined as greater than or equal to 6.0 and less than or equal to 13.2), or excellent (defined as greater than 13.2), and the hospital is determined to have a positive NPRA under § 510.305(e)), the hospital is eligible for a reconciliation payment.

(3) If the hospital's composite quality score described in § 510.315 is below acceptable, defined as less than 4.00 for a performance year, the hospital is not eligible for a reconciliation payment.

(4) If the hospital is found to be engaged in an inappropriate and systemic under delivery of care, the quality of the care provided must be considered to be seriously compromised and the hospital must be ineligible to receive or retain a reconciliation payment for any period in which such under delivery of care was found to occur.

(h) *Reconciliation report.* CMS issues each participant hospital a CJR reconciliation report for the performance year. Each CJR reconciliation report contains the following:

(1) Information on the participant hospital's composite quality score described in § 510.315.

(2) The total actual episode payments for the participant hospital.

(3) The NPRA.

(4) Whether the participant hospital is eligible for a reconciliation payment or must make a repayment to Medicare.

(5) The NPRA and subsequent reconciliation calculation amount for the previous performance year, as applicable.

(6) The reconciliation payment or repayment amount.

(i) *Subsequent reconciliation calculation.* (A) Fourteen months after the end of each performance year, CMS performs an additional calculation, using claims data available at that time, to account for final claims run-out and any additional overlap between the CJR model and other CMS models and programs as described in paragraph (h)(6)(i)(B) of this section.

(B) The subsequent reconciliation calculation accounts for cases in which a portion of the CJR discount percentage is paid out to an ACO as shared savings by reducing the reconciliation payment amount for a CJR hospital, if available, by the amount of the discount percentage paid out to the ACO as shared savings. This adjustment is only made when the participant hospital is a participant or provider/supplier in the ACO and the beneficiary in the CJR episode is assigned to one of the following ACO models or program:

(*1*) The Pioneer ACO model.

(*2*) The Medicare Shared Savings Program.

(*3*) The Next Generation ACO model.

(*4*) The Comprehensive ESRD Care Initiative.

(C) The additional calculation occurs concurrently with the reconciliation process for the most recent performance year. If the result of the subsequent calculation is different than zero, CMS applies the stop-loss and stop-gain limits in paragraph (e) of this section to the calculations in aggregate for that performance year (the initial reconciliation and the subsequent calculation) to ensure the amount does not exceed the stop-loss or stop-gain limits. CMS then applies the subsequent calculation amount to the NPRA for the most recent performance year in order to determine the reconciliation amount or repayment amount for the most recent performance year. Because hospitals will not have financial repayment responsibility for performance year 1, for the performance year 2 reconciliation report only, the subsequent calculation amount (for performance year 1) is applied to the performance year 1 NPRA to ensure that the combined amount is not less than 0. If the combined performance year 1 NPRA and subsequent calculation for performance year 1 is less than 0, the subsequent calculation amount would be capped at the value that would result in a net amount of 0 for the combined performance year 1 NPRA and subsequent calculation.

§ 510.310 Appeals process.

(a) *Notice of calculation error (first level of appeal).* Subject to the limitations on review in subpart d of this part, if a participant hospital wishes to dispute the calculation that involves a matter related to payment, reconciliation amounts, repayment amounts, or determinations associated with quality measures affecting payment, the hospital is required to provide written notice of the error, in a form and manner specified by CMS.

(1) Unless the participant hospital provides such notice, the CJR reconciliation report is deemed final 45 calendar days after it is issued.

(2) If CMS receives a timely notice of a calculation error, CMS responds in writing within 30 calendar days to either confirm that there was an error in the calculation or verify that the calculation is correct, although CMS reserves the right to an extension upon written notice to the participant hospital.

(3) If a participant hospital does not submit timely notice of a calculation error in accordance with the timelines and processes specified by CMS, then CMS deems final the CJR reconciliation report and proceeds with the payment or repayment processes, as applicable.

(4) Only participant hospitals may use the dispute resolution process described in this part.

(b) *Dispute resolution process (second level of appeal).* (1) If the participant hospital is dissatisfied with CMS's response to the notice of a calculation error, the participant hospital may request a reconsideration review in a form and manner as specified by CMS.

(2) The reconsideration review request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the participant hospital's assertion that CMS or its representatives did not accurately calculate the NPRA, the reconciliation payment, or the repayment amount in accordance with § 510.305.

(3) If CMS does not receive a request for reconsideration from the participant hospital within 10 calendar days of the issue date of CMS's response to the participant hospital's notice of calculation error, then CMS's response to the calculation error is deemed final and CMS proceeds with reconciliation payment or repayment processes, as applicable, as described in § 510.305.

(4) A CMS reconsideration official notifies the participant hospital in writing within 15 calendar days of receiving the participant hospital's review request of the following:

(i) The date, time, and location of the review.

(ii) The issues in dispute.

(iii) The review procedures.

(iv) The procedures (including format and deadlines) for submission of evidence.

(5) The CMS reconsideration official takes all reasonable efforts to schedule the review to occur no later than 30 days after the date of receipt of the notification.

(6) The provisions at § 425.804(b), (c), and (e) of this chapter are applicable to reviews conducted in accordance with the reconsideration review process for CJR.

(7) The CMS reconsideration official issues a written determination within 30 days of the review. The determination is final and binding.

(c) *Exception to the process.* If the participant hospital contests a matter that does not involve an issue contained in, or a calculation which contributes to, a CJR reconciliation report, a notice of calculation error is not required. An example of such a matter is termination of the participant hospital from the model. In those instances, if CMS does not receive a request for reconsideration from the participant hospital within 10 calendar days of the notice of the initial determination, the initial determination is deemed final and CMS proceeds with action indicated in the initial determination.

(d) *Limitations on review.* In accordance with section 1115A(d)(2) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

(1) The selection of models for testing or expansion under section 1115A of the Act.

(2) The selection of organizations, sites, or participants to test those models selected.

(3) The elements, parameters, scope, and duration of such models for testing or dissemination.

(4) Determinations regarding budget neutrality under section 1115A(b)(3) of Act.

(5) The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of Act.

(6) Decisions about expansion of the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not

expected to meet criteria described in paragraph (d)(1) or (2) of this section.

§ 510.315 Composite quality scores for determining reconciliation payment eligibility and quality incentive payments.

(a) *General.* A participant hospital's eligibility for a reconciliation payment under § 510.305(g), and the determination of quality incentive payments under paragraph (f) of this section, for a performance year depend on the hospital's composite quality score (including any quality performance points and quality improvement points earned) for that performance year.

(b) *Composite quality score.* CMS calculates a composite quality score for each participant hospital for each performance year, which equals the sum of the following:

(1) The hospital's quality performance points for the hospital-level risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty measure (NQF #1550) described in § 510.400(a)(1). This measure is weighted at 50 percent of the composite quality score.

(2) The hospital's quality performance points for the Hospital Consumer Assessment of Healthcare Providers and Systems Survey measure (NQF #0166) described in § 510.400(a)(2). This measure is weighted at 40 percent of the composite quality score.

(3) Any additional quality improvement points the hospital may earn as a result of demonstrating improvement on either or both of the quality measures in paragraphs (b)(1) and (2) of this section, as described in paragraph (d) of this section.

(4) If applicable, 2 additional points for successful THA/TKA voluntary data submission of patient-reported outcomes and limited risk variable data, as described in § 510.400(b). Successful submission is weighted at 10 percent of the composite quality score.

(c) *Quality performance points.* CMS computes quality performance points for each quality measure based on the participant hospital's performance percentile relative to the national distribution of all hospitals' performance on that measure.

(1) For the hospital-level risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty measure (NQF #1550) described in § 510.400(a)(1), CMS assigns the participant hospital measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(i) 10.00 points for ≥90th.
(ii) 9.25 points for ≥80th and <90th.
(iii) 8.50 points for ≥70th and <80th;
(iv) 7.75 points for ≥60th and <70th.
(v) 7.00 points for ≥50th and <60th.
(vi) 6.25 points for ≥40th and <50th.
(vii) 5.50 points for ≥30th and <40th.
(ix) 0.0 points for <30th.

(2) For the Hospital Consumer Assessment of Healthcare Providers and Systems Survey measure (NQF #0166) described in § 510.400(a)(2), CMS assigns the participant hospital measure value to a performance percentile and quality performance points are assigned based on the following performance percentile scale:

(i) 8.00 points for ≥90th.
(ii) 7.40 points for ≥80th and <90th.
(iii) 6.80 points for ≥70th and <80th.
(iv) 6.20 points for ≥60th and <70th.
(v) 5.60 points for ≥50th and <60th.
(vi) 5.00 points for ≥40th and <50th.
(vii) 4.40 points for ≥30th and <40th.
(ix) 0.0 points for <30th.

(d) *Quality improvement points.* If a participant hospital's quality performance percentile on an individual measure described in § 510.400(a) increases from the previous performance year by at least 3 deciles on the performance percentile scale, then the hospital is eligible to receive quality improvement points equal to 10 percent of the total available points for that individual measure.

(e) *Exception for hospitals without a measure value.* In the case of a participant hospital without a measure value that would allow CMS to assign quality performance points for that quality measure, CMS assigns the 50th percentile quality performance points to the hospital for the individual measure.

(1) A participant hospital will not have a measure value for the—

(i) Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty measure (NQF #1550) described in § 510.400(a)(1) if the hospital does not meet the minimum 25 case count; or

(ii) Hospital Consumer Assessment of Healthcare Providers and Systems Survey measure (NQF #0166) described in § 510.400(a)(2) if the hospital does not meet the minimum of 100 completed survey and does not have 4 consecutive quarters of HCAHPS data.

(ii) For either of the measures described in paragraphs (e)(1) or (2) of this section, if CMS identifies an error in the data used to calculate the measure and suppresses the measure value.

(f) *Quality incentive payments.* CMS provides incentive payments to participant hospitals that demonstrate good or excellent quality performance on the composite quality scores described in paragraph (b) of this section. These incentive payments are implemented in the form of the following reductions to the applicable discount factors described in § 510.300(c):

(1) A 1.0 percentage point reduction to the applicable discount factor for participant hospitals with good quality performance, defined as composite quality scores that are greater than or equal to 6.0 and less than or equal to 13.2.

(2) A 1.5 percentage point reduction to the applicable discount factor for participant hospitals with excellent quality performance, defined as composite quality scores that are greater than 13.2.

§ 510.320 Treatment of incentive programs or add-on payments under existing Medicare payment systems.

The CJR model does not replace any existing Medicare incentive programs or add-on payments. The target price and NPRA for a participant hospital are independent of, and do not affect, any incentive programs or add-on payments under existing Medicare payment systems.

§ 510.325 Allocation of payments for services that straddle the episode.

(a) *General.* Services included in the episode that straddle the episode are prorated so that only the portion attributable to care furnished during the episode are included in the calculation of actual episode payments.

(b) *Proration of services.* Payments for services that straddle the episode are prorated using the following methodology:

(1) *Non-IPPS inpatient services and other inpatient services.* Non-IPPS inpatient services, and services furnished by other inpatient providers that extend beyond the end of the episode are prorated according to the percentage of the actual length of stay (in days) that falls within the episode.

(2) *Home health agency services.* Home health services paid under the prospective payment system in part 484, subpart E of this chapter are prorated according to the percentage of days, starting with the first billable service date (''start of care date'') and through and including the last billable service date, that occur during the episode. This methodology is applied in the same way if the home health services begin (the start of care date) prior to the start of the episode.

(3) *IPPS services.* IPPS claim amounts that extend beyond the end of the

episode are prorated according to the geometric mean length of stay, using the following methodology:

(i) The first day of the IPPS stay is counted as 2 days.

(ii) If the actual length of stay that occurred during the episode is equal to or greater than the MS–DRG geometric mean, the normal MS–DRG payment is fully allocated to the episode.

(iii) If the actual length of stay that occurred during the episode is less than the geometric mean, the normal MS–DRG payment amount is allocated to the episode based on the number of inpatient days that fall within the episode.

(iv) If the full amount is not allocated to the episode, any remainder amount is allocated to the post-episode spending calculation (defined in § 510.2).

Subpart E—Quality Measures, Beneficiary Protections, and Compliance Enforcement

§ 510.400 Quality measures and reporting.

(a) *Reporting of quality measures.* The following quality measures are used for public reporting, for determining whether a participant hospital is eligible for reconciliation payments under § 510.305(g), and whether a participant hospital is eligible for quality incentive payments under § 510.315(f) in the performance year:

(1) Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty.

(2) Hospital Consumer Assessment of Healthcare Providers and Systems Survey.

(b) *Requirements for successful voluntary data submission of patient-reported outcomes and limited risk variable data.* To be eligible to receive the additional points added to the composite quality score for successful voluntary data submission of patient-reported outcomes and limited risk variable data, as described in § 510.315(b)(4), participant hospitals must submit the THA/TKA patient-reported outcome and limited risk variable data requested by CMS related to the pre- and post-operative periods for elective primary total hip and/or total knee arthroplasty procedures. The data must be submitted within 60 days of the end of the most recent performance period and be accompanied by the patient-reported outcomes and limited risk variable data (eleven elements finalized) as outlined in § 510.315(b)(4).

(1) For each eligible procedure all eleven risk variable data elements are required to be submitted. The eleven risk variables are as follows:

(i) Date of birth.

(ii) Race.

(iii) Ethnicity.

(iv) Date of admission to anchor hospitalization.

(v) Date of eligible THA/TKA procedure.

(vi) Medicare Health Insurance Claim Number.

(vii) Body mass index.

(viii) Use of chronic (≥90 day) narcotics.

(ix) Total painful joint count.

(x) Quantified spinal pain.

(xi) Single Item Health Literacy Screening (SILS2) questionnaire.

(2) Hospitals must also submit the amount of requested THA/TKA patient-reported outcomes data required for each year of the model in order to be considered successful in submitting voluntary data.

(i) The amount of requested THA/TKA patient-reported outcomes data to submit, in order to be considered successful will increase each subsequent year of the model over the 5 years of the model.

(ii) A phase-in approach that determines the amount of requested THA/TKA patient-reported outcomes data to submit over the 5 years of the program will be applied so that in year 1 successful submission of data would mean CMS received all requested THA/TKA patient-reported outcomes and limited risk variable data on both of the following:

(A) Greater than or equal to 50 percent of eligible procedures or greater than or equal to 50 eligible patients during the data collection period.

(B) Submission of requested THA/TKA PRO and limited risk variable data is completed within 60 days of the most recent performance period.

(3) For years 1 through 5 of the model an increasing amount of data is requested by CMS for each performance period as follows:

(i) Year 1 (2016). Submit pre-operative data on primary elective THA/TKA procedures for ≥50% or ≥50 eligible procedures performed between July 1, 2016 and August 31, 2016, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(ii) Year 2 (2017). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for ≥50% or ≥50 eligible procedures performed between July 1, 2016 through August 31, 2016; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥60% or ≥75 procedures performed between September 1, 2016 through June 30, 2017, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(iii) Year 3 (2018). Submit—

(A) POST-operative data on primary elective THA/TKA procedures for ≥60% or ≥75 procedures performed between September 1, 2016 and June 30, 2017; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥70% or ≥100 procedures performed between July 1, 2017 and June 30, 2018, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(iv) Year 4 (2019). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for ≥70% or ≥100 procedures performed between July 1, 2017 and June 30, 2018; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2018 and June 30, 2019, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(v) Year 5 (2020). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2018 and June 30, 2019 and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2019 and June 30, 2020, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(c) *Public reporting.* CMS—

(1) Makes the quality measurement results calculated for the complication and patient survey quality measures described in paragraph (a) of this section for each participant hospital in each performance year publicly available on the CMS Web site in a form and manner as determined by CMS;

(2) Shares each participant hospital's quality metrics with the hospital prior to display on the Web site; and

(3) Does not publicly report the voluntary patient-reported outcomes and limited risk variable data during this model, but does indicate whether a hospital has voluntarily submitted such data.

§ 510.405 Beneficiary choice and beneficiary notification.

(a) *Beneficiary choice.* The CJR model does not restrict Medicare beneficiaries' ability to choose any Medicare enrolled provider or supplier, or any physician or practitioner who has opted out of Medicare.

(1) As part of discharge planning and referral, participant hospitals must inform beneficiaries of all Medicare participating post-acute care providers in an area and must identify those post-acute care providers with whom they have sharing arrangements. Participant hospitals may recommend preferred providers and suppliers, consistent with applicable statutes and regulations. Participant hospitals may not limit beneficiary choice to any list of providers or suppliers in any manner other than that permitted under applicable statutes and regulations. Participant hospitals must respect patient and family preferences when they are expressed.

(2) Participant hospitals may not charge any CJR collaborator a fee to be included on any list of preferred providers or suppliers, nor may the participant hospital accept such payments.

(b) *Required beneficiary notification*—(1) *Hospital detailed notification.* Each participant hospital must provide written notice to any Medicare beneficiary that meets the criteria in § 510.205 of his or her inclusion in the CJR model. The notice must be upon admission to the participant hospital or immediately following the decision to schedule an LEJR surgery, whichever occurs later. The beneficiary notification must contain all of the following:

(i) A detailed explanation of the model and how it might be expected to affect the beneficiary's care.

(ii) Notification that the beneficiary retains freedom of choice to choose providers and services.

(iii) Explanation of how patients can access care records and claims data through an available patient portal, and how they can share access to their Blue Button® electronic health information with caregivers.

(iv) A statement that all existing Medicare beneficiary protections continue to be available to the beneficiary. These include the ability to report concerns of substandard care to Quality Improvement Organizations and 1–800–MEDICARE.

(v) A list of the providers and suppliers with whom the participant hospital has a collaborator agreement.

(2) *Physician provision of notice.* A participant hospital must require any physician that is a CJR collaborator to provide written notice of the structure of the model and the existence of the physician's sharing arrangement with the participant hospital to any Medicare beneficiary that meets the criteria specified in § 510.205. The notice must be provided at the time that the decision to undergo LEJR surgery is made.

(3) *PAC provider/supplier notification.* A participant hospital must require any provider or supplier, other than the treating physician discussed in paragraph (b)(2) of this section, with whom it has executed a collaborator agreement to provide written notice of the existence of its sharing arrangement with the participant hospital to any Medicare beneficiary that meets the criteria specified in § 510.205. The notice must be provided no later than the time at which the beneficiary first receives services from the provider or supplier during the CJR episode.

(4) *Discharge planning notice.* A participant hospital must provide the beneficiary with a written notice of any potential financial liability, associated with non-covered services recommended or presented as an option as part of discharge planning, no later than the time that the beneficiary discusses a particular PAC option or at the time the beneficiary is discharged, whichever occurs earlier.

(i) If the hospital knows or should have known that the beneficiary is considering or has decided to receive a non-covered post-acute service or other non-covered associated service or supply, the hospital must notify the beneficiary that the service would not be covered by Medicare.

(ii) If the hospital is discharging a beneficiary to a SNF prior to the occurrence of a 3 day hospital stay, and the beneficiary is being transferred to or is considering a SNF that would not qualify under the SNF 3-day waiver in § 510.610, the hospital notify the beneficiary in accordance with paragraph (b)(4)(i) of this section that the beneficiary will be responsible for costs associated with that stay except those which would be covered by Medicare Part B during a non-covered inpatient SNF stay.

§ 510.410 Compliance enforcement.

(a) *General.* Participant hospitals must comply with all of the requirements outlined in this part. Except as specifically noted in this part, the regulations under this part must not be construed to affect the payment, coverage, program integrity, or other requirements (such as those in parts 412 and 482 of this chapter) that apply to providers and suppliers under this chapter.

(b) *Failure to comply.* (1) CMS may take one or more of the remedial actions set forth in paragraph (b)(2) of this section if a participant hospital or any of the participant hospital's CJR collaborators—

(i) Fails to comply with any applicable requirements of this part or is identified as noncompliant through monitoring by HHS (including CMS and OIG) of the CJR model, including but not limited to the following:

(A) Avoiding potentially high cost patients.

(B) Targeting potentially low cost patients.

(C) Failing to provide medically appropriate services or systematically engaging in the over or under delivery of appropriate care.

(D) Failing to provide beneficiaries with complete and accurate information, including required notices.

(E) Failing to allow beneficiary choice of medically necessary options, including non-surgical options.

(F) Failing to follow the requirements related to collaborator agreements;

(ii) Has signed a collaborator agreement with a CJR collaborator if the agreement is noncompliant with the requirements of this part;

(iii) Takes any action that threatens the health or safety of patients;

(iv) Avoids at-risk Medicare beneficiaries, as this term is defined in § 425.20;

(v) Avoids patients on the basis of payer status;

(vi) Is subject to sanctions or final actions of an accrediting organization or federal, state, or local government agency that could lead to the inability to comply with the requirements and provisions of this part;

(vii) Takes any action that CMS determines for program integrity reasons is not in the best interests of the CJR model, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the CJR model;

(viii) Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions; or

(ix) Is subject to action involving violations of the physician self-referral law, civil monetary penalties law, federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to the CJR model.

(2) Remedial actions include the following:

(i) Issue a warning letter to the participant hospital.

(ii) Require the participant hospital to develop a corrective action plan, commonly referred to as a CAP.

(iii) Reduce or eliminate a participant hospital's reconciliation payment.

(iv) Require a participant hospital to terminate a collaborator agreement with a CJR collaborator and prohibit further engagement in the CJR model by that CJR collaborator.

(v) Terminate the participant hospital's participation in the CJR model.

(3) CMS may add 25 percent to a repayment amount on a participant hospital's reconciliation report if all of the following criteria are satisfied:

(i) CMS has required a corrective action plan from a participant hospital.

(ii) The participant hospital is not due a positive reconciliation payment but instead owes a repayment amount to CMS.

(iii) The participant hospital fails to timely comply with the corrective action plan or is noncompliant with the model's requirements.

Subpart F—Financial Arrangements and Beneficiary Incentives

§ 510.500 Financial arrangements under the CJR model.

(a) *General.* (1) A participant hospital may elect to enter into sharing arrangements.

(2) A participant hospital must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement. Any gainsharing payments or alignment payments made in accordance with a sharing arrangement must be made only from the participant hospital to the CJR collaborator with whom the participant hospital has signed a collaborator agreement containing a sharing arrangement.

(3) CMS may review any sharing arrangement for compliance with the requirements of this part and to ensure that it does not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(4) The participant hospital has ultimate responsibility for fully complying with all provisions of the CJR model.

(5) If a participant hospital enters into a sharing arrangement, it must update its compliance program to include oversight of sharing arrangements and compliance with the requirements of the CJR model.

(6) The board or other governing body of the participant hospital must have responsibility for overseeing the participant hospital's participation in the CJR model, its arrangements with CJR collaborators, its payment of gainsharing payments and receipt of alignment payments, and its use of beneficiary incentives in the CJR model.

(7) Participant hospitals must develop and maintain a written set of policies for selecting providers and suppliers for sharing gains and risk as CJR collaborators. This set of policies must contain criteria for selection of CJR collaborators related to, and inclusive of, the quality of care to be delivered by the CJR collaborator to beneficiaries during a CJR episode. The selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator. All collaborator agreements must require the CJR collaborator to have met, or agree to meet, the quality criteria for selection.

(b) *Sharing arrangement requirements.* Each sharing arrangement must comply with the following criteria:

(1) The sharing arrangement must be set forth in a collaborator agreement that complies with the requirements of paragraph (c) of this section.

(2) The sharing arrangement must comply with all relevant laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

(3) An individual or entity's participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.

(4) The parties must enter into a sharing arrangement before care is furnished to CJR beneficiaries under the terms of the sharing arrangement.

(5)(i) To be eligible to receive a gainsharing payment, a CJR collaborator must meet quality criteria for the calendar year for which the gainsharing payment is determined by the participant hospital. The quality criteria must be established by the participant hospital and directly related to CJR episodes of care.

(ii) To be eligible to receive a gainsharing payment or make an alignment payment, a CJR collaborator other than a PGP must directly furnish a billable service to a CJR beneficiary during a CJR episode that occurred in the calendar year in which the savings or loss was created.

(iii) To be eligible to receive a gainsharing payment, a PGP that is a CJR collaborator must meet the following criteria:

(A) The PGP must have billed for an item or service that was rendered by one or more members of the PGP to a CJR beneficiary during a CJR episode that occurred during the calendar year in which the participant hospital's internal cost savings was generated, or to which the NPRA applied, the latter of which is contained in a reconciliation payment.

(B) The PGP must contribute to a participant hospital's care redesign in the CJR model and be clinically involved in the care of CJR beneficiaries. The following is a non-exhaustive list of ways in which a PGP might be clinically involved in the care of CJR beneficiaries:

(*1*) Provide care coordination services to CJR beneficiaries during and/or after inpatient admission.

(*2*) Engage with a participant hospital in care redesign strategies, and actually perform a role in implementing such strategies, that are designed to improve the quality of care for LEJR episodes and reduce the LEJR episode spending.

(*3*) In coordination with other providers and suppliers (such as members of the PGP, participant hospitals, post-acute care providers), implement strategies designed to address and manage the comorbidities of CJR beneficiaries.

(6) No entity or individual, whether a party to a collaborator agreement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments on the volume or value of referrals or business otherwise generated by, between or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

(7) Gainsharing payments, if any, must be—

(i) Derived solely from reconciliation payments, or internal cost savings, or both;

(ii) Actually and proportionally related to the care of beneficiaries in a CJR episode;

(iii) Distributed on an annual basis (not more than once per calendar year);

(iv) Not be a loan, advance payments, or payments for referrals or other business; and

(v) Be clearly identified and comply with all provisions in this part, as well as all applicable laws, statutes, and rules.

(8) Alignment payments from a CJR collaborator to a participant hospital may be made at any interval that is agreed upon by both parties, and must—

(i) Not be issued, distributed, or paid prior to the calculation by CMS of a repayment amount reflected in a reconciliation report; and

(ii) Not be a loan, advance payments, or payments for referrals or other business.

(9) A participant hospital must not make a gainsharing payment to a CJR collaborator that is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the

provision of substandard care in CJR episodes or other integrity problems.

(10) In a calendar year, the aggregate amount of all gainsharing payments distributed by a participant hospital that are derived from a CJR reconciliation payment may not exceed the amount of the reconciliation payment the participant hospital receives from CMS.

(11) In a calendar year, the aggregate amount of all alignment payments received by the participant hospital must not exceed 50 percent of the participant hospital's repayment amount. No alignment payments may be collected by a participant hospital if it does not owe a repayment amount.

(12) The aggregate amount of all alignment payments from any one CJR collaborator to a participant hospital must not be greater than 25 percent of the participant hospital's repayment amount.

(13) A sharing arrangement must not induce the participant hospital, CJR collaborator, or any employees or contractors of the participant hospital or CJR collaborator to reduce or limit medically necessary services to any Medicare beneficiary.

(14) A sharing arrangement must not restrict the ability of a CJR collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.

(15) The methodology for determining gainsharing payments must be based, at least in part, on criteria related to, and inclusive of, the quality of care to be delivered to CJR beneficiaries during an episode and must not directly account for the volume or value of referrals or business otherwise generated by, between or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

(16) The methodology for determining alignment payments must not directly account for the volume or value of referrals or business otherwise generated by, between or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

(17) The total amount of a gainsharing payment for a calendar year paid to an individual physician or nonphysician practitioner who is a CJR collaborator must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule (PFS) for services furnished to the participant hospital's CJR beneficiaries during a CJR episode by that physician or nonphysician practitioner.

(18) The total amount of gainsharing payments for a calendar year paid to a PGP that is a CJR collaborator must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule for services that are billed by the PGP and furnished during a calendar year by members of the PGP to the participant hospital's CJR beneficiaries during CJR episodes.

(19) The participant hospital's determination of internal cost savings must satisfy the following criteria:

(i) Internal cost savings are calculated in accordance with generally accepted accounting principles and Government Auditing Standards (The Yellow Book).

(ii) All amounts determined to be internal cost savings must reflect actual, internal cost savings achieved by the participant hospital through implementation of care redesign elements identified and documented by the participant hospital. Internal cost savings does not include savings realized by any individual or entity that is not the participant hospital.

(iii) Internal cost savings may not reflect ''paper'' savings from accounting conventions or past investment in fixed costs.

(20) All gainsharing payments and any alignment payments must meet the requirements set forth in this section and be administered by the participant hospital in accordance with generally accepted accounting principles. In no event may the participant hospital receive any amounts from a CJR collaborator under a sharing arrangement that are not alignment payments.

(21) All gainsharing payments and alignment payments must be made through EFT.

(c) *Contents of collaborator agreement.* Each collaborator agreement must satisfy the following criteria:

(1) The collaborator agreement must contain a description of the sharing arrangement between the participant hospital and the CJR collaborator regarding gainsharing payments and alignment payments. This description must specify the following:

(i) The parties to the sharing arrangement.

(ii) The date of the sharing arrangement.

(iii) The purpose and scope of the sharing arrangement.

(iv) The financial or economic terms of the sharing arrangement, including the frequency of payment, and the methodology and accounting formula for determining the amount of any gainsharing payment or alignment payment.

(v) Safeguards to ensure that alignment payments are made solely for purposes related to sharing responsibility for funds needed to repay Medicare in the CJR model.

(vi) Plans regarding care redesign.

(vii) Changes in care coordination or delivery that is applied to the participant hospital or CJR collaborators or both.

(viii) A description of how success will be measured.

(ix) Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out changes to care under the CJR model.

(2) The collaborator agreement must contain a requirement that the CJR collaborator and its employees and contractors must comply with the applicable provisions of this part (including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees) and all other applicable laws and regulations.

(3) The collaborator agreement must require the CJR collaborator to be in compliance with all Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the agreement.

(4) The collaborator agreement must require the CJR collaborator to have a compliance program that includes oversight of the collaborator agreement and compliance with the requirements of the CJR model.

(5) The collaborator agreement must set forth a specific methodology for accruing, calculating, and verifying the internal cost savings generated by the participant hospital based on the care redesign elements specifically associated with the particular CJR collaborator.

(i) The methodology must set out the specific care redesign elements to be undertaken by the participant hospital or the CJR collaborator or both.

(ii) The methodology must be based, at least in part, on criteria related to, and inclusive of, the quality of care to be delivered to CJR beneficiaries during an episode and must not directly account for the volume or value of referrals or business otherwise generated by, between or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

(iii) The specific methodologies for accruing and calculating internal cost savings must be transparent, measurable, and verifiable in accordance with generally accepted

accounting principles and Government Auditing Standards (The Yellow Book).

(6) The collaborator agreement must set forth the quality criteria established by the participant hospital that will be used in determining the gainsharing payment.

(7) The collaborator agreement must require the participant hospital to recoup gainsharing payments paid to CJR collaborators if gainsharing payments contain funds derived from a CMS overpayment on a reconciliation report, or were based on the submission of false or fraudulent data.

(d) *Documentation requirements.* (1) Documentation of any collaborator agreement containing a sharing arrangement must be contemporaneous with the establishment of the arrangement.

(2) A participant hospital must maintain accurate current and historical lists of all CJR collaborators, including names and addresses of each CJR collaborator. The participant hospital must update the lists on at least a quarterly basis and publicly report the current and historical lists of CJR collaborators on a public-facing Web page on the participant hospital's Web site.

(3) The participant hospital and CJR collaborator must maintain contemporaneous documentation of the payment or receipt of any gainsharing payment or alignment payment. The documentation must identify at least the following: The nature of the payment (gainsharing payment or alignment payment); the identity of the parties making and receiving the payment; the date of the payment; the amount of the payment; and the date and amount of any recoupment of all or a portion of a CJR collaborator's gainsharing payment.

(4) The participant hospital must keep records of the following:

(i) Its process for determining and verifying the eligibility of CJR collaborators to participate in Medicare.

(ii) Information confirming the organizational readiness of the participant hospital to measure and track internal cost savings.

(iii) The participant hospital's plan to track internal cost savings.

(iv) Information on the accounting systems used to track internal cost savings.

(v) A description of current health information technology, including systems to track reconciliation payments and internal cost savings.

(vi) The participant hospital's plan to track gainsharing payments and alignment payments.

(vii) Whether the participant hospital recouped any gainsharing payments received by a CJR collaborator that contain funds derived from a CMS overpayment on a reconciliation report, or were based on the submission of false or fraudulent data.

(e) *Access to records and record retention.* All participant hospitals and CJR collaborators who enter into sharing arrangements must:

(1) Provide to CMS, the OIG, and the Comptroller General or their designees scheduled and unscheduled access to all books, contracts, records, documents, and other evidence (including data related to utilization and payments, quality criteria, billings, lists of CJR collaborators, sharing arrangements, and distribution arrangements, and the documentation required under paragraph (d) of this section) sufficient to enable the audit, evaluation, inspection, or investigation of the individual's or entity's compliance with CJR requirements, the quality of services furnished, the obligation to repay any reconciliation payments owed to CMS, or the calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, or distribution payments.

(2) Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the participant hospital's participation in the CJR model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the participant hospital at least 30 calendar days before the normal disposition date; or

(ii) There has been a dispute or allegation of fraud or similar fault against the participant hospital or any CJR collaborator, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

§ 510.505 Distribution arrangements.

(a) *General.* (1) A PGP that has entered into a collaborator agreement with a participant hospital may distribute all or a portion of any gainsharing payment it receives from the hospital only in accordance with a distribution arrangement.

(2) All distribution arrangements must comply with the provisions of paragraph (b) of this section and all applicable laws and regulations, including the fraud and abuse laws.

(b) *Requirements.* (1) All distribution arrangements must be in writing and signed by the PGP and practice collaboration agent.

(2) Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The distribution arrangement must require the practice collaboration agent to comply with the requirements set forth in this part.

(4) The opportunity to receive a distribution payment must not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the participant hospital, PGP, other CJR collaborators, practice collaboration agents, and any individual or entity affiliated with a participant hospital, CJR collaborator, or practice collaboration agent.

(5) Methodologies for determining distribution payments must not directly account for volume or value of referrals, or business otherwise generated, by, between or among the participant hospital, PGP, other CJR collaborators, practice collaboration agents, and any individual or entity affiliated with a participant hospital, CJR collaborator, or practice collaboration agent.

(6) A practice collaboration agent is eligible to receive a distribution payment only if the PGP billed for an item or service furnished by the practice collaboration agent to a CJR beneficiary during a CJR episode that occurred during the calendar year in which the participating hospital accrued the internal cost savings or earned the reconciliation payment that comprise the gainsharing payment made to the PGP.

(7) When a PGP receives a gainsharing payment from a participant hospital in accordance with a sharing arrangement, all monies contained in such a gainsharing payment must be shared only with the physician or nonphysician practitioners that are PGP members that furnished a service to a CJR beneficiary during an episode of care in the calendar year from which the NPRA, as that term is defined in this part, or internal cost savings was generated, either or both of which are the only permitted sources of funds for a gainsharing payment.

(8) The total amount of distribution payments for a calendar year paid to a practice collaboration agent must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule for services billed by the PGP and furnished by the practice collaboration agent to the participant hospital's CJR beneficiaries during a CJR episode.

(9) With respect to the distribution of any gainsharing payment received by a

PGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment.

(10) All distribution payments must be made through EFT.

(11) The practice collaboration agents must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(12) The distribution arrangement must not—

(i) Induce a practice collaboration agent to reduce or limit medically necessary services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(13) The PGP must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 510.500(e), including the relevant written agreements, the date and amount of any distribution payment, the identity of each practice collaboration agent who received a distribution payment, and a description of the methodology and accounting formula for determining the amount of any distribution payment.

(14) The PGP may not enter into a distribution arrangement with any member of the PGP that has a collaborator agreement in effect with a participant hospital.

§ 510.510 Enforcement authority.

(a) *OIG authority.* OIG authority is not limited or restricted by the provisions of the CJR model, including the authority to audit, evaluate, investigate, or inspect the participant hospital, CJR collaborators, or any other person or entity or their records, data, or information, without limitation.

(b) *Other authorities.* None of the provisions of the CJR model limits or restricts the authority of any other government agency permitted by law to audit, evaluate, investigate, or inspect the participant hospital, CJR collaborators, or any other person or entity or their records, data, or information, without limitation.

§ 510.515 Beneficiary incentives under the CJR model.

(a) *General.* Participant hospitals may choose to provide in-kind patient engagement incentives to beneficiaries in a CJR episode, subject to the following conditions:

(1) The incentive must be provided directly by the participant hospital or by an agent of the hospital under the hospital's direction and control to the beneficiary during a CJR episode of care.

(2) The item or service provided must be reasonably connected to medical care provided to a beneficiary during an episode.

(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as listed in paragraph (b) of this section, for a beneficiary in a CJR episode by engaging the beneficiary in better managing his or her own health.

(4) The item or service must not be tied to the receipt of items or services outside the CJR episode of care.

(5) The item or service must not be tied to the receipt of items or services from a particular provider or supplier.

(6) The availability of the items or services must not be advertised or promoted except that a beneficiary may be made aware of the availability of the items or services at the time the beneficiary could reasonably benefit from them.

(7) The cost of the items or services must not be shifted to another federal health care program, as defined at section 1128B(f) of the Act.

(b) *Goals of the CJR model.* The following are the particular clinical goals of the CJR model, which may be advanced through beneficiary incentives:

(1) Beneficiary adherence to drug regimens.

(2) Beneficiary adherence to a care plan.

(3) Reduction of readmissions and complications resulting from LEJR procedures.

(4) Management of chronic diseases and conditions that may be affected by the lower extremity joint replacement procedure.

(c) *Documentation of beneficiary incentives.* (1) Participant hospitals must maintain documentation of items and services furnished as beneficiary incentives that exceed $25 in retail value.

(2) The documentation must be contemporaneous with the provision of the items and services and must include at least the following:

(i) The date the incentive is provided.

(ii) The identity of the beneficiary to whom the item or service was provided.

(3) The participant hospital must retain the required documentation in accordance with paragraph (e) of this section.

(d) *Technology provided to a beneficiary.* (1) Items or services involving technology provided to a beneficiary may not exceed $1,000 in retail value for any one beneficiary in any one CJR episode.

(2) Items or services involving technology provided to a beneficiary must be the minimum necessary to advance a clinical goal, as listed in paragraph (b) of this section, for a beneficiary in a CJR episode.

(3) Items of technology exceeding $100 in retail value must—

(i) Remain the property of the participant hospital; and

(ii) Be retrieved from the beneficiary at the end of the CJR episode. The participant hospital must document all retrieval attempts, including the ultimate date of retrieval. Documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

(e) *Documentation and maintenance of records.* All participant hospitals that provide in-kind patient engagement incentives to beneficiaries in CJR episodes must:

(1) Provide to CMS, the OIG, and the Comptroller General or their designee(s) scheduled and unscheduled access to all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the participant hospital's compliance with CJR requirements for beneficiary incentives.

(2) Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the participant hospital's participation in the CJR model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the participant hospital at least 30 calendar days before the normal disposition rate; or

(ii) There has been a dispute or allegation of fraud or similar fault against the participant hospital, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

Subpart G—Waivers

§ 510.600 Waiver of direct supervision requirement for certain post-discharge home visits.

(a) *General.* CMS waives the requirement in § 410.26(b)(5) of this chapter that services and supplies furnished incident to a physician's service must be furnished under the direct supervision of the physician (or other practitioner) to permit home visits as specified in this section. The services furnished under this waiver are not considered to be ''hospital services,'' even when furnished by the clinical staff of the hospital.

(b) *General supervision of qualified personnel.* The waiver of the direct

supervision requirement in § 410.26(b)(5) of this chapter applies only in the following circumstances:

(1) The home visit is furnished during the episode to a beneficiary who has been discharged from an anchor hospitalization.

(2) The home visit is furnished at the beneficiary's home or place of residence.

(3) The beneficiary does not qualify for home health services under sections 1835(a) and 1814(a) of the Act at the time of any such home visit.

(4) The visit is furnished by clinical staff under the general supervision of a physician or non-physician practitioner. Clinical staff are individuals who work under the supervision of a physician or other qualified health care professional, and who are allowed by law, regulation, and facility policy to perform or assist in the performance of a specific professional service, but do not individually report that professional service.

(5) No more than 9 visits are furnished to the beneficiary during the episode.

(c) *Payment.* Up to 9 post-discharge home visits per CJR episode may be billed under Part B by the physician or nonphysician practitioner or by the participant hospital to which the supervising physician has reassigned his or her billing rights.

(d) *Other requirements.* All other Medicare rules for coverage and payment of services incident to a physician's service continue to apply.

§ 510.605 Waiver of certain telehealth requirements.

(a) *Waiver of the geographic site requirements.* Except for the geographic site requirements for a face-to-face encounter for home health certification, CMS waives the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act for episodes being tested in the CJR model, but only for services that—

(1) May be furnished via telehealth under existing requirements; and

(2) Are included in the episode in accordance with § 510.200(b).

(b) *Waiver of the originating site requirements.* Except for the originating site requirements for a face-to-face encounter for home health certification, CMS waives the originating site requirements under section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act for episodes being tested in the CJR model to permit a telehealth visit to originate in the beneficiary's home or place of residence, but only for services that—

(1) May be furnished via telehealth under existing requirements; and

(2) Are included in the CJR episode in accordance with § 510.200(b).

(c) *Waiver of selected payment provisions.* (1) CMS waives the payment requirements under section 1834(m)(2)(A) so that the facility fee normally paid by Medicare to an originating site for a telehealth service is not paid if the service is originated in the beneficiary's home or place of residence.

(2) CMS waives the payment requirements under section 1834(m)(2)(B) to allow the distant site payment for telehealth home visit HCPCS codes unique to this model to more accurately reflect the resources involved in furnishing these services in the home by basing payment upon the comparable office visit relative value units for work and malpractice under the Physician Fee Schedule.

(d) *Other requirements.* All other requirements for Medicare coverage and payment of telehealth services continue to apply, including the list of specific services approved to be furnished by telehealth.

§ 510.610 Waiver of SNF 3-day rule.

(a) *Waiver of the SNF 3-day rule.* For episodes being tested in the CJR model in performance years 2 through 5, CMS waives the SNF 3-day rule for coverage of a SNF stay for a CJR beneficiary following the anchor hospitalization, but only if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of CJR beneficiary admission to the SNF.

(1) CMS determines the qualified SNFs for each calendar quarter based on a review of the most recent rolling 12 months of overall star ratings on the Five-Star Quality Rating System for SNFs on the Nursing Home Compare Web site. Qualified SNFs are rated an overall of 3 stars or better for at least 7 of the 12 months.

(2) CMS posts to the CMS Web site the list of qualified SNFs in advance of the calendar quarter and the waiver only applies for a beneficiary who has been discharged from an anchor hospitalization if the SNF is included on the applicable calendar quarter list for the date of the beneficiary's admission to the SNF.

(b) *Other requirements.* All other Medicare rules for coverage and payment of Part A-covered SNF services continue to apply.

§ 510.615 Waiver of certain post-operative billing restrictions.

(a) *Waiver to permit certain services to be billed separately during the 90-day post-operative global surgical period.* CMS waives the billing requirements for global surgeries to allow the separate billing of certain post-discharge home visits described under § 510.600, including those related to recovery from the surgery, as described in paragraph (b) of this section, for episodes being tested in the CJR model.

(b) *Services to which the waiver applies.* Up to 9 post-discharge home visits, including those related to recovery from the surgery, per CJR episode may be billed separately under Part B by the physician or nonphysician practitioner, or by the participant hospital to which the physician or nonphysician practitioner has reassigned his or her billing rights.

(c) *Other requirements.* All other Medicare rules for global surgery billing during the 90-day post-operative period continue to apply.

§ 510.620 Waiver of deductible and coinsurance that otherwise apply to reconciliation payments or repayments.

(a) *Waiver of deductible and coinsurance.* CMS waives the requirements of sections 1813 and 1822(a) of the Act for Medicare Part A and Part B payment systems only to the extent necessary to make reconciliation payments or receive repayments based on the NPRA that reflect the episode payment methodology under the final payment model for CJR participant hospitals.

(b) *Reconciliation payments or repayments.* Reconciliation payments or repayments do not affect the beneficiary cost-sharing amounts for the Part A and Part B services provided under the CJR model.

Subparts H–J [Reserved]

Subpart K—Model Termination

§ 510.900. Termination of the CJR model.

CMS may terminate the CJR model for reasons including but not limited to the following:

(a) CMS determines that it no longer has the funds to support the CJR model.

(b) CMS terminates the model in accordance with section 1115A(b)(3)(B) of the Act. As provided by section 1115A(d)(2) of the Act, termination of the model is not subject to administrative or judicial review.

Dated: November 2, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 9, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–29438 Filed 11–16–15; 4:15 pm]

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Part III

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 218

Takes of Marine Mammals Incidental to Specified Activities; U.S. Navy Training and Testing Activities in the Northwest Training and Testing Study Area; Final Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 218

[Docket No. 140109018–5999–02]

RIN 0648–BD89

Takes of Marine Mammals Incidental to Specified Activities; U.S. Navy Training and Testing Activities in the Northwest Training and Testing Study Area

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

ACTION: Final rule.

SUMMARY: Upon application from the U.S. Navy (Navy), we (the National Marine Fisheries Service) are issuing regulations under the Marine Mammal Protection Act (MMPA) to govern the unintentional taking of marine mammals incidental to training and testing activities conducted in the Northwest Training and Testing (NWTT) Study Area from November 2015 through November 2020. These regulations allow us to issue Letters of Authorization (LOAs) for the incidental take of marine mammals during the Navy's specified activities and timeframes, set forth the permissible methods of taking, set forth other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, and set forth requirements pertaining to the monitoring and reporting of the incidental take. These regulations also allow us to authorize modifications to watchstander requirements for observed behavior of marine mammals during Major Training Events (MTEs) in the Hawaii-Southern California Training and Testing (HSTT), Atlantic Fleet Training and Testing (AFTT), Mariana Islands Training and Testing (MITT), and Gulf of Alaska Training (GOA) study areas. Modifications to the Navy watchstander requirements include a revision to regulatory text in current regulations governing the taking and importing of marine mammals during training and/or testing activities in these study areas. There are no MTEs associated with Navy training and testing activities in the NWTT Study Area.

DATES: *Effective date:* November 24, 2015. *Applicability date:* November 9, 2015, through November 8, 2020.

ADDRESSES: To obtain an electronic copy of the Navy's application or other referenced documents, visit the internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental/military.htm.* Documents cited in this rule may also be viewed, by appointment, during regular business hours, at 1315 East-West Highway, SSMC III, Silver Spring MD 20912.

FOR FURTHER INFORMATION CONTACT: John Fiorentino, Office of Protected Resources, NMFS, (301) 427–8477.

SUPPLEMENTARY INFORMATION:

Availability

A copy of the Navy's LOA application, which contains a list of the references used in this document, may be obtained by visiting the internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental/military.htm.* The Navy's Final Environmental Impact Statement/Overseas Environmental Impact Statement (FEIS/OEIS) for the NWTT Study Area, which also contains a list of the references used in this document, may be viewed at *http://www.nwtteis.com.* Documents cited in this notice may also be viewed, by appointment, during regular business hours, at the aforementioned address (see **ADDRESSES**).

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce 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.

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 National Defense Authorization Act of 2004 (NDAA) (Pub. L. 108–136) removed the ''small numbers'' and ''specified geographical region'' limitations indicated above and amended the definition of ''harassment'' as it applies to a ''military readiness activity'' to read as follows (section 3(18)(B) of the MMPA): ''(i) any act that injures or has the significant potential to injure a marine mammal or marine mammal stock in the wild [Level A Harassment]; or (ii) any act that disturbs or is likely to disturb a marine mammal or marine mammal stock in the wild by causing disruption of natural behavioral patterns, including, but not limited to, migration, surfacing, nursing, breeding, feeding, or sheltering, to a point where such behavioral patterns are abandoned or significantly altered [Level B Harassment].''

Summary of Request

On December 19, 2013, NMFS received an application (version (v)1 dated December 18, 2013) from the Navy requesting two LOAs for the take of 25 species of marine mammals incidental to Navy training and testing activities to be conducted in the NWTT Study Area over 5 years. On October 1, 2014, the Navy submitted a revised LOA application (v2 dated September 26, 2014) to reflect updates to exposure estimates based on emergent changes to specific types of training activities which were addressed in the Navy's supplemental EIS/OEIS for the NWTT Study Area. The revised application also provided an update to the effects analysis for Guadalupe fur seals (summarized in the Analysis of Guadalupe Fur Seal Exposures section of the proposed rule, which published on June 3, 2015 (80 FR 31737)) to more realistically reflect potential impacts from offshore Navy training and testing events. On November 7, 2014, the Navy submitted a revised LOA application (v3 dated November 7, 2014) to address: (a) An inadvertent error in the recommended mitigation zone for mine countermeasure and neutralization training events; (b) removal of the time delay firing underwater explosive training activity; (c) correction or clarification of certain mitigation measures applied to testing, and (d) revised mitigation for pinniped haulouts. On November 21, 2014, the Navy submitted a revised LOA application (v4 dated November 7, 2014) to correct inadvertent errors in the exposure calculations. On April 2, 2015, the Navy submitted a final revision to the LOA application (v5 dated April 2, 2015) (hereinafter referred to as the LOA application) to incorporate and update population density estimates for the Hood Canal stock of harbor seals and remove the ship strike mortality request.

The Navy is requesting separate 5-year LOAs for training and testing activities to be conducted from 2015 through 2020. The NWTT Study Area is composed of established maritime operating and warning areas in the eastern north Pacific Ocean region, to include the Strait of Juan de Fuca, Puget Sound, and Western Behm Canal in southeastern Alaska. The Study Area includes the existing Northwest Training Range Complex, the Keyport Range Complex, Carr Inlet Operations Area, Southeast Alaska Acoustic Measurement Facility (SEAFAC), and Navy pierside locations where sonar maintenance or testing may occur (see Figure 1–1 of the LOA application for a map of the NWTT Study Area). The activities conducted within the NWTT Study Area are classified as military readiness activities. The Navy states that these activities may expose some of the marine mammals present within the NWTT Study Area to sound from underwater acoustic sources and explosives. The Navy is requesting authorization to take 25 marine mammal species by Level B (behavioral) harassment; 5 of those marine mammal species may be taken by injury (Level A harassment). The Navy is not requesting mortality takes for any species.

The Navy's LOA application and the NWTT FEIS/OEIS contain acoustic thresholds that, in some instances, represent changes from what NMFS has used to evaluate the Navy's activities for previous authorizations. The revised thresholds, which the Navy developed in coordination with NMFS, are based on the evaluation and inclusion of new information from recent scientific studies; a detailed explanation of how they were derived is provided in the NWTT FEIS/OEIS Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis Technical Report (available at *http://www.nwtteis.com*). The revised thresholds are adopted for this rulemaking after providing the public with an opportunity for review and comment via the proposed rule for this action, which published on June 3, 2015 (80 FR 31737).

NOAA is currently in the process of developing Acoustic Guidance on thresholds for onset of auditory impacts from exposure to sound, which will be used to support assessments of the effects of anthropogenic sound on marine mammals. To develop this Guidance, NOAA is compiling, interpreting, and synthesizing the best information currently available on the effects of anthropogenic sound on marine mammals, and is committed to finalizing the Guidance through a systematic, transparent process that involves internal review, external peer review, and public comment.

In December 2013, NOAA released for public comment a ''Draft Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammals: Acoustic Threshold Levels for Onset of Permanent and Temporary Threshold Shifts'' (78 FR 78822). The Draft Guidance was generally consistent with the Navy's PTS/TTS criteria used in the NWTT FEIS/OEIS and detailed within Finneran and Jenkins (2012). Prior to the finalization of this guidance by NOAA, the Navy suggested revisions to the criteria (*e.g.,* auditory weighting functions and PTS/TTS thresholds) based on a number of studies available since the Navy's Phase 2 modeling, including Finneran *et al.* (2005), Finneran *et al.* (2010), Finneran and Schlundt (2013), Kastelein *et al.* (2012a), Kastelein *et al.* (2012b), Kastelein *et al.* (2014a), Kastelein *et al.* (2014b), Popov *et al.* (2013), and Popov *et al.* (2011). In January 2015, the Navy submitted a draft proposal (Finneran 2015) to NOAA staff for their consideration.

Finneran (2015) proposed new weighting functions and thresholds for predicting PTS/TTS in marine mammals. The methodologies presented within this paper build upon the methodologies used to develop the criteria used within the Navy's NWTT FEIS/OEIS (Finneran and Jenkins, 2012) and incorporate relevant auditory research made available since 2012. While Finneran and Jenkins (2012) presented a conservative approach to development of auditory weighting functions where data was limited, Finneran (2015) synthesizes a wide range of auditory data, including newly available studies, to predict refined auditory weighting functions and corresponding TTS thresholds across the complete hearing ranges of functional hearing groups. Finneran (2015) also developed updated threshold shift growth functions to facilitate the development of new PTS thresholds.

During the development process of NOAA's Draft Guidance, NOAA chose to incorporate Finneran (2015) into its Draft Guidance prior to its finalization. As a result, the Navy's proposal (Finneran 2015) was submitted for peer review by external subject matter experts, in accordance with the process previously conducted for NOAA's Draft Guidance. Peer review comments were received by NOAA in April 2015. NOAA subsequently developed a Peer Review Report, which was published on its Web site on July 31, 2015. The published report documents the Navy's proposal (Finneran 2015) that underwent peer review, the peer-review comments, and NOAA's responses to those comments. NOAA then incorporated this information into revised Draft Guidance which was published in the **Federal Register** for public review and comment (80 FR 45642) on July 31, 2015. The auditory weighting functions and PTS/TTS thresholds provided in that revised Draft Guidance will not be adopted by NOAA or applied to applicants until Final Guidance is issued. At the time of this rulemaking, Final Guidance has not been issued. Therefore, the Navy has not adopted these proposed criteria in its NWTT FEIS/OEIS. However, the underlying science contained within Finneran (2015) has been addressed qualitatively within the applicable sections of the Final EIS/OEIS and this rulemaking.

If the proposed criteria in Finneran (2015) were adopted by NOAA, incorporated into its Final Guidance, and applied to the Navy in the future, predicted numbers of PTS/TTS would change for most functional hearing groups. However, because Finneran (2015) relies on much of the same data as the auditory criteria presented in the Navy's NWTT FEIS/OEIS, these changes would not be substantial, and in most cases would result in a reduction in the predicted impacts. Predicted PTS/TTS would be reduced over much to all of their hearing range for low-frequency cetaceans and phocids. Predicted PTS/TTS for mid-frequency and high-frequency cetaceans would be reduced for sources with frequencies below about 3.5 kHz and remain relatively unchanged for sounds above this frequency. Predicted auditory effects on otariids would increase for frequencies between about 1 kHz and 20 kHz and decrease for frequencies above and below these points, although otariids remain the marine mammals with the least sensitivity to potential PTS/TTS. Overall, predicted auditory effects within this rulemaking would not change significantly.

In summary, NOAA's continued evaluation of all available science for the Acoustic Guidance could result in changes to the acoustic criteria used to model the Navy's activities for this rulemaking, and, consequently, the enumerations of ''take'' estimates. However, at this time, the results of prior Navy modeling described in this rule represent the best available estimate of the number and type of take that may result from the Navy's use of acoustic sources in the NWTT Study Area. Further, consideration of the

revised Draft Guidance and information contained in Finneran (2015) does not alter our assessment of the likely responses of marine mammals to acoustic sources employed by Navy in the NWTT Study Area, or the likely fitness consequences of those responses. Finally, while acoustic criteria may also inform mitigation and monitoring decisions, this rulemaking requires a robust adaptive management program that regularly addresses new information and allows for modification of mitigation and/or monitoring measures as appropriate.

NMFS is also authorizing modifications to watchstander requirements, which do not affect current mitigation measures, for observed behavior of marine mammals during MTEs in the HSTT, AFTT, MITT, and GOA study areas. With these modifications the Navy would no longer be required to report individual marine mammal sighting information when mitigation is not being implemented during the MTEs. After 5 years of collecting marine mammal sighting data for all animals sighted during MTEs, NMFS and the Navy have determined that without the ability to obtain species information this data set does not provide for any meaningful analysis beyond that which may be possible using mitigation-related observations alone. The Navy and NMFS have thoroughly investigated several potential uses for the data prior to reaching this conclusion. Additionally, this reporting requirement places an undue administrative burden on ships watch teams, which was undue given the limited value of the information collected, as was described during the Adaptive Management Process. The Navy will continue to collect marine mammal sighting data during MTEs for every instance when any form of mitigation is employed such as powering down or securing sonar, maneuvering the ship, or delaying an event—in other words, in instances where animals are closer to the sound source around which mitigation measures are implemented. This data is useful in supporting mitigation effectiveness analyses and also may be helpful in supporting an understanding of the frequency with which marine mammals (generally, not by species) may be encountered or detected in close proximity to a particular source (*e.g.,* where the likelihood of auditory or other injury is higher). Additionally, the Navy will continue to implement its separate Integrated Comprehensive Monitoring Program, which includes studies that are specifically designed to contribute to our understanding of the animals affected and how Navy training and testing impacts them. These modifications shall be implemented through the revision of regulatory text for existing regulations governing the taking of marine mammals incidental to training and/or testing activities in HSTT, AFTT, MITT, and GOA study areas. Revisions to the regulatory text are provided in the regulatory text at the end of this final rule. There are no MTEs or marine mammal sighting reporting requirements associated with Navy training and testing activities in the NWTT study area, therefore this revision is not applicable in NWTT.

Description of the Specified Activity

The proposed rule (80 FR 31738, June 3, 2015) and NWTT FEIS/OEIS include a complete description of the Navy's specified training and testing activities incidental to which NMFS is authorizing take of marine mammals in this final rule. Sonar use and underwater detonations are the stressors most likely to result in impacts on marine mammals that could rise to the level of harassment. Detailed descriptions of these activities are provided in the NWTT FEIS/OEIS and LOA application (*http://www.nmfs.noaa.gov/pr/permits/incidental/military.htm*) and are summarized here.

Overview of Training Activities

The Navy routinely trains in the NWTT Study Area in preparation for national defense missions. Training activities and exercises covered in the Navy's LOA request are briefly described below, and in more detail within Chapter 2 of the NWTT FEIS/OEIS. Training activities are categorized into eight functional warfare areas (anti-air warfare; amphibious warfare; strike warfare; anti-surface warfare; anti-submarine warfare; electronic warfare; mine warfare; and naval special warfare). The Navy determined that the following stressors used in these warfare areas are most likely to result in impacts on marine mammals:

- Anti-surface warfare (impulsive sources [underwater detonations])
- Anti-submarine warfare (non-impulsive sources [active sonar], impulsive underwater detonations)
- Mine warfare (non-impulsive sources, impulsive underwater detonations)

The Navy's activities in anti-air warfare, electronic warfare, and naval special warfare do not involve stressors that could result in harassment of marine mammals. Therefore, these activities are not discussed further. The analysis and rationale for excluding these warfare areas are contained in the NWTT FEIS/OEIS.

Overview of Testing Activities

Testing activities covered in the Navy's LOA request are briefly described below, and in more detail within Chapter 2 of the NWTT FEIS/OEIS. The Navy researches, develops, tests, and evaluates new platforms, systems and technologies. Many tests are conducted in realistic conditions at sea, and can range in scale from testing new software to operating portable devices to conducting tests of live weapons (such as the Service Weapon Test of a torpedo) to ensure they function as intended. Testing activities may occur independently of or in conjunction with training activities.

Many testing activities are conducted similarly to Navy training activities and are also categorized under one of the primary mission areas described above. Other testing activities are unique and are described within their specific testing categories. Because each test is conducted by a specific component of the Navy's research and acquisition community, which includes the Navy's Systems Commands and the Navy's scientific research organizations, the testing activities described in the LOA application are organized first by that particular organization as described below and in the order as presented.

The Navy describes and analyzes the effects of its testing activities within the NWTT FEIS/OEIS. In its assessment, the Navy concluded that acoustic stressors from the use of underwater acoustic sources and underwater detonations resulted in impacts on marine mammals that rose to the level of harassment as defined under the MMPA. Therefore, the LOA application for the NWTT Study Area provides the Navy's assessment of potential effects from these stressors in terms of the various activities that produce them.

The individual commands within the research and acquisition community included in the NWTT FEIS/OEIS and in the LOA application are:

- Naval Sea Systems Command (NAVSEA). Within NAVSEA are the following field activities:
  - Naval Undersea Warfare Center (NUWC) Division, Keyport
  - Naval Surface Warfare Center, Carderock Division (NSWCCD), Detachment Puget Sound
  - NSWCCD Southeast Alaska Acoustic Measurement Facility (SEAFAC)
  - Puget Sound Naval Shipyard and Intermediate Maintenance Facility
  - Various NAVSEA program offices

• Naval Air Systems Command (NAVAIR)

Description of Sonar, Ordnance, Targets, and Other Systems

The Navy uses a variety of sensors, platforms, weapons, and other devices to meet its mission. Training and testing with these systems may introduce acoustic (sound) energy into the environment. This section describes and organizes sonar systems, ordnance, munitions, targets, and other systems to facilitate understanding of the activities in which these systems are used. Underwater sound is described as one of two types for the purposes of the LOA application: Impulsive and non-impulsive. Sonar and similar sound producing systems are categorized as non-impulsive sound sources. Underwater detonations of explosives and other percussive events are impulsive sounds.

Sonar and Other Active Acoustic Sources

Modern sonar technology includes a variety of sonar sensor and processing systems. The simplest active sonar emits sound waves, or ''pings,'' sent out in multiple directions and the sound waves then reflect off of the target object in multiple directions. The sonar source calculates the time it takes for the reflected sound waves to return; this calculation determines the distance to the target object. More sophisticated active sonar systems emit a ping and then rapidly scan or listen to the sound waves in a specific area. This provides both distance to the target and directional information. Even more advanced sonar systems use multiple receivers to listen to echoes from several directions simultaneously and provide efficient detection of both direction and distance. The Navy rarely uses active sonar continuously throughout activities. When sonar is in use, the pings occur at intervals, referred to as a duty cycle, and the signals themselves are very short in duration. For example, sonar that emits a 1-second ping every 10 seconds has a 10-percent duty cycle. The Navy's largest hull-mounted mid-frequency sonar source nominally emits a 1-second ping every 50 seconds representing a 2% duty cycle. The Navy utilizes sonar systems and other acoustic sensors in support of a variety of mission requirements. Primary uses include the detection of and defense against submarines (anti-submarine warfare) and mines (mine warfare); safe navigation and effective communications; use of unmanned undersea vehicles; and oceanographic surveys. Sources of sonar and other active acoustic sources include surface ship sonar, sonobuoys, torpedoes, range pingers, and unmanned underwater vehicles.

Ordnance and Munitions

Most ordnance and munitions used during training and testing events fall into three basic categories: Projectiles (such as gun rounds), missiles (including rockets), and bombs. Ordnance can be further defined by their net explosive weight, which considers the type and quantity of the explosive substance without the packaging, casings, bullets, etc. Net explosive weight (NEW) is the trinitrotoluene (TNT) equivalent of energetic material, which is the standard measure of strength of bombs and other explosives. For example, a 12.7-centimeter (cm) shell fired from a Navy gun is analyzed at about 9.5 pounds (lb) (4.3 kilograms (kg)) of NEW. The Navy also uses non-explosive ordnance in place of high explosive ordnance in many training and testing events. Non-explosive ordnance look and perform similarly to high explosive ordnance, but lack the main explosive charge.

Defense Countermeasures

Naval forces depend on effective defensive countermeasures to protect themselves against missile and torpedo attack. Defensive countermeasures are devices designed to confuse, distract, and confound precision-guided munitions. Defensive countermeasures analyzed in the LOA application include acoustic countermeasures, which are used by surface ships and submarines to defend against torpedo attack. Acoustic countermeasures are either released from ships and submarines, or towed at a distance behind the ship.

Mine Warfare Systems

The Navy divides mine warfare systems into two categories: Mine detection and mine neutralization. Mine detection systems are used to locate, classify, and map suspected mines, on the surface, in the water column, or on the seafloor. The Navy analyzed the following mine detection systems for potential impacts to marine mammals:

• Towed or hull-mounted mine detection systems. These detection systems use acoustic and laser or video sensors to locate and classify suspect mines. Fixed and rotary wing platforms, ships, and unmanned vehicles are used for towed systems, which can rapidly assess large areas.

• Airborne Laser Mine Detection Systems. Airborne laser detection systems work in concert with neutralization systems. The detection system initially locates mines and a neutralization system is then used to relocate and neutralize the mine.

• Unmanned/remotely operated vehicles. These vehicles use acoustic and video or lasers to locate and classify mines and provide unique capabilities in nearshore littoral areas, surf zones, ports, and channels.

Mine neutralization systems disrupt, disable, or detonate mines to clear ports and shipping lanes, as well as littoral, surf, and beach areas in support of naval amphibious operations. Mine neutralization systems can clear individual mines or a large number of mines quickly. The Navy analyzed the following mine neutralization systems for potential impacts to marine mammals:

• Towed influence mine sweep systems. These systems use towed equipment that mimic a particular ship's magnetic and acoustic signature triggering the mine and causing it to explode.

• Towed mechanical mine sweeping systems. These systems tow a sweep wire to snag the line that attaches a moored mine to its anchor and then uses a series of cables and cutters to sever those lines. Once these lines are cut, the mines float to the surface where Navy personnel can neutralize the mines.

• Unmanned/remotely operated mine neutralization systems. Surface ships and helicopters operate these systems, which place explosive charges near or directly against mines to destroy the mine.

• Projectiles. Small- and medium-caliber projectiles, fired from surface ships or hovering helicopters, are used to neutralize floating and near-surface mines.

• Diver emplaced explosive charges. Operating from small craft, divers put explosive charges near or on mines to destroy the mine or disrupt its ability to function.

Explosive charges are used during mine neutralization system training activities; however, only non-explosive mines or mine shapes would be used.

Classification of Non-Impulsive and Impulsive Sources Analyzed

In order to better organize and facilitate the analysis of about 300 sources of underwater non-impulsive sound or impulsive energy, the Navy developed a series of source classifications, or source bins. This method of analysis provides the following benefits:

- Allows for new sources to be covered under existing authorizations, as long as those sources fall within the parameters of a ''bin;''
- Simplifies the data collection and reporting requirements anticipated under the MMPA;
- Ensures a conservative approach to all impact analysis because all sources in a single bin are modeled as the loudest source (*e.g.,* lowest frequency, highest source level, longest duty cycle, or largest net explosive weight within that bin);
- Allows analysis to be conducted more efficiently, without compromising the results;
- Provides a framework to support the reallocation of source usage (hours/explosives) between different source bins, as long as the total number and severity of marine mammal takes remain within the overall analyzed and authorized limits. This flexibility is required to support evolving Navy training and testing requirements, which are linked to real world events.

A description of each source classification is provided in Tables 1–3. Non-impulsive sources are grouped into bins based on the frequency, source level when warranted, and how the source would be used. Impulsive bins are based on the net explosive weight of the munitions or explosive devices. The following factors further describe how non-impulsive sources are divided:

- Frequency of the non-impulsive source:
  - Low-frequency sources operate below 1 kilohertz (kHz)
  - Mid-frequency sources operate at or above 1 kHz, up to and including 10 kHz
  - High-frequency sources operate above 10 kHz, up to and including 100 kHz
  - Very high-frequency sources operate above 100 kHz, but below 200 kHz
- Source level of the non-impulsive source:
  - Greater than 160 decibels (dB), but less than 180 dB
  - Equal to 180 dB and up to 200 dB
  - Greater than 200 dB

How a sensor is used determines how the sensor's acoustic emissions are analyzed. Factors to consider include pulse length (time source is on); beam pattern (whether sound is emitted as a narrow, focused beam, or, as with most explosives, in all directions); and duty cycle (how often a transmission occurs in a given time period during an event).

There are also non-impulsive sources with characteristics that are not anticipated to result in takes of marine mammals. These sources have low source levels, narrow beam widths, downward directed transmission, short pulse lengths, frequencies beyond known hearing ranges of marine mammals, or some combination of these factors. These sources were not modeled by the Navy, but are qualitatively analyzed in Table 1–4 of the LOA application and in the NWTT FEIS/OEIS. These sources generally meet the following criteria:

- Acoustic sources with frequencies greater than 200 kHz (based on known marine mammal hearing ranges)
- Sources with source levels less than 160 dB

TABLE 1—IMPULSIVE TRAINING AND TESTING SOURCE CLASSES ANALYZED

Source class	Representative munitions	Net explosive weight (lbs)
E1	Medium-caliber projectiles	0.1–0.25
E3	Large-caliber projectiles	>0.5–2.5
E4	Improved Extended Echo Ranging Sonobuoy	>2.5–5.0
E5	5 in. (12.7 cm) projectiles	>5–10
E8	250 lb. bomb, lightweight torpedo	>60–100
E10	1,000 lb. bomb, Air-to-Surface Missile	>250–500
E11	650 lb. mine, heavyweight torpedo	>500–650
E12	2,000 lb. bomb	>650–1,000

TABLE 2—NON-IMPULSIVE TRAINING SOURCE CLASSES ANALYZED

Source class category	Source class	Description
Mid-Frequency (MF): Tactical and non-tactical sources that produce mid-frequency (1 to 10 kHz) signals.	MF1	Active hull-mounted surface ship sonar (*e.g.*, AN/SQS–53C and AN/SQS–60).
	MF3	Active hull-mounted submarine sonar (*e.g.*, AN/BQQ–10).
	MF4	Active helicopter-deployed dipping sonar (*e.g.*, AN/AQS–22 and AN/AQS–13).
	MF5	Active acoustic sonobuoys (*e.g.*, AN/SSQ–62 DICASS [2]).
	MF11	Hull-mounted surface ship sonar with an active duty cycle greater than 80%.
High-Frequency (HF) and Very High-Frequency (VHF): Tactical and non-tactical sources that produce high-frequency (greater than 10 kHz but less than 200 kHz) signals.	HF1	Active hull-mounted submarine sonar (*e.g.*, AN/BQQ–15).
	HF4	Active mine detection, classification, and neutralization sonar (*e.g.*, AN/SQS–20).
	HF6	Active sources (equal to 180 dB and up to 200 dB).
Anti-Submarine Warfare (ASW): Tactical sources such as active sonobuoys and acoustic countermeasures systems used during ASW training activities.	ASW2	MF active Multistatic Active Coherent (MAC) sonobuoy (*e.g.*, AN/SSQ–125).
	ASW3	MF active towed active acoustic countermeasure systems (*e.g.*, AN/SLQ–25 NIXIE).

TABLE 3—NON-IMPULSIVE TESTING SOURCE CLASSES ANALYZED

Source class category	Source class	Description
Low-Frequency (LF): Sources that produce low-frequency (less than 1 kilohertz [kHz]) signals.	LF4	Low-frequency sources equal to 180 dB and up to 200 dB.
	LF5	Low-frequency sources less than 180 dB.
Mid-Frequency (MF): Tactical and non-tactical sources that produce mid-frequency (1 to 10 kHz) signals.	MF1	Active hull-mounted surface ship sonar (*e.g.*, AN/SQS–53C and AN/SQS–60).
	MF3	Hull-mounted submarine sonar (*e.g.*, AN/BQQ–10).
	MF4	Helicopter-deployed dipping sonar (*e.g.*, AN/AQS–22 and AN/AQS–13).
	MF5	Active acoustic sonobuoys (*e.g.*, DICASS).
	MF6	Active underwater sound signal devices (*e.g.*, MK–84).
	MF8	Active sources (greater than 200 dB).
	MF9	Active sources (equal to 180 dB and up to 200 dB).
	MF10	Active sources (greater than 160 dB, but less than 180 dB) not otherwise binned.
	MF11	Hull-mounted surface ship sonar with an active duty cycle greater than 80%.
	MF12	High duty cycle—variable depth sonar.
High-Frequency (HF) and Very High-Frequency (VHF): Tactical and non-tactical sources that produce high-frequency (greater than 10 kHz but less than 200 kHz) signals.	HF1	Hull-mounted submarine sonar (*e.g.*, AN/BQQ–10).
	HF3	Hull-mounted submarine sonar (classified).
	HF5 [1]	Active sources (greater than 200 dB).
	HF6	Active sources (equal to 180 dB and up to 200 dB).
	VHF2	Active sources with a frequency greater than 100 kHz, up to 200 kHz with a source level less than 200 dB.
Anti-Submarine Warfare (ASW): Tactical sources such as active sonobuoys and acoustic countermeasures systems used during the conduct of ASW testing activities.	ASW1	Mid-frequency Deep Water Active Distributed System (DWADS).
	ASW2	Mid-frequency Multistatic Active Coherent sonobuoy (*e.g.*, AN/SSQ–125)—sources analyzed by number of items (sonobuoys).
	ASW2	Mid-frequency sonobuoy (*e.g.*, high duty cycle)—Sources that are analyzed by hours.
	ASW3	Mid-frequency towed active acoustic countermeasure systems (*e.g.*, AN/SLQ–25).
	ASW4	Mid-frequency expendable active acoustic device countermeasures (*e.g.*, MK–3).
Torpedoes (TORP): Source classes associated with the active acoustic signals produced by torpedoes.	TORP1	Lightweight torpedo (*e.g.*, MK–46, MK–54).
	TORP2	Heavyweight torpedo (*e.g.*, MK–48, electric vehicles).
Acoustic Modems (M): Systems used to transmit data acoustically through water.	M3	Mid-frequency acoustic modems and similar sources (up to 210 dB) (*e.g.*, Underwater Emergency Warning System, Aid to Navigation).
Swimmer Detection Sonar (SD): Systems used to detect divers and submerged swimmers.	SD1	High-frequency sources with short pulse lengths, used for the detection of swimmers and other objects for the purpose of port security.
Synthetic Aperture Sonar (SAS): Sonar in which active acoustic signals are post-processed to form high-resolution images of the seafloor..	SAS2	High frequency unmanned underwater vehicle (UUV) (*e.g.*, UUV payloads).

[1] **Notes:** (1) For this analysis, HF5 consists of only one source; the modeling was conducted specifically for that source. (2) DICASS = Directional Command Activated Sonobuoy System Proposed Action.

Training and Testing

The training and testing activities that the Navy proposes to conduct in the NWTT Study Area are listed in Tables 4–6. Detailed information about each activity (stressor, training or testing event, description, sound source, duration, and geographic location) can be found in the LOA application and in Appendix A of the NWTT FEIS/OEIS. NMFS used the detailed information in the LOA application and in Appendix A of the NWTT FEIS/OEIS to analyze the potential impacts from training and testing activities on marine mammals. The Navy's activities are anticipated to meet training and testing needs in the years 2015–2020.

Correction to Sonar Testing Activities

During the development of the Navy's NWTT Draft, Supplemental and Final EIS/OEIS, 8 proposed life cycle pierside sonar testing events involving surface ships at Naval Station (NS) Everett were incorrectly modeled as 8 life cycle pierside sonar testing events involving submarines at Naval Base Kitsap (NBK)—Bremerton. The Navy identified this error while considering, at the request of NMFS, the overlap of NWTT activities within biologically important areas. Although documents released to the public for comment, including the NWTT Draft, Supplemental and Final EIS/OEIS, the Navy's LOA application, and NMFS' proposed rule qualitatively describe life cycle pierside sonar testing events as occurring at both NBK—Bremerton and Naval Station Everett, the quantitative analysis of impacts on marine mammals that could result from these activities is based on modeling data for more events occurring at NBK—Bremerton and fewer events than

required occurring at Naval Station Everett. Additionally, both the FEIS/OEIS and the proposed rule already included and considered quantitative analysis for Naval Station Everett pierside surface ship sonar maintenance training events, events which are similar in both conduct and effects to life cycle pierside sonar testing events.

The Navy corrected the error by eliminating 8 life cycle pierside sonar testing events involving submarines and their associated hours at NBK—Bremerton and adding 8 life cycle pierside sonar testing events involving surface ships and their associated hours to Naval Station Everett. This correction results in a reduction of hours in the MF3 bin (submarine sonar) and an addition of hours to the MF1 bin (surface ship sonar). Life cycle pierside sonar testing events involving submarines require use of up to 2 hours of MF3 sonar per event. Life cycle pierside sonar testing events involving surface ships require use of up to 4 hours of MF1 sonar per event. Given this difference between submarine and surface ship life cycle pierside sonar testing, elimination of the 8 submarine events at NBK—Bremerton will result in an overall reduction of 16 MF3 hours and addition of the 8 surface ship events at Naval Station Everett will result in an overall increase of 32 MF1 hours.

These revisions have been incorporated in this final rule (Table 5). Further, the updated predicted exposures resulting from this correction are included in the estimated Take of Marine Mammals section of this rule and depicted in Table 18, and the resulting analysis is discussed in the Analysis and Negligible Impact Determination section of this rule.

Summary of Non-Impulsive and Impulsive Sources

Table 4 provides a quantitative annual summary of training activities by sonar and other active acoustic source class analyzed in the Navy's LOA request.

TABLE 4—ANNUAL HOURS OF SONAR AND OTHER ACTIVE ACOUSTIC SOURCES USED DURING TRAINING WITHIN THE NWTT STUDY AREA

Source class category	Source class	Annual use
Mid-Frequency (MF) Active sources from 1 to 10 kHz	MF1	166 hours.
	MF3	70 hours.
	MF4	4 hours.
	MF5	896 items.
	MF11	16 hours.
High-Frequency (HF) Tactical and non-tactical sources that produce signals greater than 10kHz but less than 100kHz.	HF1	48 hours.
	HF4	384 hours.
	HF6	192 hours.
Anti-Submarine Warfare (ASW)	ASW2	720 items.
	ASW3	78 hours.

Table 5 provides a quantitative annual summary of testing activities by sonar and other active sources analyzed in the Navy's LOA request.

TABLE 5—ANNUAL HOURS OF SONAR AND OTHER ACTIVE ACOUSTIC SOURCES USED DURING TESTING WITHIN THE NWTT STUDY AREA

Source class category	Source class	Annual use
Low-Frequency (LF): Sources that produce signals less than 1 kHz	LF4	110 hours.
	LF5	71 hours.
Mid-Frequency (MF): Tactical and non-tactical sources that produce signals from 1 to 10 kHz	MF1	32 hours.
	MF3	145 hours.
	MF4	10 hours.
	MF5	273 items.
	MF6	12 items.
	MF8	40 hours.
	MF9	1,183 hours.
	MF10	1,156 hours.
	MF11	34 hours.
	MF12	24 hours.
High-Frequency (HF) and Very High-Frequency (VHF): Tactical and non-tactical sources that produce signals greater than 10 kHz but less than 200 kHz.	HF1	161 hours.
	HF3	145 hours.
	HF5 [1]	360 hours.
	HF6	2,099 hours.
Very High-Frequency (VHF): Tactical and non-tactical sources that produce signals greater than 100 kHz but less than 200 kHz.	VHF2	35 hours.
Anti-Submarine Warfare (ASW): Tactical sources used during ASW training and testing activities	ASW1	16 hours.
	ASW2 [2]	64 hours.
	ASW2 [2]	170 items.
	ASW3	444 hours.
	ASW4	1,182 hours.
Torpedoes (TORP): Source classes associated with active acoustic signals produced by torpedoes	TORP1	315 items.
	TORP2	299 items.

TABLE 5—ANNUAL HOURS OF SONAR AND OTHER ACTIVE ACOUSTIC SOURCES USED DURING TESTING WITHIN THE NWTT STUDY AREA—Continued

Source class category	Source class	Annual use
Acoustic Modems (M): Transmit data acoustically through the water	M3	1,519 hours.
Swimmer Detection Sonar (SD): Used to detect divers and submerged swimmers	SD1	757 hours.
Synthetic Aperture Sonar (SAS): Sonar in which active acoustic signals are post-processed to form high-resolution images of the seafloor.	SAS2	798 hours.

[1] For this analysis, HF5 consists of only one source; the modeling was conducted specifically for that source.
[2] The ASW2 bin contains sources that are analyzed by hours and some that are analyzed by count of items. There is no overlap of the numbers in the two rows.

Table 6 provides a quantitative annual summary of training explosive source classes analyzed in the Navy's LOA request.

TABLE 6—PROPOSED ANNUAL NUMBER OF IMPULSIVE SOURCE DETONATIONS DURING TRAINING IN THE NWTT STUDY AREA

Explosive class	Net explosive weight (NEW)	Annual in-water detonations (training)
E1	(0.1 lb.–0.25 lb.)	48
E3	(>0.5 lb.–2.5 lb.)	6
E5	(>5 lb.–10 lb.)	80
E10	(>250 lb.–500 lb.)	4
E12	(>650 lb.–1000 lb.)	10

Table 7 provides a quantitative annual summary of testing explosive source classes analyzed in the Navy's LOA request.

TABLE 7—PROPOSED ANNUAL NUMBER OF IMPULSIVE SOURCE DETONATIONS DURING TESTING IN THE NWTT STUDY AREA

Explosive class	Net explosive weight (NEW)	Annual in-water detonations (testing)
E3	(>0.5 lb.–2.5 lb.)	72.
E4	(>2.5 lb.–5 lb.)	140 (70 buoys).
E8	(>60 lb.–100 lb.)	3.
E11	(>500 lb.–650 lb.)	3.

Other Stressors—Vessel Strikes

In addition to potential impacts to marine mammals from activities during which explosives or sonar and other active acoustic sources are used, the Navy also considered potential ship strike impacts to marine mammals, which are discussed below. The Navy concluded that no additional stressors would result in a take and require authorization under the MMPA.

Vessel strikes may occur from surface operations and sub-surface operations (excluding bottom crawling, unmanned underwater vehicles). Vessels used as part of the Navy's NWTT training and testing activities (proposed action) include ships, submarines and boats ranging in size from small, 16-foot (ft.) (5-meter [m]) rigid hull inflatable boats to aircraft carriers with lengths up to 1,092 ft. (333 m). Representative Navy vessel types, lengths, and speeds used in both training and testing activities are shown in Table 8.

TABLE 8—REPRESENTATIVE NAVY VESSEL TYPES, LENGTHS, AND SPEEDS USED WITHIN THE NWTT STUDY AREA

Vessel type	Example(s)	Length	Typical operating speed	Max speed
Aircraft Carrier	Aircraft Carrier	>900 ft (>300 m)	10–15 knots	30+ knots.
Surface Combatants	Cruisers, Destroyers, Littoral Combat Ships	330–660 ft (100–200 m).	10–15 knots	30+ knots.
Support Craft/Other	Range Support Craft, Combat Rubber Raiding Craft, Landing Craft, Utility; Submarine Tenders, Yard Patrol Craft, Protection Vessels, Barge.	16–250 ft (5–80 m)	Variable	20 knots.
Support Craft/Other—Specialized High Speed.	Patrol Coastal Ships, Patrol Boats, Rigid Hull Inflatable Boat, High Speed Protection Vessels.	33–130 ft (10–40 m)	Variable	50+ knots.
Submarines	Fleet Ballistic Missile Submarines, Attack Submarines, Guided Missile Submarines.	330–660 ft (100–200 m).	8–13 knots	20+ knots.

Large Navy ships greater than 65 ft. (20 m) generally operate at speeds in the range of 10–15 knots for fuel conservation when cruising. Submarines generally operate at speeds in the range of 8–13 knots during transit and slower for certain tactical maneuvers. Small craft (for purposes of this discussion less than 65 ft. [20 m] in length) have much more variable speeds, dependent on the mission. While these speeds are representative, some vessels operate outside of these speeds due to unique training, testing, or safety requirements for a given event. Examples include increased speeds needed for flight operations, full speed runs to test engineering equipment, time critical positioning needs, etc. Examples of decreased speeds include speeds less than 5 knots or completely stopped for launching small boats, certain tactical maneuvers, target launch or retrievals, etc.

The number of Navy vessels in the Study Area varies based on training and testing schedules. Most activities include either one or two vessels, with an average of one vessel per activity, and last from a few hours up to 2 weeks. Vessel movement and the use of in-water devices as part of the proposed action would be concentrated in certain portions of the Study Area (such as Western Behm Canal [Alaska] or Hood Canal in the inland waters portion of the

Study Area) but may occur anywhere within the Study Area.

The Navy analyzed the potential environmental impacts of approximately 286 ongoing annual Maritime Security Operations events in Puget Sound and the Strait of Juan de Fuca. Included in this activity are approximately 226 annual Transit Protection System training events. These critical events have been occurring since 2006 and exercise the Navy's Transit Protection System, where up to nine escort vessels provide protection during all nuclear ballistic missile submarine (SSBN) transits between the vessel's homeport and the dive/surface point in the Strait of Juan de Fuca or Dabob Bay. During a Transit Protection System event, the security escorts enforce a moving 1,000yard security zone around the SSBN to prevent other vessels from approaching while the SSBN is in transit on the surface. These events include security escort vessels, U.S. Coast Guard personnel and their ancillary equipment and weapons systems. The Transit Protection System involves the movement of security vessels and also includes periodic exercises and firearms training (with blank rounds). Given the relative slow speed of the escorted and blocking vessels and multiple lookouts, no marine mammal vessel strikes are expected as a result of these events.

In addition to Transit Protection System events, the Navy would conduct approximately 60 annual maritime security escort training events with Coastal Riverine Group boats that conduct force protection for designated vessels and movements. These Coastal Riverine Group boat crews train to protect ships while entering and leaving ports. Other missions include ensuring compliance with vessel security zones for ships in port and at anchor, conducting patrols to counter waterborne threats, and conducting harbor approach defense. Special consideration will be given to the presence of marine mammals during training events. Training will be paused until marine mammals have cleared the area, or the training area will be temporarily relocated.

Navy policy (Chief of Naval Operations Instruction 3100.6H) requires Navy vessels to report all whale strikes. That information is collected by the Office of the Chief of Naval Operations Energy and Environmental Readiness Division (OPNAV N45) and cumulatively provided to NMFS on an annual basis. In addition, the Navy and NMFS also have standardized regional reporting protocols for communicating to regional NMFS stranding coordinators information on any Navy vessel strikes as soon as possible. These communication procedures will remain in place for the duration of the LOAs. There are no records of any Navy vessel strikes to marine mammals during training or testing activities in the NWTT Study Area.

Duration and Location

Training and testing activities will be conducted in the NWTT Study Area for the reasonably foreseeable future. The description of the location of authorized activities has not changed from what was provided in the proposed rule (80 FR 31737, June 3, 2015; pages 31747–31749) and NWTT FEIS/OEIS (*http://www.nwtteis.com*). For a complete description, please see those documents. The Study Area is composed of established maritime operating and warning areas in the eastern North Pacific Ocean region, including areas of the Strait of Juan de Fuca, Puget Sound, and Western Behm Canal in southeastern Alaska. The Study Area includes air and water space within and outside Washington state waters, and outside the state waters of Oregon and Northern California. The Study Area includes four existing range complexes and facilities: The Northwest Training Range Complex (NWTRC), the Keyport Range Complex, Carr Inlet Operations Area, and SEAFAC. In addition to these range complexes, the Study Area also includes Navy pierside locations where sonar maintenance and testing occurs as part of overhaul, modernization, maintenance and repair activities at NAVBASE Kitsap, Bremerton; NAVBASE Kitsap, Bangor; and Naval Station Everett.

Description of Marine Mammals in the Area of the Specified Activities

Twenty-nine marine mammal species are known to occur in the Study Area, including seven mysticetes (baleen whales), 16 odontocetes (dolphins and toothed whales), and six pinnipeds (seals and sea lions). The Description of Marine Mammals in the Area of the Specified Activities section was included in the proposed rule (80 FR 31737, June 3, 2015, 2014; pages 31749–31750). Table 9 of the proposed rule provided a list of marine mammals with possible or confirmed occurrence within the NWTT Study Area, including stock, abundance, and status.

The proposed rule, the Navy's LOA application, and the NWTT FEIS/OEIS include a complete description of information on the status, distribution, abundance, vocalizations, density estimates, and general biology of marine mammal species in the Study Area. In addition, NMFS publishes annual stock assessment reports for marine mammals, including some stocks that occur within the Study Area (*http://www.nmfs.noaa.gov/pr/species/mammals*).

Potential Effects of Specified Activities on Marine Mammals

In the Potential Effects of Specified Activities on Marine Mammals section of the proposed rule (80 FR 31737, June 3, 2015; pages 31752–31769), we included a qualitative discussion of the different ways that Navy training and testing activities may potentially affect marine mammals without consideration of mitigation and monitoring measures. That information has not changed and is not repeated here.

Mitigation

Under section 101(a)(5)(A) of the MMPA, NMFS must set forth the ''permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.'' NMFS' duty under this ''least practicable adverse impact'' standard is to prescribe mitigation reasonably designed to minimize, to the extent practicable, any adverse population-level impacts, as well as habitat impacts. While population-level impacts are minimized by reducing impacts on individual marine mammals, not all takes have a reasonable potential for translating to population-level impacts. NMFS' objective under the ''least practicable adverse impact'' standard is to design mitigation targeting those impacts on individual marine mammals that are reasonably likely to contribute to adverse population-level effects.

The NDAA of 2004 amended the MMPA as it relates to military readiness activities and the ITA process such that ''least practicable adverse impact'' shall include consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the ''military readiness activity.'' The training and testing activities described in the Navy's LOA application are considered military readiness activities.

In *Conservation Council for Hawaii* v. *National Marine Fisheries Service,* No. 1:13–cv–00684 (D. Hawaii March 31, 2015), the court stated that NMFS ''appear[s] to think that [it] satisf[ies] the statutory 'least practicable adverse impact' requirement with a 'negligible impact' finding.'' In light of the court's decision, we take this opportunity to make clear our position that the

''negligible impact'' and ''least practicable adverse impact'' requirements are distinct, even though the focus of both is on population-level impacts.

A population-level impact is an impact on the population numbers (survival) or growth and reproductive rates (recruitment) of a particular marine mammal species or stock. As we noted in the preamble to our general MMPA implementing regulations, not every population-level impact violates the negligible impact requirement. As we explained, the negligible impact standard does not require a finding that the anticipated take will have ''no effect'' on population numbers or growth rates: ''The statutory standard does not require that the same recovery rate be maintained, rather that no significant effect on annual rates of recruitment or survival occurs . . . [T]he key factor is the significance of the level of impact on rates of recruitment or survival. Only insignificant impacts on long-term population levels and trends can be treated as negligible.'' See 54 FR 40338, 40341–42 (September 29, 1989). Nevertheless, while insignificant impacts on population numbers or growth rates may satisfy the negligible impact requirement, such impacts still must be mitigated, to the extent practicable, under the ''least practicable adverse impact'' requirement. Thus, the negligible impact and least practicable adverse impact requirements are clearly distinct, even though both focus on population-level effects.

As explained in the proposed rule, any mitigation measure(s) prescribed by NMFS should be able to accomplish, have a reasonable likelihood of accomplishing (based on current science), or contribute to accomplishing one or more of the general goals listed below:

a. Avoid or minimize injury or death of marine mammals wherever possible (goals b, c, and d may contribute to this goal).

b. Reduce the numbers of marine mammals (total number or number at biologically important time or location) exposed to received levels of MFAS/HFAS, underwater detonations, or other activities expected to result in the take of marine mammals (this goal may contribute to a, above, or to reducing harassment takes only).

c. Reduce the number of times (total number or number at biologically important time or location) individuals would be exposed to received levels of MFAS/HFAS, underwater detonations, or other activities expected to result in the take of marine mammals (this goal may contribute to a, above, or to reducing harassment takes only).

d. Reduce the intensity of exposures (either total number or number at biologically important time or location) to received levels of MFAS/HFAS, underwater detonations, or other activities expected to result in the take of marine mammals (this goal may contribute to a, above, or to reducing the severity of harassment takes only).

e. Avoid or minimize adverse effects to marine mammal habitat (including acoustic habitat), paying special attention to the food base, activities that block or limit passage to or from biologically important areas, permanent destruction of habitat, or temporary destruction/disturbance of habitat during a biologically important time.

f. For monitoring directly related to mitigation—increase the probability of detecting marine mammals, thus allowing for more effective implementation of the mitigation (shut-down zone, etc.).

Our final evaluation of measures that meet one or more of the above goals includes consideration of the following factors in relation to one another: The manner in which, and the degree to which, the successful implementation of the mitigation measures is expected to reduce population-level impacts to marine mammal species and stocks and impacts to their habitat; the proven or likely efficacy of the measures; and the practicability of the suite of measures for applicant implementation, including consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

NMFS reviewed the proposed activities and the suite of proposed mitigation measures as described in the Navy's LOA application to determine if they would result in the least practicable adverse effect on marine mammals. NMFS described the Navy's proposed mitigation measures in detail in the proposed rule (80 FR 31738, June 3, 2015; pages 31771–31780). NMFS worked with the Navy in the development of the Navy's initially proposed measures, and they are informed by years of experience and monitoring. As described in the Mitigation Conclusions below and in responses to comments, and in the NWTT FEIS/OEIS, some additional measures were considered and analyzed, but ultimately not chosen for implementation. However, some area-specific mitigation measures considered by the Navy and NMFS for the Navy's low use of mid-frequency active sonar and other activities in certain areas of particular importance to marine mammals have been clarified or updated below (see *Consideration of Time/Area Limitation*) and in the Comments and Responses section of this rule. These additional area-specific measures are also included in the regulatory text (see § 218.144 Mitigation) at the end of this rule. Below are the mitigation measures as agreed upon by the Navy and NMFS. For additional details regarding the Navy's mitigation measures, see Chapter 5 in the NWTT FEIS/OEIS.

- At least one Lookout during the training and testing activities provided in Table 9;
- Mitigation zones ranging from 70 yards (yd) (64 m) to 2.5 nautical miles (nm) during applicable activities that involve the use of impulsive and non-impulsive sources to avoid or reduce the potential for onset of the lowest level of injury, PTS, out to the predicted maximum range (Table 10).
- For all training activities and for testing activities involving surface ships, vessels shall maneuver to keep at least 500 yd (457 m) away from whales and 200 yd (183 m) away from all other marine mammals (except bow riding dolphins, and pinnipeds hauled out on man-made navigational and port structures and vessels) during vessel movements. These requirements do not apply if a vessel's safety is threatened and to the extent that vessels are restricted in their ability to maneuver (*e.g.* launching and recovering aircraft or landing craft, towing activities, mooring, etc.) (Table 10).
- For testing activities not involving surface ships (*e.g.* range craft), vessels shall maneuver to keep at least 100 yd (91 m) away from marine mammals (except bow-riding dolphins, pinnipeds hauled out on man-made navigational and port structures and vessels, and pinnipeds during test body retrieval) during vessel movements. These requirements do not apply if a vessel's safety is threatened and to the extent that vessels are restricted in their ability to maneuver (*e.g.* launching and recovering aircraft or landing craft, towing activities, mooring, etc.) (Table 10).
- The Navy will ensure that towed in-water devices being towed from manned platforms avoid coming within a mitigation zone of 250 yd (229 m) for all training events and testing activities involving surface ships, and a mitigation zone of 100 yd (91 m) for testing activities not involving surface ships (*e.g.* range craft) around any observed marine mammal, providing it is safe to do so.
- Mitigation zones ranging from 200 yd (183 m) to 1,000 yd (914 m) during

activities that involve the use of non-explosive practice munitions.

• The Navy is clarifying its existing speed protocol: While in transit, Navy vessels shall be alert at all times, use extreme caution, and proceed at a ''safe speed'' so that the vessel can take proper and effective action to avoid a collision with any sighted object or disturbance, including any marine mammal or sea turtle and can be stopped within a distance appropriate to the prevailing circumstances and conditions.

TABLE 9—LOOKOUT MITIGATION MEASURES FOR TRAINING AND TESTING ACTIVITIES WITHIN THE NWTT STUDY AREA

Number of lookouts	Training and testing activities
1–2	Low-Frequency and Hull Mounted Mid-Frequency Active Sonar.
1–2	High-Frequency and Non-Hull Mounted Mid-Frequency Active Sonar.
1	Improved Extended Echo Ranging Sonobuoys (testing only).
1	Explosive Signal Underwater Sound Buoys Using >0.5–2.5 Pound Net Explosive Weight.
2	Mine Countermeasures and Neutralization Activities Using Positive Control Firing Devices (training only).
1–2	Gunnery Exercises Using Surface Target (training only).
1	Missile Exercises Using Surface Target (training only).
1 (minimum)	Bombing Exercises—Explosive (training only).
1–2	Torpedo—Explosive (testing only).[1]
1	Weapons Firing Noise During Gunnery Exercises (training only).
1 (minimum)	Vessel Movement.
1	Towed In-Water Device.
1	Gunnery Exercises—Non-Explosive (training only).
1	Bombing Exercises—Non-Explosive (training only).

[1] For explosive torpedo tests from aircraft, the Navy will have one Lookout positioned in an aircraft; for explosive torpedoes tested from a surface ship, the Navy is proposing to use the Lookout procedures currently implemented for hull-mounted mid-frequency active sonar activities.

TABLE 10—PREDICTED RANGES TO TTS, PTS, AND RECOMMENDED MITIGATION ZONES FOR EACH ACTIVITY CATEGORY

Activity category	Bin (representative source)[1]	Predicted average range to TTS	Predicted average range to PTS	Predicted maximum range to PTS	Recommended mitigation zone
Non-Impulsive Sound					
Low-Frequency and Hull-Mounted Mid-Frequency Active Sonar[2].	SQS–53 ASW hull-mounted sonar (MF1).	4,251 yd. (3,887 m) for one ping.	100 yd. (91 m) for one ping.	Not applicable	Training: 1,000 yd. (914 m) and 500 yd. (457 m) power downs and 200 yd. (183 m) shutdown for cetaceans, 100 yd. (91 m) mitigation zone for pinnipeds (excludes haulout areas). Testing: 1,000 yd. (914 m) and 500 yd. (457 m) power downs for sources that can be powered down and 200 yd. (183 m) shutdown for cetaceans, 100 yd. (91 m) for pinnipeds (excludes haulout areas).
High-Frequency and Non-Hull-Mounted Mid-Frequency Active Sonar[2].	AQS–22 ASW dipping sonar (MF4).	226 yd. (207 m) for one ping.	20 yd. (18 m) for one ping.	Not applicable	Training: 200 yd. (183 m). Testing: 200 yd. (183 m) for cetaceans, 100 yd. (91 m) for pinnipeds (excludes haulout areas).
Explosive and Impulsive Sound					
Improved Extended Echo Ranging Sonobuoys.	Explosive sonobuoy (E4).	237 yd. (217 m).	133 yd. (122 m).	235 yd. (215 m).	Training: n/a. Testing: 600 yd. (549 m).
Signal Underwater Sound (SUS) buoys using >0.5–2.5 lb. NEW.	Explosive sonobuoy (E3).	178 yd. (163 m).	92 yd. (84 m).	214 yd. (196 m).	Training: 350 yd. (320 m). Testing: 350 yd. (320 m).
Mine Countermeasure and Neutralization Activities (positive control).	>0.5 to 2.5 lb NEW (E3).	495 yd. (453 m).	145 yd. (133 m).	373 yd. (341 m).	Training: 400 yd. (336 m). Testing: n/a.
Gunnery Exercises—Small- and Medium-Caliber (Surface Target).	25 mm projectile (E1).	72 yd. (66 m)	48 yd. (44 m).	73 yd. (67 m)	Training: 200 yd. (183 m). Testing: n/a.
Gunnery Exercises—Large-Caliber (Surface Target).	5 in. projectiles (E5 at the surface)[3].	210 yd. (192 m).	110 yd. (101 m).	177 yd. (162 m).	Training: 600 yd. (549 m). Testing: n/a.
Missile Exercises up to 500 lb. NEW (Surface Target).	Harpoon missile (E10).	1,164 yd. (1,065 m).	502 yd. (459 m).	955 yd. (873 m).	Training: 2,000 yd. (1.8 km). Testing: n/a.

TABLE 10—PREDICTED RANGES TO TTS, PTS, AND RECOMMENDED MITIGATION ZONES FOR EACH ACTIVITY CATEGORY—Continued

Activity category	Bin (representative source) [1]	Predicted average range to TTS	Predicted average range to PTS	Predicted maximum range to PTS	Recommended mitigation zone
Bombing Exercises	MK–84 2,000 lb. bomb (E12).	1,374 yd. (1,256 m).	591 yd. (540 m).	1,368 yd. (1,251 m).	Training: 2,500 yd. (2.3 km). Testing: n/a.
Lightweight Torpedo (Explosive) Testing.	MK–46 torpedo (E8).	497 yd. (454 m).	245 yd. (224 m).	465 yd. (425 m).	Training: n/a. Testing: 2,100 yd. (1.9 km).
Heavyweight Torpedo (Explosive) Testing.	MK–48 torpedo (E11).	1,012 yd. (926 m).	472 yd. (432 m).	885 yd. (809 m).	Training: n/a. Testing: 2,100 yd. (1.9 km).

[1] This table does not provide an inclusive list of source bins; bins presented here represent the source bin with the largest range to effects within the given activity category.

[2] High-frequency and non-hull-mounted mid-frequency active sonar category includes unmanned underwater vehicle and torpedo testing activities.

[3] The representative source Bin E5 has different range to effects depending on the depth of activity occurrence (at the surface or at various depths).

Notes: ASW = anti-submarine warfare, in. = inch, km = kilometer, m = meter, mm = millimeter, n/a = Not Applicable, NEW = net explosive weight, PTS = permanent threshold shift, TTS = temporary threshold shift, yd. = yard.

Consideration of Time/Area Limitations

Area-Specific Mitigation

The Navy has previously placed certain voluntary limitations on their activities in Puget Sound and coastal areas. These limitations have been incorporated into the final rule.

Puget Sound

MFAS Training: Currently, the Navy is not conducting nor is it proposing to conduct training with mid-frequency active hull-mounted sonar on vessels while underway in Puget Sound and the Strait of Juan de Fuca. The Navy's process since 2003 requires approval prior to operating mid-frequency active hull-mounted sonar in Puget Sound and the Strait of Juan de Fuca. The Navy will continue the permission and approval process, in place since 2003, through U.S. Pacific Fleet's designated authority for all mid-frequency active hull-mounted sonar on vessels while training underway in Puget Sound and Strait of Juan de Fuca.

Pierside Maintenance/Testing of Sonar Systems: Pierside maintenance and testing of sonar systems within Puget Sound and the Strait of Juan de Fuca will also require approval by U.S. Pacific Fleet's designated authority or System Command designated authority as applicable and must be conducted in accordance with Navy's Protective Measures Assessment Protocol (PMAP) for ship and submarine active sonar use, to include use of lookouts. Use of active sonar for anti-terrorism force protection or for safe navigation within the Puget Sound or Strait of Juan de Fuca, or for testing activities within the Dabob Bay Range is always permitted for safety of ship/national security reasons. This scheme has been functioning appropriately since 2003 and there has been, as reflected in annual reports submitted to NMFS for the Northwest Training Range Complex, limited active sonar use for maintenance and testing across Puget Sound and no use for training purposes has been approved in that timeframe.

Civilian Port Defense Exercise (Maritime Homeland Defense/Security Mine Countermeasure Exercise): Prior to Maritime Homeland Defense/Security Mine Countermeasure Integrated Exercises, the Navy will conduct pre-event planning and training to ensure environmental awareness of all exercise participants. When this event is proposed to be conducted in Puget Sound, Navy event planners will consult with Navy biologists who will contact NMFS (Protected Resources Division, West Coast Marine Species Branch Chief) during the planning process in order to determine likelihood of gray whale or southern resident killer whale presence in the proposed exercise area as planners consider specifics of the event.

Non-Explosive Gunnery Exercises: One gunnery exercise, Small Boat Attack, involves only blank rounds and no targets. However, because of the exercise location in Puget Sound, prior to Small Boat Attack training, the Navy will conduct pre-event planning and training to ensure environmental awareness of all exercise participants. When this event is proposed to be conducted in and around Naval Station Everett, Naval Base Kitsap Bangor, or Naval Base Kitsap Bremerton in Puget Sound, Navy event planners will consult with Navy biologists who will contact NMFS early in the planning process in order to determine the extent marine mammals may be present in the immediate vicinity of proposed exercise area as planners consider the specifics of the event.

Mine Neutralization: The Navy conducts Explosive Ordnance Disposal (EOD) Mine Neutralization events in only two designated locations within the Inland Waters of the NWTT Study Area. A process has been in place requiring approval from U.S. Third Fleet prior to conducting EOD underwater detonations. The Navy will continue the permission and approval process through U.S. Third Fleet for in-water explosives training conducted at Hood Canal or Crescent Harbor.

Coastal Areas

The Navy will conduct Missile Exercises using high explosives at least 50 nm from shore in the NWTRC Offshore Area. The Navy will conduct BOMBEX (high explosive munitions) events at least 50 nm from shore, and will conduct BOMBEX (non-explosive practice munitions) events at least 20 nm from shore.

Feeding and Migration Areas

The Navy's and NMFS' analysis of effects to marine mammals considers emergent science regarding locations where cetaceans are known to engage in specific activities (*e.g.,* feeding, breeding/calving, or migration) at certain times of the year that are important to individual animals as well as populations of marine mammals (see discussion in Van Parijs, 2015). Where data were available, Van Parijs (2015) identified areas that are important in this way and named the areas Biologically Important Area (BIA). It is important to note that the BIAs were not meant to define exclusionary zones, nor were they meant to be locations that

serve as sanctuaries from human activity, or areas analogous to marine protected areas (see Ferguson *et al.* (2015a) regarding the envisioned purpose for the BIA designations). The delineation of BIAs does not have direct or immediate regulatory consequences, although it is appropriate to consider them as part of the body of science that may inform mitigation decisions, depending on the circumstances. The intention was that the BIAs would serve as resource management tools and that their boundaries be dynamic and considered along with any new information as well as, ''existing density estimates, range-wide distribution data, information on population trends and life history parameters, known threats to the population, and other relevant information'' (Van Parijs, 2015).

The Navy and NMFS have supported and will continue to support the Cetacean and Sound Mapping project, including providing representation on the Cetacean Density and Distribution Mapping Working Group (CetMap) developing the BIAs, which informed NMFS' identification of BIAs. The same marine mammal density data present in the Navy's Density Database Technical Report (U.S. Department of the Navy, 2014) and used in the analysis for the NWTT FEIS/OEIS and this rule were used in the development of BIAs. The final products, including U.S. West Coast BIAs, from this mapping effort were completed and published in March 2015 (Aquatic Mammals, 2015; Calambokidis *et al.,* 2015; Ferguson *et al.,* 2015a, 2015b; Van Parijs, 2015). 131 BIAs for 24 marine mammal species, stocks, or populations in seven regions within U.S. waters were identified (Ferguson *et al.,* 2015a). BIAs in the West Coast of the continental U.S. with the potential to overlap portions of the Study Area include the following feeding and migration areas: Northern Puget Sound Feeding Area for gray whales (March-May); Northwest Feeding Area for gray whales (May-November); Northbound Migration Phase A for gray whales (January-July); Northbound Migration Phase B for gray whales (March-July); Northern Washington Feeding Area for humpback whales (May-November); Stonewall and Heceta Bank Feeding Area for humpback whales (May-November); and Point St. George Feeding Area for humpback whales (July-November) (Calambokidis *et al.,* 2015).

NMFS' Office of Protected Resources routinely considers available information about marine mammal habitat use to inform discussions with applicants regarding potential spatio-temporal limitations on their activities that might help effect the least practicable adverse impact on species or stocks and their habitat. BIAs are useful tools for planning and impact assessments and are being provided to the public via this Web site: *www.cetsound.noaa.gov.* While these BIAs are useful tools for analysts, any decisions regarding protective measures based on these areas must go through the normal MMPA evaluation process (or any other statutory process that the BIAs are used to inform); the designation of a BIA does not pre-suppose any specific management decision associated with those areas, nor does it have direct or immediate regulatory consequences.

During the April 2014 annual adaptive management meeting in Washington, DC, NMFS and the Navy discussed the BIAs that might overlap with portions of the NWTT Study Area, what Navy activities take place in these areas (in the context of what their effects on marine mammals might be or whether additional mitigation might be necessary), and what measures could be implemented to reduce impacts in these areas (in the context of their potential to reduce marine mammal impacts and their practicability). Upon request by NMFS the Navy prepared an assessment of these BIAs, including the degree of spatial overlap of their action areas and activities as well as an analysis of potential impacts or lack of impacts for each BIA. The Navy determined that there was some very limited, to no direct spatial overlap with the marine mammal feeding and migration areas for the majority of the NWTT Study Area (as depicted in Figures 3.4–2—3.4–4 of the NWTT FEIS/OEIS). There is even less overlap with the actual training and testing activities based on historical training and testing profiles. The majority of overlap involves vessel transit activity rather than actual acoustic training and testing activities. The following paragraphs go into more detail on the spatial and activity overlap with marine mammal feeding and migration areas.

Spatial Overlap of NWTT Study Area and BIAs

Gray whale areas: There is no direct spatial overlap between the Study Area and four of the offshore gray whale feeding areas—Grays Harbor, WA; Depoe Bay, OR; Cape Blanco and Orford Reef, OR; and Pt. St. George, CA. The NWTT Study Area does overlap with the newly designated offshore gray whale Northwest WA feeding area and the Northern Puget Sound gray whale feeding area. There is no overlap of the gray whale migrations corridor(s) and the NWTT Study Area, with the exception of a portion of the NW coast of Washington approximately from Pacific Beach (WA) and extending north to the Strait of Juan de Fuca.

Humpback whale areas: The offshore Northern WA humpback whale feeding area is located entirely within the Study Area boundaries. The humpback whale feeding area at Stonewall and Hecta Bank only partially overlaps with the Study Area, and the feeding area at Point St. George has extremely limited overlap with the Study Area.

Training and Testing Activity Overlap

Gray whale areas: The gray whale NW Washington feeding area abuts to the shoreline of the NW coast of WA and lies adjacent to the main shipping channel between the Strait of Juan de Fuca and the Pacific Ocean. There is a small likelihood of Navy vessel movement in the gray whale feeding area mapped along the northern coast of Washington as ships transit to the offshore training and testing areas. Based on approximate historically used locations and the proposed training and testing activities described in the NWTT FEIS/OEIS, there is no direct spatial overlap of any training or testing activities within this feeding area. The majority of activities occur greater than 12 nm offshore, thus significantly reducing the potential for overlap. Furthermore, the Navy's LOA request describes mitigation measures that it will implement to avoid vessel strikes, such as continuing to use extreme caution and a safe speed when transiting, maneuvering to keep at least 500 yards from whales observed in a vessel's path, and not approaching whales head-on, provided it is safe to do so. The Navy will also be required to report any vessel strike. The Navy and NMFS concluded that these mitigation measures in addition to historical training and testing profiles indicate that additional mitigations are not warranted for this feeding area.

Vessel movement associated with both training and testing activities is likely to occur within the gray whale feeding area in Northern Puget Sound. Navy ships cannot avoid transiting through this area in order to exit the Puget Sound. Figure 3.0–5 in the NWTT FEIS/OIES depicts average ship traffic density within the major shipping routes within the Pacific Northwest. Overall vessel traffic near Everett, whose port is within or adjacent to the Northern Puget Sound feeding area, is relatively low compared to other inland water areas. The Navy's proportion of the total vessel traffic is extremely minimal with only 6 surface ships

homeported at Naval Station Everett. Therefore, while there is overlap, the potential for Navy vessels to interact with feeding gray whales within this area is low, especially given the short time period (March–May) that whales will be present. The Navy's request describes mitigation measures that it will implement to avoid vessel strikes, such as continuing to use extreme caution and a safe speed when transiting, maneuvering to keep at least 500 yards from whales observed in a vessel's path, and not approaching whales head-on, provided it is safe to do so. The Navy will also be required to report any vessel strike. (Note that the Navy does not find vessel strikes likely to occur given there is no recorded occurrence of vessel strike of any species of marine mammal, including gray whales, by Navy ships during training or testing in the Northwest).

The following training and testing activities occur at Naval Station Everett which appears to be located within the Northern Puget Sound gray whale feeding area; annual pierside sonar maintenance training, annual life-cycle hull-mounted sonar testing, and Maritime Homeland Defense/Security Mine Countermeasure exercises which could occur once every other year (3 events out of 5 years). Acoustic emissions would propagate into this feeding area from these activities. However it is highly unlikely that gray whales would be within the vicinity of the piers or the shorelines around Naval Station Everett based on historical data of their presence (Calambokidis *et al.,* 2015). In the case of Maritime Homeland Defense/Security Mine Countermeasure exercises, acoustic emissions would be very infrequent, transitory, and happen with a high degree of temporal variability; activities would occur for a limited time (less than 2 weeks) and generally utilize HF and VHF active sonar for mine detection that operates outside of the functional hearing and vocalization range for mysticetes, and has less acoustic energy and shorter propagation distances. Based on the acoustic modeling potentially one gray whale take by TTS could occur from the activities at Naval Station Everett. However, since the scheduling of these activities is dependent upon deployment cycles and maintenance schedules the activities may not occur during periods when gray whales are present within this area for feeding. Further, Navy mitigation measures for acoustic activities include avoiding the conduct of acoustic and explosive activities in the immediate vicinity of all marine mammals, including gray whales, and include power down and shutdown procedures to reduce the potential for exposures to whales from sonar events.

Given this area's location in Puget Sound, the vast majority of sound and disturbance in the area will be the result of non-Navy vessel traffic. As such, precluding Navy activity at Naval Station Everett and in Northern Puget Sound would be of little to no biological benefit to the gray whales. Furthermore, given pending overseas deployment needs and individual ship readiness cycles to support those deployments, the time of year when maintenance occurs cannot be proscribed. As for the Maritime Homeland Defense exercise, the location in which it would occur provides realistic conditions necessary to effectively train personnel to protect a major port and the vital assets (ships, cargo) and shipping channels near those ports. This training event, which may include a pierside component, cannot be relocated without losing realism given the ships/cargo and transit lanes requiring protection are in fixed locations. Moreover, as described in the area-specific mitigation section above, the Navy will require approval from designated authorities prior to conducting mine countermeasure and neutralization underwater detonations at Hood Canal or Crescent Harbor, hull-mounted mid-frequency active sonar training on vessels while underway in Puget Sound and the Strat of Juan de Fuca, and pierside maintenance or testing in Puget Sound or the Strait of Juan de Fuca. In summary, the Navy and NMFS conclude that seasonal avoidance of the use of acoustic sources within the Northern Puget Sound feeding area is unlikely to further reduce impacts to gray whales in this area which are already estimated to be extremely low (*i.e.* one Level B TTS take) and would negatively impact readiness in a significant manner.

The Navy acknowledges that gray whales migrate along the entire western coast of the United States, typically within 15 nm of the shore in the NWTT Study Area, but possibly anywhere over the continental shelf, and that a small subset of the gray whale population may enter Puget Sound during their migrations. Vessel movement associated with virtually all of the training and testing activities proposed in the NWTT FEIS/OEIS will occur and has been occurring in areas potentially used by migrating gray whales for decades; however, the majority of the Navy's vessel traffic and training and testing occur outside the 12 nm line, thus significantly reducing the overlap, since the gray whale migration areas only extend 10 nm offshore. Navy vessels are not the only vessel traffic that these migrating whales may encounter as Navy vessels represent a small fraction of total vessel traffic within the Greater Puget Sound and offshore areas (see Figure 3.0–5 of the NWTT FEIS/OIS). The Figure shows little correlation of impedance or interference to gray whale migration in areas where Navy vessels transit and training and testing activities have historically occurred or are expected to continue into the reasonably foreseeable future in the NWTT Study Area. In fact, with the shipping density data overlapped, it is evident that while shipping traffic is heavy into the Strait of Juan de Fuca, as well as within the shipping lanes of Puget Sound, this traffic does not restrict or interfere with the annual north and south bound migration of gray whales nor their movements in Puget Sound. Some training and most testing activities will include acoustic emissions within or propagating into areas potentially used by migrating gray whales. However, these activities may not always be timed during periods in which the gray whales are present. The Navy has requested a small number of Level B (behavioral) gray whale takes for all activities occurring within the offshore NWTT Study Area. As described in the Navy's LOA application and this final rule, the Navy is seeking authorization for 17 Level B (TTS) takes of gray whales annually (6 from training activities and 11 from testing activities) from activities occurring throughout the offshore Study Area. The Navy's LOA request describes mitigation measures that it will implement to avoid vessel strikes, such as continuing to use extreme caution and a safe speed when transiting, maneuvering to keep at least 500 yards from whales observed in a vessel's path, and not approaching whales head-on, provided it is safe to do so. The Navy will also be required to report any vessel strike. However, the Navy does not find vessel strikes likely to occur given there is no recorded occurrence of vessel strike of any species of marine mammal, including gray whales, by Navy ships during training or testing in the Northwest. Navy mitigation measures for acoustic activities also include avoiding the conduct of acoustic and explosive activities in the immediate vicinity of all marine mammals, including gray whales. Further, as described in the area-specific mitigation section above, the Navy will require approval from designated authorities prior to conducting mine countermeasure and neutralization underwater detonations at Hood Canal

or Crescent Harbor, hull-mounted mid-frequency active sonar training on vessels while underway in Puget Sound and the Strat of Juan de Fuca, and pierside maintenance or testing in Puget Sound or the Strait of Juan de Fuca. The Navy and NMFS concluded that based on the mitigations in place, historical training and testing profiles, limited estimated effects, and no evidence of ship strikes to migrating gray whales within the Study area that no additional mitigations are warranted in the gray whale migration areas.

Humpback whale areas: Vessel movement is likely to occur in at least some of the humpback whale BIAs, including the designated humpback whale feeding area mapped at the mouth of the Strait of Juan de Fuca. Historical ship density (majority of which is non-Navy vessels) depicted in Figure 3.0–5 of the NWTT FEIS/OEIS is high in the Northern Washington humpback whale feeding area. However, Navy vessel traffic is extremely minimal in comparison to commercial ship traffic, with typically only 20 ships and submarines homeported in the Puget Sound region. Therefore, Navy vessel traffic is low within this feeding area. There is an extremely low likelihood of any Navy vessel movements occurring within the two southern humpback whale feeding areas, especially given that the Point St. George feeding area only overlaps the very eastern boundary of the Study Area. The Navy's LOA request describes mitigation measures that it will implement to avoid vessel strikes, such as continuing to use extreme caution and a safe speed when transiting, maneuvering to keep at least 500 yards from whales observed in a vessel's path, and not approaching whales head-on, provided it is safe to do so. The Navy will also be required to report any vessel strike. (Note that neither the Navy nor NMFS find vessel strikes likely to occur given there is no recorded occurrence of vessel strike of any species of marine mammal, including gray whales, by Navy ships during training or testing in the Northwest).

Based on a review of the historic activity profiles and the proposed training activities described in the NWTT FEIS/OEIS, there would be no direct spatial overlap of training activities with any designated feeding areas for humpbacks in the offshore portion of the NWTT Study Area. There is a generally low probability of potential acoustic overlap with the specifically identified feeding areas. Any propagation of sound from training activities into the Northern Washington humpback whale feeding area would mostly likely result from hull-mounted sonar maintenance or systems checks as vessels are transiting to other areas within and outside of the NWTT Study Area. The Navy estimates very low impacts to humpback whales from offshore training activities involving sonar, and no impacts from any explosive events. Only 12 total Level B (7 behavioral, 5 TTS) takes of humpback whales are anticipated annually from all training activities combined occurring within the offshore Study Area, not just those areas overlapping with the feeding areas. Requiring Navy vessels to avoid this feeding area and utilize acoustic systems further offshore would position ships into higher dense traffic waters based on commercial shipping density data in that area. In addition to the fact that avoidance would not be expected to notably reduce takes, avoidance of these feeding areas during Navy training could create safety concerns by forcing the Navy to delay maintenance and systems checks until ships are farther from shore and homeport infrastructure that could have assisted in addressing potential technical issues.

For testing activities, there is a chance that countermeasure testing could propagate non-impulsive sound into the Northern Washington humpback whale feeding area adjacent to the Strait of Juan de Fuca. These testing activities would be transitory, last from three to eight hours, and are conducted sporadically in any given geographic location. These countermeasure testing activities may be scheduled for any time of year based upon the availability of assets (ships and/or aircraft) needed to support the tests. Though the Navy does not expect to conduct tests within this feeding area, it would be difficult to ensure that all countermeasure testing was conducted far enough from the site to avoid sound propagation into it since some countermeasure devices propagate mid-frequency sound a long distance, so it is possible that some amount of sound from these measures conducted outside of the area may propagate into the feeding area some limited number of times. Conducting this testing further from port and from support facilities would increase event costs, time, and fuel required to complete them, as well as limit available sites suitable to support the testing requirements and limit Navy's use of the existing Quinault Range Site. Avoidance of this area would negatively impact readiness, while likely only providing a small potential reduction in marine mammal sound exposure.

Occasional shallow water testing with sonobuoys would overlap the Stonewall and Heceta Bank humpback whale feeding area offshore of Oregon. The shallow water features in the area affect bottom reflecting, scattering, and absorption of the sound and typically create a more challenging environment to test sonobuoys in due to other surface sound sources (commercial/recreational boats). These conditions allow aircrews to gain understanding of how noise from other sources will impact underwater signal detection. However, these sonobuoy testing events are infrequent (fewer than 50 per year) and of short-duration (less than a day). These events occur sporadically throughout the year and will not necessarily occur during time periods of humpback whale feeding. It is unlikely that this limited testing of sonobuoys would have any biologically meaningful effect on humpback whale feeding behavior in this area; however, avoidance of this area would negatively impact readiness. The Navy estimates very low impacts to humpback whales from offshore testing activities involving sonar and no impacts from explosive testing. Only 45 Level B (6 behavioral, 39 TTS) takes of humpback whales are anticipated annually from all testing activities occurring within the offshore Study Area, not just those areas overlapping with the feeding areas. Based on the Navy's existing mitigation measures for these activities, the low numbers of potential take to all humpback whales not just those within the feeding areas, the lack of prior ship strikes of humpback whales within the Study Area, and the impacts to readiness from avoiding or relocating activities the Navy and NMFS conclude that further mitigation within the humpback whale feeding areas is not warranted.

In summary, the Navy's and NMFS' analysis indicates that there is generally low use of the BIAs and the modeling supports that there are limited impacts to gray whales and humpbacks throughout the entire NWTT study area. There is the potential for the most overlap between Navy activities within the following threes feeding areas—the Humpback Whale Northern Washington feeding area, Stonewall Heceta Bank feeding area, and the Gray Whale Northern Puget Sound feeding area. Very few takes are expected to result from activities within these feeding areas, and the nature of these activities along with the required mitigation measures would result in the least practicable adverse impacts on the species and their habitat. However, the Navy has agreed to monitor, and provide NMFS with reports of, hull-mounted mid-frequency and high frequency active sonar use during

training and testing in the months specified in the following three feeding areas to the extent that active sonar training or testing does occur in these feeding areas: Humpback Whale Northern Washington feeding area (May through November); Stonewall and Heceta Bank feeding area (May through November) and Gray Whale Northern Puget Sound Feeding Area (March through May). The Navy will provide this information annually in the classified exercise report to the extent sonar use in those areas can be distinguished from data retrieved in Navy's system. The intent would be to inform future adaptive management discussions about future mitigation adjustments should sonar use increase above the existing low use/low overlap description provided by the Navy or if new science provides a biological basis for increased protective measures.

If additional biologically important areas are identified by NMFS after finalization of this rule and the Navy's NWTT FEIS/OEIS, the Navy and NMFS will use the Adaptive Management process to assess whether any additional mitigation should be considered in those areas. Results of the species-specific assessment of potential impacts to humpback and gray whales in their respective BIAs within the Study Area are included in Chapter 3.4.3 and Chapter 5.3.4.1.11 of the NWTT FEIS/OEIS and in the Species/Group Specific Analysis below. As we learn more about marine mammal density, distribution, and habitat use (and the BIAs are updated), NMFS and the Navy will continue to reevaluate appropriate time-area measures through the Adaptive Management process outlined in these regulations.

Marine Protected Areas

Marine protected areas (MPAs) in the National System of MPAs potentially occurring within the Study Area are listed and described in Section 6.1.2 of the NWTT FEIS/OEIS (Marine Protected Areas, Table 6.1–2). As shown in Figure 6.1–1 of the NWTT FEIS/OEIS, proposed Navy training and testing activities in the Study Area do not overlap these MPAs (with the exception of the Olympic Coast National Marine Sanctuary (OCNMS), discussed below). The NWTT FEIS/OEIS has been prepared in accordance with the requirements to avoid harm to the natural and cultural resources of existing National System MPAs. Navy activities, should they occur within or near a MPA, would fully abide by the regulations of the individual MPA (see Table 6.1–2 of the NWTT FEIS/OEIS for information See Section 6.1.2 of the NWTT FEIS/OEIS (Marine Protected Areas) for more information.

Olympic Coast National Marine Sanctuary

To the extent practicable, the Navy currently avoids conducting activities within the OCNMS, and expects this practice to continue. However, some Navy NWTT activities may occur within the OCNMS. The Navy has been conducting training and testing offshore of the coast of Washington for decades. The area provides variable bathymetries, and training and testing challenges to simulate potential operational scenarios. There is relatively small spatial overlap between the NWTT Offshore Area and the OCNMS. For training activities occurring in the Offshore Area, less than 3% would be expected to occur within the OCNMS. Most training events would occur outside the boundaries of the OCNMS. Although the Navy is specifically authorized to conduct certain activities within the OCNMS, the Navy currently conducts very limited training within the OCNMS and does not use explosives within the OCNMS. Non-explosive bombing exercises will also not occur in the OCNMS. The Navy expects this level and type of activity to continue into the reasonably foreseeable future.

While active sonar and ASW activities are authorized within the OCNMS, the Navy uses its Protective Measures Assessment Protocol (PMAP) program to inform all users of active sonar that the OCNMS is within the NWTT Study Area. PMAP informs users that no high explosives are authorized in the OCNMS. The Navy proposes to continue use of PMAP in this manner for awareness and notification. The Navy has also agreed to monitor, and provide NMFS with reports of, hull-mounted mid-frequency and high-frequency active sonar use during training and testing in the OCNMS.

Federal agency actions that are likely to injure sanctuary resources are subject to consultation with the NOAA Office of National Marine Sanctuaries (ONMS) under section 304(d) of the National Marine Sanctuaries Act (NMSA). The Navy and NMFS initiated joint consultation with ONMS through the submittal of a Sanctuary Resource Statement (SRS) on September 8, 2015. Within the Navy's SRS, only a subset of NWTT activities, primarily non-impulsive testing events, were identified as possibly occurring routinely within OCNMS because of the existing Quinault Range which overlaps portions of OCNMS. Furthermore, these events would be spatially and temporarily separated throughout the year as well as from any preceding event. ONMS provided recommended alternatives to the Navy and NMFS to further protect sanctuary resources on October 23, 2015. On November 9, 2015, the Navy and NMFS jointly responded in writing to each of the ONMS recommendations.

Notification of Marine Mammal Stranding

Navy personnel shall ensure that NMFS is notified immediately (or as soon as clearance procedures allow) if a stranded marine mammal is found during or shortly after, and in the vicinity of, any Navy training exercise utilizing MFAS, HFAS, or underwater explosive detonations. See *General Notification of Injured or Dead Marine Mammals* in the Reporting section below for details on the communication and reporting requirements if a marine mammal stranding is observed.

Mitigation Conclusions

NMFS has carefully evaluated the Navy's proposed mitigation measures—many of which were developed with NMFS' input during the first phase of Navy Training and Testing authorizations—and considered a range of other measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. Based on our evaluation of the Navy's proposed measures, as well as other measures considered by NMFS, NMFS has determined that the Navy's proposed mitigation measures (especially when the adaptive management component is taken into consideration (see Adaptive Management, below)) are adequate means of effecting the least practicable adverse impacts on marine mammals species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, while also considering personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Monitoring

Section 101(a)(5)(A) of the MMPA states that in order to issue an ITA for an activity, 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 LOAs 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.

Integrated Comprehensive Monitoring Program (ICMP)

The Navy's ICMP is intended to coordinate monitoring efforts across all regions and to allocate the most appropriate level and type of effort for each range complex based on a set of standardized objectives, and in acknowledgement of regional expertise and resource availability. The ICMP is designed to be flexible, scalable, and adaptable through the adaptive management and strategic planning processes to periodically assess progress and reevaluate objectives. Although the ICMP does not specify actual monitoring field work or projects, it does establish top-level goals that have been developed in coordination with NMFS. As the ICMP is implemented, detailed and specific studies will be developed which support the Navy's top-level monitoring goals. In essence, the ICMP directs that monitoring activities relating to the effects of Navy training and testing activities on marine species should be designed to contribute towards one or more of the following top-level goals:

- An increase in our understanding of the likely occurrence of marine mammals and/or ESA-listed marine species in the vicinity of the action (*i.e.,* presence, abundance, distribution, and/or density of species);
- An increase in our understanding of the nature, scope, or context of the likely exposure of marine mammals and/or ESA-listed species to any of the potential stressor(s) associated with the action (*e.g.,* tonal and impulsive sound), through better understanding of one or more of the following: (1) The action and the environment in which it occurs (*e.g.,* sound source characterization, propagation, and ambient noise levels); (2) the affected species (*e.g.,* life history or dive patterns); (3) the likely co-occurrence of marine mammals and/or ESA-listed marine species with the action (in whole or part) associated with specific adverse effects, and/or; (4) the likely biological or behavioral context of exposure to the stressor for the marine mammal and/or ESA-listed marine species (*e.g.,* age class of exposed animals or known pupping, calving or feeding areas);
- An increase in our understanding of how individual marine mammals or ESA-listed marine species respond (behaviorally or physiologically) to the specific stressors associated with the action (in specific contexts, where possible, *e.g.,* at what distance or received level);
- An increase in our understanding of the impacts of the activity on marine mammal or ESA-listed species habitat;
- An increase in our understanding of how anticipated individual responses to individual stressors or anticipated combinations of stressors, and/or impacts to habitat, may impact either: (1) The long-term fitness and survival of an individual; or (2) the population, species, or stock (*e.g.,* through effects on annual rates of recruitment or survival);
- An increase in our understanding of the effectiveness of mitigation and monitoring measures;
- A better understanding and record of the manner in which the authorized entity complies with the ITA and Incidental Take Statement;
- An increase in the probability of detecting marine mammals (through improved technology or methods), both specifically within the safety zone (thus allowing for more effective implementation of the mitigation) and in general, to better achieve the above goals; and
- A reduction in the adverse impact of activities to further achieve the least practicable level, as defined in the MMPA.

Monitoring would address the ICMP top-level goals through a collection of specific regional and ocean basin studies based on scientific objectives. Quantitative metrics of monitoring effort (*e.g.,* 20 days of aerial surveys) would not be a specific requirement. The adaptive management process and reporting requirements would serve as the basis for evaluating performance and compliance, primarily considering the quality of the work and results produced, as well as peer review and publications, and public dissemination of information, reports, and data. Details of the ICMP are available online (*http://www.navymarinespeciesmonitoring.us/*).

Strategic Planning Process for Marine Species Monitoring

The Navy also developed the Strategic Planning Process for Marine Species Monitoring, which establishes the guidelines and processes necessary to develop, evaluate, and fund individual projects based on objective scientific study questions. The process uses an underlying framework designed around top-level goals, a conceptual framework incorporating a progression of knowledge, and in consultation with a Scientific Advisory Group and other regional experts. The Strategic Planning Process for Marine Species Monitoring would be used to set intermediate scientific objectives, identify potential species of interest at a regional scale, and evaluate and select specific monitoring projects to fund or continue supporting for a given fiscal year. This process would also address relative investments to different range complexes based on goals across all range complexes, and monitoring would leverage multiple techniques for data acquisition and analysis whenever possible. The Strategic Planning Process for Marine Species Monitoring is also available online (*http://www.navymarinespeciesmonitoring.us/*).

Past Monitoring in the NWTT Study Area

NMFS has received multiple years' worth of annual exercise and monitoring reports addressing active sonar use and explosive detonations within portions of the NWTT Study Area and other Navy range complexes. The data and information contained in these reports have been considered in developing mitigation and monitoring measures for the proposed training and testing activities proposed to occur within the NWTT Study Area. The Navy's annual exercise and monitoring reports may be viewed at: *http://www.nmfs.noaa.gov/pr/permits/incidental/military.htm* and *http://www.navymarinespeciesmonitoring.us.* NMFS' summary of the Navy's annual monitoring reports was included in the proposed rule (80 FR 31738, June 3, 2015; pages 31781–31783).

Other Regional Navy-Funded Monitoring Efforts

Additional marine mammal studies are being funded or conducted by the Navy outside of and in addition to the Navy's commitments in the NWTT Study Area and other Navy range complexes. NMFS' summary of the Navy's other regional monitoring efforts was included in the proposed rule (80 FR 31738, June 3, 2015; pages 31781–31783).

Proposed Monitoring for the NWTT Study Area

Based on discussions between the Navy and NMFS, future Navy compliance monitoring should address ICMP top-level goals through a series of regional and ocean basin study questions with a prioritization and funding focus on species of interest as identified for each range complex. The ICMP will also address relative investments to different range complexes based on goals across all range complexes, and monitoring will leverage multiple techniques for data

acquisition and analysis whenever possible.

Within the NWTT Study Area, the Navy's initial recommendation for species of interest includes blue whale, fin whale, humpback whale, Southern Resident killer whale (offshore portion of their annual movements), and beaked whales. Navy monitoring for NWTT under this LOA authorization and concurrently in other areas of the Pacific Ocean will therefore be structured to address region-specific and species-specific study questions in consultation with NMFS. The following projects will be funded or have been funded to support the NWTT monitoring program:

A. Modeling the Distribution of Southern Resident Killer Whales in the Pacific Northwest

As an early start to NWTT monitoring, in July 2014 the Navy provided funding ($209,000) to NMFS' Northwest Fisheries Science Center (NWFSC) to jointly participate in a new NWTT-specific study: Modeling the distribution of southern resident killer whales in the Pacific Northwest. The goal of this new study is to provide a more scientific understanding of endangered southern resident killer whale winter distribution off the Pacific Northwest coast. The end product will be a Bayesian space-state model for predicting the offshore winter occurrence of southern resident killer whales. The project will consist of analysis of existing NMFS data (passive acoustic detections, satellite tag tracks) as well as new data collection from fall 2014 through spring 2016, some of which is being accomplished with the Navy's funding. The Navy has also provided NMFS NWFSC funds to support the FY16 fieldwork associated with the larger southern resident killer whale Habitat Model Project to collect biopsy samples, prey remains, fecal, mucus, and regurgitation samples. The goal of this field work is to determine the prey selected by southern resident killer whales throughout their range, but particularly in the coastal waters of the US, mainly from Cape Flattery to the Columbia River).

Details of the study can be found at: *http://www.navymarinespecies monitoring.us/regions/pacific/current-projects/.*

The main tasks the study supports include:

- Identification and classification of marine mammal detections from acoustic recorders.
- Acquisition and field deployment of satellite-linked transmitters to track and determine southern resident killer whales movements.
- Deployment of autonomous underwater acoustic recorders in and adjacent to the coastal and shelf/slope waters of Washington State. Navy funding will allow 10 additional recorders to be purchased and deployed along with four NMFS recorders for a total of 14 deployed recorders.
- Estimation of the probability of Southern Resident killer whale detection on acoustic recorders.
- Development of the state-space occurrence models.
- Development of predicative maps of the seasonal annual occurrence of southern resident killer whales.
- Development a cost efficient strategy for the deployment of acoustic recorders in and adjacent to Pacific Northwest Navy ranges.
- Reporting.

B. Pacific Northwest Pinniped Satellite Tracking Project

This project began in FY14 and will continue through FY16. Navy provided funding to the Alaska Fisheries Science Center to conduct satellite tagging and behavioral monitoring of sea lions in the Pacific Northwest in proximity to Navy facilities. The goal of the study is to fill in data gaps that exist in identifying the location of local foraging areas and documenting the percentage of time pinniped species are hauled out or utilizing the waters near Puget Sound naval facilities. The objectives of this study include:

- Census data of the adult males that haulout at Naval Station Everett, and Naval Base Kitsap-Bremerton/Bangor to develop minimum population estimates for the inland waters;
- Monthly correction factors from tagging data to correct count data from census locations;
- Geographical distribution and foraging behavior of California sea lion adult males in the inland waters of Washington, specifically relative to Navy installations;
- Migration and foraging behavior of California sea lions in coastal Washington, Oregon, and California.

C. Marine Mammal Aerial Surveys in the Pacific Northwest, Inland Puget Sound Waters

This project began in FY13 and will continue through FY16. The goal of this effort was to fill critical data gaps regarding the current abundance and population status of marine mammal species within the inland waters of Puget Sound and in relation to Navy training and testing locations. The objectives of this task are to:

- Collect data to estimate the abundance and densities of marine mammals in inland waters of Puget Sound;
- Document the distribution, habitat use, and behaviors of each species observed.

A more detailed description of the Navy's planned projects starting in 2015 (and some continuing from previous years) is available at the Navy's Marine Species Monitoring web portal: *http://www.navymarinespeciesmonitoring.us/.* The Navy will update the status of its monitoring program and funded projects through their Marine Species Monitoring web portal.

Ongoing Navy Research

The U.S. Navy is one of the world's leading organizations in assessing the effects of human activities on the marine environment, including marine mammals. From 2004 through 2013, the Navy has funded over $240M specifically for marine mammal research. Navy scientists work cooperatively with other government researchers and scientists, universities, industry, and non-governmental conservation organizations in collecting, evaluating, and modeling information on marine resources. They also develop approaches to ensure that these resources are minimally impacted by existing and future Navy operations. It is imperative that the Navy's Research and Development (R&D) efforts related to marine mammals are conducted in an open, transparent manner with validated study needs and requirements. The goal of the Navy's R&D program is to enable collection and publication of scientifically valid research as well as development of techniques and tools for Navy, academic, and commercial use. Historically, R&D programs are funded and developed by the Office of the Chief of Naval Operations Energy and Environmental Readiness Division and Office of Naval Research (ONR), Code 322 Marine Mammals and Biological Oceanography Program. Since the 1990s, the primary focus of these programs has been on understanding the effects of sound on marine mammals, including physiological, behavioral and ecological effects. ONR's current Marine Mammals and Biology Program thrusts include, but are not limited to: (1) Monitoring and detection research; (2) integrated ecosystem research including sensor and tag development; (3) effects of sound on marine life (such as hearing, behavioral response studies, physiology [diving and stress], and PCAD); and (4) models and databases for environmental compliance.

To manage some of the Navy's marine mammal research programmatic elements, OPNAV N45 developed in

2011 a new Living Marine Resources (LMR) Research and Development Program (*http://www.lmr.navy.mil/*). The goal of the LMR Research and Development Program is to identify and fill knowledge gaps and to demonstrate, validate, and integrate new processes and technologies to minimize potential effects to marine mammals and other marine resources. Key elements of the LMR program include:

- Providing science-based information to support Navy environmental effects assessments for research, development, acquisition, testing, and evaluation as well as Fleet at-sea training, exercises, maintenance, and support activities.
- Improving knowledge of the status and trends of marine species of concern and the ecosystems of which they are a part.
- Developing the scientific basis for the criteria and thresholds to measure the effects of Navy-generated sound.
- Improving understanding of underwater sound and sound field characterization unique to assessing the biological consequences resulting from underwater sound (as opposed to tactical applications of underwater sound or propagation loss modeling for military communications or tactical applications).
- Developing technologies and methods to monitor and, where possible, mitigate biologically significant consequences to living marine resources resulting from naval activities, emphasizing those consequences that are most likely to be biologically significant.

Navy Research and Development

Navy Funded—Both the LMR and ONR R&D programs periodically fund projects within the NWTT Study Area. Some data and results from these R&D projects are summarized in the Navy's annual range complex monitoring reports, and available on NMFS' Web site (*http://www.nmfs.noaa.gov/pr/permits/incidental/military.htm*) and the Fleet's new marine species monitoring Web site (*http://www.navymarinespeciesmonitoring.us/regions/pacific/current-projects/*). In addition, the Navy's Range Complex monitoring during training and testing activities is coordinated with the R&D monitoring in a given region to leverage research objectives, assets, and studies where possible under the ICMP.

The integration between the Navy's new LMR R&D program and related range complex monitoring will continue and improve during the applicable period of the rulemaking with results presented in NWTT annual monitoring reports.

Other National Department of Defense Funded Initiatives—Strategic Environmental Research and Development Program (SERDP) and Environmental Security Technology Certification Program (ESTCP) are the DoD's environmental research programs, harnessing the latest science and technology to improve environmental performance, reduce costs, and enhance and sustain mission capabilities. The Programs respond to environmental technology requirements that are common to all of the military Services, complementing the Services' research programs. SERDP and ESTCP promote partnerships and collaboration among academia, industry, the military Services, and other Federal agencies. They are independent programs managed from a joint office to coordinate the full spectrum of efforts, from basic and applied research to field demonstration and validation.

Adaptive Management

The final regulations governing the take of marine mammals incidental to Navy training and testing activities in the NWTT Study Area contain an adaptive management component carried over from previous authorizations. Although better than 5 years ago, our understanding of the effects of Navy training and testing activities (*e.g.,* MFAS/HFAS, underwater detonations) on marine mammals is still relatively limited, and yet the science in this field is evolving fairly quickly. These circumstances make the inclusion of an adaptive management component both valuable and necessary within the context of 5-year regulations for activities that have been associated with marine mammal mortality in certain circumstances and locations.

The reporting requirements associated with this rule are designed to provide NMFS with monitoring data from the previous year to allow NMFS to consider whether any changes are appropriate. NMFS and the Navy would meet to discuss the monitoring reports, Navy R&D developments, and current science and whether mitigation or monitoring modifications are appropriate. The use of adaptive management allows NMFS to consider new information from different sources to determine (with input from the Navy regarding practicability) on an annual or biennial basis if mitigation or monitoring measures should be modified (including additions or deletions). Mitigation measures could be modified if new data suggests that such modifications would have a reasonable likelihood of reducing adverse effects to marine mammals and if the measures are practicable.

The following are some of the possible sources of applicable data to be considered through the adaptive management process: (1) Results from monitoring and exercises reports, as required by MMPA authorizations; (2) compiled results of Navy funded R&D studies; (3) results from specific stranding investigations; (4) results from general marine mammal and sound research; and (5) any information which reveals that marine mammals may have been taken in a manner, extent, or number not authorized by these regulations or subsequent LOAs.

Reporting

In order to issue an ITA for an activity, section 101(a)(5)(A) of the MMPA states that NMFS must set forth ''requirements pertaining to the monitoring and reporting of such taking.'' Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring. NMFS described the proposed Navy reporting requirements in the proposed rule (80 FR 31738, June 3, 2015; page 31784). Reports from individual monitoring events, results of analyses, publications, and periodic progress reports for specific monitoring projects will be posted to the Navy's Marine Species Monitoring web portal: *http://www.navymarinespeciesmonitoring.us* and NMFS' Web site: *http://www.nmfs.noaa.gov/pr/permits/incidental/military.htm.* There are several different reporting requirements that are further detailed in the regulatory text at the end of this document and summarized below.

General Notification of Injured or Dead Marine Mammals

Navy personnel would ensure that NMFS (the appropriate Regional Stranding Coordinator) is notified immediately (or as soon as clearance procedures allow) if an injured, stranded, or dead marine mammal is found during or shortly after, and in the vicinity of, any Navy training exercise utilizing MFAS, HFAS, or underwater explosive detonations. The Navy would provide NMFS with species identification or a description of the animal(s), the condition of the animal(s) (including carcass condition if the animal is dead), location, time of first discovery, observed behaviors (if alive), and photographs or video (if available).

Vessel Strike

Since the publication of the proposed rule, NMFS has added the following language to address monitoring and reporting measures specific to vessel strike. Most of this language comes directly from the Stranding Response Plan for other Navy Phase 2 rulemakings. This section has also been included in the regulatory text at the end of this document. Vessel strike during Navy training and testing activities in the Study Area is not anticipated; however, in the event that a Navy vessel strikes a whale, the Navy shall do the following:

Immediately report to NMFS (pursuant to the established Communication Protocol) the:

- Species identification (if known);
- Location (latitude/longitude) of the animal (or location of the strike if the animal has disappeared);
- Whether the animal is alive or dead (or unknown); and
- The time of the strike.

As soon as feasible, the Navy shall report to or provide to NMFS, the:

- Size, length, and description (critical if species is not known) of animal;
- An estimate of the injury status (*e.g.,* dead, injured but alive, injured and moving, blood or tissue observed in the water, status unknown, disappeared, etc.);
- Description of the behavior of the whale during event, immediately after the strike, and following the strike (until the report is made or the animal is no longer sighted);
- Vessel class/type and operational status;
- Vessel length;
- Vessel speed and heading; and
- To the best extent possible, obtain a photo or video of the struck animal, if the animal is still in view.

Within 2 weeks of the strike, provide NMFS:

- A detailed description of the specific actions of the vessel in the 30-minute timeframe immediately preceding the strike, during the event, and immediately after the strike (*e.g.,* the speed and changes in speed, the direction and changes in direction, other maneuvers, sonar use, etc., if not classified);
- A narrative description of marine mammal sightings during the event and immediately after, and any information as to sightings prior to the strike, if available; and use established Navy shipboard procedures to make a camera available to attempt to capture photographs following a ship strike.

NMFS and the Navy will coordinate to determine the services the Navy may provide to assist NMFS with the investigation of the strike. The response and support activities to be provided by the Navy are dependent on resource availability, must be consistent with military security, and must be logistically feasible without compromising Navy personnel safety. Assistance requested and provided may vary based on distance of strike from shore, the nature of the vessel that hit the whale, available nearby Navy resources, operational and installation commitments, or other factors.

Annual Monitoring Reports

The Navy shall submit an annual report of the NWTT monitoring describing the implementation and results of the NWTT monitoring efforts from the previous calendar year. Data collection methods will be standardized across range complexes and study areas to allow for comparison in different geographic locations. Although additional information will be gathered, the protected species observers collecting marine mammal data pursuant to the NWTT monitoring plan shall, at a minimum, provide the same marine mammal observation data required in § 218.145. The report shall be submitted either 90 days after the calendar year, or 90 days after the conclusion of the monitoring year to be determined by the Adaptive Management process.

The NWTT Monitoring Report may be provided to NMFS within a larger report that includes the required Monitoring Plan reports from multiple range complexes and study areas (the multi-Range Complex Annual Monitoring Report). Such a report would describe progress of knowledge made with respect to monitoring plan study questions across all Navy ranges associated with the ICMP. Similar study questions shall be treated together so that progress on each topic shall be summarized across all Navy ranges. The report need not include analyses and content that does not provide direct assessment of cumulative progress on the monitoring plan study questions.

Annual Exercise and Testing Reports

The Navy shall submit preliminary reports detailing the status of authorized sound sources within 21 days after the anniversary of the date of issuance of the LOA. The Navy shall submit detailed reports 3 months after the annual anniversary of the date of issuance of the LOA. The detailed annual reports shall describe the level of training and testing conducted during the reporting period, and a summary of sound sources used (total annual hours or quantity [per the LOA] of each bin of sonar or other non-impulsive source; total annual number of each type of explosive exercises; total annual expended/detonated rounds [missiles, bombs, etc.] for each explosive bin; and improved Extended Echo-Ranging System (IEER)/sonobuoy summary, including total number of IEER events conducted in the Study Area, total expended/detonated rounds (buoys), and total number of self-scuttled IEER rounds. The analysis in the detailed reports will be based on the accumulation of data from the current year's report and data collected from previous reports.

The annual classified exercise reports will also include the amount of hull-mounted mid-frequency and high frequency active sonar use during training and testing activities in the OCNMS and in the months specified for the following three feeding areas (to the extent that active sonar training or testing does occur in these areas): The Humpback Whale Northern Washington feeding area (May through November); the Stonewall and Heceta Bank feeding area (May through November) and the Gray Whale Northern Puget Sound Feeding Area (March through May).

5-Year Close-out Exercise and Testing Report

This report will be included as part of the 2020 annual exercise or testing report. This report will provide the annual totals for each sound source bin with a comparison to the annual allowance and the 5-year total for each sound source bin with a comparison to the 5-year allowance. Additionally, if there were any changes to the sound source allowance, this report will include a discussion of why the change was made and include the analysis to support how the change did or did not result in a change in the EIS and final rule determinations. The report will be submitted 3 months after the expiration of the rule. NMFS will submit comments on the draft close-out report, if any, within 3 months of receipt. The report will be considered final after the Navy has addressed NMFS' comments, or 3 months after the submittal of the draft if NMFS does not provide comments.

Comments and Responses

On June 3, 2015 (80 FR 31738), NMFS published a proposed rule in response to the Navy's request to take marine mammals incidental to training and testing activities in the NWTT Study Area and requested comments, information, and suggestions concerning the request. During the 45-day public

comment period, NMFS received over 100 comments (including several duplicates) from the Marine Mammal Commission (Commission), non-governmental organizations, Tribes, and private citizens. Comments were collectively submitted in a letter on behalf of the Animal Legal Defense Fund, Animal Welfare Institute, Center for Biological Diversity, Earthjustice, Environmental Protection Information Center, Friends of the Earth, Friends of the San Juans, The Humane Society of the United States, InterTribal Sinkyone Wilderness Council, Klamath Forest Alliance, Natural Resources Defense Council, New York Whale and Dolphin Action League, Northcoast Environmental Center, Ocean Mammal Institute, Orca Network, Surfrider Foundation—Mendocino Coast Chapter, Carol Van Strum, and the Whale and Dolphin Conservation (hereinafter referred to as Animal Legal Defense Fund *et al.*). Comments specific to section 101(a)(5)(A) of the MMPA and NMFS' analysis of impacts to marine mammals are summarized, sorted into general topic areas, and addressed below and/or throughout the final rule. Comments specific to the NWTT FEIS/OEIS, which NMFS participated in developing as a cooperating agency and adopted, or that were also submitted to the Navy during the NWTT DEIS/OEIS public comment period are addressed in Appendix E (Public Participation) of the NWTT FEIS/OEIS. Some commenters presented technical comments on the general behavioral risk function that are largely identical to those posed during the comment period for proposed rules for the Atlantic Fleet Training and Testing (AFTT), Hawaii-Southern California Training and Testing (HSTT), and Mariana Islands Training and Testing (MITT) study areas, predecessors to the NWTT rule. The behavioral risk function remains unchanged since then, and here we incorporate our responses to those initial technical comments (78 FR 73010, Acoustic Thresholds, page 73038; 78 FR 78106, Acoustic Thresholds, page 78129; 80 FR 46112, Criteria and Thresholds, page 46146). Full copies of the comment letters may be accessed at *http://www.regulations.gov.*

Activity

Comment 1: The Animal Legal Defense Fund *et al.* commented that the Navy's training and testing activities and resulting takes are ''a picture of harm that exceeds anything the Navy has proposed for the area in the past.'' The commenters further expressed particular concerns for southern resident killer whales, blue whales, fin whales, harbor porpoises, and beaked whales.

Response: The Navy has been conducting largely the same training and testing activities using the same type of equipment in the NWTT Study Area for decades without any evidence of harm to marine species as a result of those activities. The takes authorized by this rule are comparable to what is currently authorized for the same training and testing activities that have been occurring for decades in the NWTT Study Area, and are less than what is authorized in other Navy training and testing areas (*e.g.,* AFTT, HSTT). In particular, see Section 3.4.4.1 of the NWTT FEIS/OEIS (Summary of Monitoring and Observations During Navy Activities) and the Long Term Consequences section of this rule regarding the likely long-term consequences from those activities. Also note that as described in Section 1.9 of the NWTT FEIS/OEIS, previous analyses have taken place regarding a comprehensive understanding of Navy activities in the Pacific Northwest involving training and testing at sea. Specifically with regard to the Proposed Action, see the September 2010 Northwest Training Range Complex FEIS/OEIS and the May 2010 Final Environmental Impact Statement/Overseas Environmental Impact Statement NAVSEA NUWC Keyport Range Complex Extension FEIS/OEIS.

Please see Section 3.4.3.1.18 of the NWTT FEIS/OEIS (Application of the Marine Mammal Protection Act to Potential Acoustic and Explosive Effects) and the Estimated Take of Marine Mammals section of the proposed rule for a description of ''take'' and note that the overwhelming majority of takes predicted for all species—including those mentioned above by the commenters—are short-term behavioral responses to relatively short-term activities (Level B harassment). Further, the majority of these Level B takes are expected to be in the form of milder responses (*i.e.,* lower-level exposures that still rise to the level of take, but would be less severe in the ranges of responses that qualify as a take) and are not expected to have deleterious impacts on the fitness of any individuals or long-term consequences to populations of marine mammals. Effects on marine mammals will minimized through the Navy's implementation of the following mitigation measures (among others): (1) The use of lookouts to monitor for marine mammals and begin powerdown and shutdown of sonar when marine mammals are detected within ranges where the received sound level is likely to result in temporary threshold shift (TTS) or injury; (2) the use of mitigation zones that avoid exposing marine mammals to levels of explosives likely to result in injury or death of marine mammals; and (3) vessel maneuvering protocols. NMFS and the Navy have also worked to develop a robust monitoring plan to improve our understanding of the environmental effects resulting from the use of active sonar and underwater explosives. Additionally, the proposed rule includes an adaptive management component that allows for timely modification of mitigation or monitoring measures based on new information, when appropriate.

Regarding southern resident killer whales, and as discussed in the Group and Species-Specific Analysis section of this rule, the Navy's acoustic analysis predicts only 2 instances of Level B harassment (behavioral reaction) of southern resident killer whales from sonar and other active acoustic sources during annual training activities in the Study Area. The Navy has not asked for, and NMFS has not authorized, any takes resulting from mortality or injury for southern resident killer whales. No injury or mortality is predicted by the acoustic impact modeling, or anticipated to result from the continuation of Navy training and testing, which has been occurring in the area for decades. The Navy and NMFS considered numerous studies analyzing the impact from chronic noise associated with vessel traffic as well as other threats, and these are cited in the NWTT FEIS/OEIS, Section 3.4.2.4 (General Threats) and Section 3.4.3.1.5 (Physiological Stress). As described in the Biological Opinion, the available scientific information does not provide evidence that exposure to acoustic stressors from Navy training and testing activities will impact the fitness of any individuals of this species. Therefore, exposure to acoustic stressors will not have population or species level impacts.

NMFS considered the distribution of southern resident killer whales in its effects analysis. The majority of the Navy's proposed training and testing activities would not occur in the southern resident killer whale's designated critical habitat (NMFS, 2006). Furthermore, the majority of testing events would occur in Hood Canal, where southern resident killer whales are not believed to be present (southern resident killer whales have not been reported in Hood Canal or Dabob Bay since 1995 [NMFS, 2008c]), while the majority of training activities

would occur in the offshore portions of the Study Area, where they are only present briefly during their annual migration period. As the commenters noted, NMFS issued a 12-month finding on a petition to revise the critical habitat for this species earlier this year (80 FR 9682, Feb. 24, 2015); however, as stated in that notice, NMFS does not anticipate developing a proposed rule for comment until 2017. The Navy and NMFS will consider as appropriate any revisions to the critical habitat designation. Finally, to further support awareness of southern resident killer whale in the Study Area, prior to Maritime Homeland Defense/Security Mine Countermeasure Integrated Exercises, the Navy will conduct pre-event planning and training to ensure environmental awareness of all exercise participants. When this event is proposed to be conducted in Puget Sound, Navy event planners will consult with Navy biologists who will contact NMFS during the planning process in order to determine the likelihood of gray whale or southern resident killer whale presence in the proposed exercise area as planners consider the specifics of the event.

As discussed in the Group and Species-Specific Analysis section of this rule, take numbers for ESA-listed mysticetes are also predicted to be low relative to estimated stock abundances, and occasional behavioral reactions are predicted to occur at low received levels and are unlikely to cause long-term consequences for individuals or populations. Furthermore, there is no designated critical habitat for mysticetes in the Study Area.

The number of harbor porpoises behaviorally harassed by exposure to MFAS/HFAS in the Study Area is higher than the other species because of the low Level B harassment threshold (we assume for the purpose of estimating take that all harbor porpoises exposed to 120 dB or higher MFAS/HFAS will be taken by Level B behavioral harassment), which essentially makes the ensonified area of effects significantly larger than for the other species. However, the fact that the threshold is a step function and not a curve (and assuming uniform density) means that the vast majority of the takes occur in the very lowest levels that exceed the threshold (it is estimated that approximately 80 percent of the takes are from exposures to 120 dB to 126 dB), which means that anticipated behavioral effects are not expected to be severe (*e.g.,* temporary avoidance). See the Analysis and Negligible Impact Determination section of this rule for further information regarding the expected impacts to harbor porpoises.

Moore and Barlow (2013) have noted a decline in beaked whale populations in a broad area of the Pacific Ocean within the U.S. Exclusive Economic Zone. However, there are scientific caveats and limitations to the data used for that analysis, as well as oceanographic and species assemblage changes on the U.S. Pacific coast not thoroughly addressed. Although Moore and Barlow (2013) have noted a decline in the overall beaked whale population along the Pacific coast, in the small fraction of that area where the Navy has been training and testing with sonar and other systems for decades (the Navy's Southern California (SOCAL) Range Complex), higher densities and long-term residency by individual Cuvier's beaked whales suggest that the decline noted elsewhere is not apparent where Navy sonar use is most intense. Navy sonar training and testing is not conducted along a large part of the U.S. west coast from which Moore and Barlow (2013) drew their survey data. In Southern California, based on a series of surveys from 2006 to 2008 and a high number encounter rate, Falcone *et al.* (2009) suggested the ocean basin west of San Clemente Island may be an important region for Cuvier's beaked whales given the number of animals encountered there. Follow-up research (Falcone and Schorr, 2012, 2014) in this same location suggests that Cuvier's beaked whales may have population sub-units with higher than expected residency, particularly in the Navy's instrumented Southern California Anti-Submarine Warfare Range. Encounters with multiple groups of Cuvier's and Baird's beaked whales indicated not only that they were prevalent on the range where Navy routinely trains and tests, but also that they were potentially present in much higher densities than had been reported for anywhere along the U.S. west coast (Falcone *et al.,* 2009, Falcone and Schorr, 2012). This finding is also consistent with concurrent results from passive acoustic monitoring that estimated regional Cuvier's beaked whale densities were higher where Navy trains in the SOCAL training and testing area than indicated by NMFS's broad scale visual surveys for the U.S. west coast (Hildebrand and McDonald, 2009). See the Analysis and Negligible Impact Determination section of this rule for further information regarding the expected impacts to beaked whales.

Marine Mammal Density Estimates

Comment 2: The Commission stated that it was unsure how the Navy determined that extrapolated densities better represent expected densities than densities from relevant environmental suitability (RES) models in the absence of density data. The Commission recommended that NMFS require the Navy to (1) account for uncertainty in extrapolated density estimates for all species by using the upper limit of the 95% confidence interval or the arithmetic mean plus two standard deviations and (2) then re-estimate the numbers of takes accordingly.

Response: As noted in the Commission's comment, the Navy coordinated with NMFS scientists at the Southwest Fisheries Science Center (SWFSC) and the National Marine Mammal Laboratory (NMML) to help identify the best available density estimates for marine mammals occurring in the Study Area. Regarding the use of extrapolated density estimates from the SWFSC rather than using estimates from RES models, in the Pacific Ocean the distribution patterns predicted by the RES model do not correspond well to known species distribution patterns. RES density estimates for some of the other Navy Study Areas (*e.g.,* HSTT) were found to be orders of magnitude different from density estimates derived from multiple years of systematic line-transect survey data (Department of the Navy 2014—Navy Marine Species Density Database Technical Report). Therefore, in the absence of density data, extrapolation of density estimates from well-studied regions to lesser-known regions was deemed more appropriate than using RES data, which have shown to be inconsistent with what is known to be a more representative estimate of species density.

The use of a mean density estimate is consistent with the approach taken by NMFS to estimate and report the populations of marine mammals in the Stock Assessment Reports, and the estimated mean is thus considered the ''best available data.'' Adjusting the mean estimates as suggested would result in unreasonable take estimates, particularly given the very high coefficients of variation (CVs) associated with most marine mammal density estimates. Note that the CVs in the Navy's marine species density database for the California Current Ecosystem represent the interannual variability in marine mammal occurrence; the CV does not represent uncertainty in the model predicted density estimates. Further, the Navy's acoustic model includes conservative estimates of all parameters (*e.g.,* assumes that the animals do not move horizontally, assumes they are always head-on to the sound source so that they receive the maximum amount of energy, etc.), which results in a more conservative

(*i.e.,* greater) assessment of potential impacts.

Comment 3: The Commission recommended that NMFS require the Navy to (1) incorporate data from Raum-Suryan *et al.* (2004) and Call *et al.* (2007) and consult with scientists at NMML regarding unpublished data to revise the areas used in estimating Steller sea lion densities in the offshore and Western Behm Canal areas, (2) incorporate data from Robinson *et al.* (2012) into the areas used in estimating northern elephant seal densities in the offshore and Western Behm Canal areas, (3) incorporate data from Weise *et al.* (2006) and consult with scientists at NMML regarding unpublished data to revise the areas used in estimating California sea lion densities in the offshore area, and (4) incorporate data from Ream *et al.* (2005), Lea *et al.* (2009), Melin *et al.* (2012), Pelland *et al.* (2014), and Sterling *et al.* (2014) and consult with scientists at NMML to revise its northern fur seal density estimates by using movement and dispersion data from tagged fur seals specific to the study area and scaled to the population.

Response: With respect to estimating Steller sea lion (SSL) density offshore and in the Western Behm Canal, the Navy Pacific Marine Species Density Database Technical Report (Department of the Navy, 2014) used the eastern stock of SSL (highest stock estimate was used), multiplied by 0.25 (Bonnell and Bowlby, 1992) to get at-sea numbers. This numbers was then divided by the area of the eastern stock of SSL (1,244,000 km^2) to get a uniform distribution density estimate. Raum-Suryan *et al.* (2005) and Call *et al.* (2007) present the movement, dispersal and haulout use of juvenile (Call et al.) and juvenile and pups (Raum-Suryan *et al.*). Both papers confirm SSLs are present in the offshore and Western Behm Canal portions of the NWTT. However, these papers present information on haul out use, round trip duration, and distance of a subset of the available population, which may be useful for small estimates of area use. This information is limited to juveniles and pups, and does not represent the range of area that is potentially covered by all SSLs in the eastern stock of SSLs. Therefore, as most literature indicates a wide variety of dispersal and movement among age classes and sex, the uniform distribution was used. In short, this information does not change the analysis presented in the NWTT FEIS/OEIS. See the Revised May 2015) Navy Marine Species Density Database Technical Report available at *http://www.nwtteis.com.*

With regard to the density of northern elephant seals, the area used for calculation was based on all animals in the LeBouef *et al.* (2000) paper and was mistakenly reported in the Technical Report as only females. The Robinson *et al.* (2012) study presents reinforcing data on the presence of northern elephant seals in both the NWTRC offshore and Western Behm Canal portions of the NWTT Study Area and the incorporation of the Robinson study would not change the analysis of impacts on the stock.

The Weise *et al.* (2006) paper adds to the information regarding movements of a subset of animals under ''anomalous'' conditions and for the majority of the Pacific coast of North America, which is outside the NWTT Study Area. Given these factors, it was not included in the definition of area. However, the findings are not inconsistent with the current analysis; California sea lions are assumed to be present in the Study Area. The Navy has also taken into account monitoring data on California sea lions in the Study Area, as presented in Section 3.4.2.29 (California Sea Lion [*Zalophus californianus]*) of the NWTT FEIS/OEIS, including that from local researchers (*i.e.,* NMML) in the Pacific Northwest. Ream *et al.* (2005), Melin *et al.* (2012) and Lea *et al.* (2009) all indicate that there is some use of the nearshore areas of the NWTT off Washington and Oregon by pups and females, and those findings are not inconsistent with the current analysis. Regarding Pelland *et al.* (2014) and Sterling *et al.* (2014), who document a highly pelagic distribution of northern fur seals through the offshore areas of the Study Area where the majority of training would occur, the Navy used these studies to develop its at-sea densities, described in the Pacific Marine Species Density Database Technical Report, which were derived as Study Area-wide single density values by season (U.S. Department of the Navy, 2014b). Pelland *et al.* (2014) and Sterling *et al.* (2014) were discussed in the *Analysis of Guadalupe Fur Seal Exposures* in the proposed rule

The Commission's suggested novel method of determining a density of pinnipeds based on the presence of tagged animals and then ''scaled to the population'' may be investigated in the future as the science and methodology evolves. NMFS, along with the Navy, will continue to work with researchers and scientists at NMML in the development of future at-sea analyses.

Comment 4: The Commission recommended that NMFS require the Navy to (1) revise its abundance estimates to include data from Allen and Angliss (2014) and Carretta *et al.* (2014) to determine Steller sea lion and northern fur seal densities in both the offshore and Western Behm Canal areas, (2) update the Guadalupe fur seal take estimates based on the revised northern fur seal density estimates and provide better justification for the reduction in Guadalupe fur seal takes for the offshore area, and (3) revise its abundance estimates to include updated data for harbor seals in the Western Behm Canal area, if available.

Response: The Navy used the best available science and consulted with regional marine mammal experts in the derivation of the data used in the analysis. The Navy incorporated abundance estimates for Steller sea lions and northern fur seals from the most recent (2014) stock assessment reports (Caretta *et al.,* 2015, Allen and Angliss, 2015) into the NWTT FEIS/OEIS (see Section 3.4.2.28.2 Abundance and 3.4.2.30.2 Abundance). The reported increase in abundance estimates does not result in a significant change in the density estimates and does not affect the impact assessment.

Regarding the reduction in Guadalupe fur seal takes for the offshore area, the Navy's September 26, 2014 revision to the LOA application included an update to the effects analysis for Guadalupe fur seals to more realistically reflect potential impacts from offshore Navy training and testing activities. The analysis used to modify the Guadalupe fur seal takes is fully described in Analysis of Guadalupe Fur Seal Exposures in the proposed rule (80 FR 31738, June 3, 2015; page 31792).

The Navy's Marine Species Density Database Technical Report, was revised in May 2015 to update the density estimates for harbor seals in the NWTT Study Area. The report is available at *http://www.nwtteis.com.* These updates did not affect marine mammal densities used for acoustic impact modeling nor change the results of the acoustics effects analysis.

Comment 5: The Commission recommended that NMFS require the Navy to use Hubner *et al.*'s (2001) harbor seal haul-out correction factors of 1.50 for the offshore area, 1.85 for the Strait of Juan de Fuca and San Juan Islands, 1.51 for Eastern Bays, and 1.36 for Puget Sound rather than a pooled correction factor of 1.53. The proportion of seals at sea for each of those areas also should be adjusted accordingly and then incorporated with the relevant abundance estimates to derive the appropriate density estimates.

Response: The Navy corresponded with Huber and other regional harbor seal scientists at the NMML regarding

appropriate haul out correction factors. While Huber *et al.* (2001) did report a regional correction factor for each survey site, analysis of variance (ANOVA) results in the same paper concluded there was no significant difference between any of the locations and proportion ashore. Therefore, the regional combined haulout factor can be viewed as a conservative approach. The Navy did, however, apply the revised stock assessment (2014 SAR) for the Hood Canal resident population of harbor seals.

Comment 6: The Commission recommended that NMFS require the Navy to use a haul-out correction factor of 1.49 rather than 0.198 to determine the overall abundance of harbor seals for the Western Behm Canal area and apply a correction of 0.33 to determine the proportion of the overall abundance at sea, which then is used to derive the density estimate.

Response: With regard to Western Behm Canal, the description of the correction factor, as reported in the Marine Mammal Occurrence/Density Report (U.S. Department of the Navy, 2010, prepared in support of Navy activities at the Southeast Alaska Acoustic Measurement Facility [SEAFAC]), is confusingly written as 0.198. The text was written as ''Total seals were calculated as the 1,094 seals hauled out in the area (Withrow *et al.,* 1999) plus an at sea correction factor of 0.198 of the haul-out count (Allen and Angliss, 2010).'' The ''plus'' in this language was meant to indicate that the Simpkins 1.198 factor was used to achieve a total population of 1,310. The at-sea proportion based on the Simpkins value (which Allen and Angliss used) would be approximately 216 animals, and this value is reported in the Navy's Marine Species Density Database Technical Report. While the confusing language was carried into the Technical Report, the methodology is the same as presented in the Commission's comment and the density reported would not change.

Using a mean haulout correction factor of 1.47 would revise the density estimate from 0.29 seals per km^2 to 0.56 seals per km^2. Given that Southeast Alaska (Clarence Strait) stock of harbor seals would not be exposed to sound that would exceed the current impact thresholds (as listed in Section 3.4 [Marine Mammals] of the NWTT FEIS/OEIS), it is unlikely that any revisions to density values will result in a change in modeled effects.

Comment 7: The Commission recommended that NMFS require the Navy to provide the methods by which species-specific densities were calculated for each area and each season and cite the primary literature from which the data originated.

Response: The Navy Pacific Marine Species Density Database Technical Report (Department of the Navy, 2014) includes individual species-specific descriptions of the density estimates used for each area and each season. The seasonal delineation used by the Navy is specifically described in the Technical Report (Section 3.2). Due to the many different sources of data used, all sections incorporate by reference the literature from which the estimates were taken. In addition, Chapter 3.3 (Information on Density Data Sources Considered and Included) of the Technical Report provides additional details on the main data sources used (and for many of the systematic surveys maps are included to show the extent of the study area or transects surveyed). For those cases where density estimates were taken directly from an existing report (*e.g.,* U.S. Department of the Navy, 2010, Marine Mammal Occurrence/Density Report), a general description is provided but it is beyond the scope of this document to summarize all the information contained in each of the reports that are incorporated by reference.

The technical report is available on the NWTT FEIS/OEIS Web site at: *http://nwtteis.com/DocumentsandReferences/NWTTDocuments/SupportingTechnicalDocuments.aspx.* The Navy continues to use the best available science, and this information will be considered in future projects.

Criteria and Thresholds

Comment 8: The Commission recommended that NMFS require the Navy to update Finneran and Jenkins (2012) to include the appropriate justification for its use of the 6-dB extrapolation factor between explosive and acoustic sources; use 151 dB rather than 152 dB re 1 µPa2-sec as the TTS threshold for high-frequency cetaceans exposed to acoustic sources; use 145 rather than 146 dB re 1 µPa2-sec as the TTS threshold for high-frequency cetaceans for explosive sources; and based on these changes to the TTS thresholds, adjust the PTS thresholds for high-frequency cetaceans by increasing the amended TTS threshold by 20 dB for acoustic sources and 15 dB for explosive sources, and adjust the behavioral thresholds by decreasing the amended TTS thresholds by 5 dB for explosive sources.

Response: At the time the acoustic criteria and thresholds were developed, no direct measurements of TTS due to non-impulsive sound exposures were available for any high-frequency cetacean; therefore, the relationship between onset-TTS sound exposure level (SEL)-based thresholds (Type II weighted) for mid-frequency cetaceans exposed to impulsive and non-impulsive sounds (beluga data) was used to derive the onset-TTS threshold for high-frequency cetaceans exposed to non-impulsive sounds (6-dB difference). The derived high-frequency cetacean non-impulsive onset TTS threshold is consistent with data recently published by Kastelein, *et al.* (2012) on TTS measured after exposing a harbor porpoise to non-impulsive sounds.

The acoustic and explosive thresholds were adjusted based on weighting the exposures from the original research from which the thresholds were derived with the Type II weighing functions. The weighted threshold is not derived by a simple amplitude shift. The high-frequency cetacean onset TTS threshold is based on the onset-TTS threshold derived from data in Lucke *et al.* (2009) for impulsive exposures. This threshold was subsequently adjusted in Finneran and Jenkins (2012) to reflect Type II high-frequency cetacean weighting. Therefore, a simple 19.4 dB adjustment to the thresholds presented in Southall *et al.* (2007) is not appropriate.

As detailed in Finneran and Jenkins (2012), the thresholds presented incorporate new findings since the publication of Southall *et al.* (2007) and the evolution of scientific understanding since that time. Please note that Dr. Finneran was one of the authors for Southall *et al.* (2007) and so is completely familiar with the older conclusions present in the 2007 publication; therefore, Dr. Finneran was able to integrate that knowledge into the development of the refined approach that was presented in Finneran and Jenkins (2012), based on evolving science since 2007. NMFS is confident that the thresholds and criteria used in the NWTT analysis have already incorporated the correct balance of conservative assumptions that tend towards overestimation in the face of uncertainty. Details regarding the process are provided in Section 3.4.3.1.14 (Quantitative Analysis) of the NWTT EIS/OEIS. In addition, the summary of the thresholds used in the analysis are presented in Section 3.4.3.1.10 (Thresholds and Criteria for Predicting Acoustic and Explosive Impacts on Marine Mammals).

Comment 9: The Commission recommended that NMFS require the Navy to (1) adjust the behavioral response function (BRF_1) for low-frequency cetaceans and BRF_2 for mid- and high-frequency cetaceans (except

harbor porpoises and beaked whales), phocids, and otariids with appropriate *K* and *A* parameters based on the basement parameter and the weighted TTS thresholds and (2) recalculate its behavioral take estimates for all marine mammals exposed to acoustic sources based on those revised BRFs.

Response: Please see the NWTT FEIS/OEIS, Section 3.4.3.1.10 (Thresholds and Criteria for Predicting Acoustic and Explosive Impacts on Marine Mammals) and Finneran and Jenkins (2012) for details describing how the criteria and thresholds used in the analysis were derived. Hearing impairment such as TTS is based on an SEL threshold and behavior is based on the sound pressure level of the highest ping received. The predicted higher order effect from the acoustic effects model is the potential effect that is reported. Note that Level B harassment includes both predicted TTS and behavioral responses.

Regarding the raw number of exposures presented in the modeling technical report (Navy Marine Species Modeling Team, 2013) and the difference between the non-TTS exposures for harbor porpoise when compared to Dall's porpoise and *Kogia* spp, note that, as presented in the NWTT FEIS/OEIS, Section 3.4.3.1.12.1 (Sonar and Other Active Acoustic Sources), a sound pressure level of 120 dB re 1 µPa is used in this analysis as a threshold for predicting behavioral responses in harbor porpoises, whereas for the high-frequency cetaceans like Dall's porpoise and *Kogia* spp. (see Table 3.4–6 of the NWTT FEIS/OEIS), the behavioral response threshold is the received level SPL: BRF_2 using Type 1 weighting. Additionally, these species have unique density distributions and dive profiles which can result in very different modeling results.

Regarding the confusion about TTS and behavioral takes, note that over time, for some events, such as slow moving or stationary sources and stationary animats, PTS and TTS takes increase with multiple pings and increased energy. However, multiple pings would not cause the outer range of the behavioral takes to increase. Therefore, the fixed pool of animals that are taken (PTS + TTS + behavioral) does not change but, over time, some TTS become PTS, and some behavioral takes become TTS. The result of this is that, ultimately, the behavioral takes are reduced and become smaller, eventually fewer than the number of TTS.

Comment 10: The Animal Legal Defense Fund *et al.* commented that the Navy and NMFS failed to set proper thresholds for threshold shift and injury. They base this on the following: First, NMFS's direct extrapolation of data from bottlenose dolphins and belugas to low-frequency cetaceans is not justifiable and insufficiently conservative. Second, NMFS makes no attempt to account for the potential bias in Space and Naval Warfare Systems Command's (SPAWAR) bottlenose dolphin data, particularly the age of the subjects used in these influential studies and their situation for years within a noisy bay. Third, NMFS's weighting curve for high-frequency cetaceans is not sufficiently conservative in light of ongoing studies, as by Ron Kastelein. Fourth, NMFS's analysis fails to incorporate empirical data on both humans and marine mammals indicating that permanent threshold shift can occur at levels previously thought to cause temporary threshold shift only.

Response: NMFS disagrees. The criteria and thresholds for determining potential effects on marine species used in the NWTT EIS/OEIS, the LOA application, and the proposed rule were developed based on best available science. See the cited Finneran and Jenkins (2012; Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis Technical Report), which can be found at *http://www.nwtteis.com.*

Regarding the commenters' first point, NMFS disagrees that the thresholds are unjustified and insufficiently conservative. Please see the discussion presented in the NWTT FEIS/OEIS Section 3.4.2.3.3 (Low-Frequency Cetaceans) and Section 3.4.3.1.11 (Frequency Weighting) to understand the derivation of the thresholds and criteria for low frequency cetaceans. Specifically it was the low- and high-frequency cetacean weighting functions (see Southall *et al.* (2007) that were extrapolated from the dolphin data because of the suspected similarities of greatest susceptibility at best frequencies of hearing consistent with the best available science. The Navy uses experimentally derived mid-frequency cetacean thresholds to assess PTS and TTS for low-frequency cetaceans, since mid-frequency cetaceans are the most similar to the low frequency group (see Southall *et al.* (2007); Finneran and Jenkins (2012)). Although the mid-frequency criteria and thresholds are applied to low frequency cetaceans, exposures and threshold sound exposure levels are weighted using the low frequency cetacean weighting function rather than the mid-frequency which provides higher susceptibility to low frequency sound, consistent with their inferred frequencies of best hearing. Data for low frequency cetaceans considered in the analysis also includes that from Ketten (2014) for blue whales and minke whales, Ketten and Mountain (2014) for humpback whales, and Cranford and Krysl (2015) for fin whales. Observed vocalization frequencies, observed reactions to playback of sounds, anatomical analyses of the auditory system (Cranford and Krysl (2015); Houser *et al.* (2001); Ketten (2014); Ketten and Mountain (2014); Parks *et al.,* (2007)), and a general understanding of mammalian hearing are the reasons and science behind why the methodology in the NWTT FEIS/OEIS and the proposed rule is justifiable. NMFS disagrees that the approach is not conservative given that low frequency cetaceans do not echolocate and that the physiology of mysticetes indicates a lack of sensitivity to high frequency sound.

NMFS disagrees with the commenters' second point, as the data used in the analysis included many animals and species at multiple experimental facilities around the world as well as auditory measurements on wild animals that had stranded, in addition to anatomical analyses of the auditory system of mysticetes (Cranford and Krysl (2015); Houser *et al.* (2001); Ketten (2014); Ketten and Mountain (2014); Parks *et al.* (2007)). Direct measurement of hearing sensitivity exists for approximately 25 species of marine mammals, including the following cetacean species: Atlantic white-sided dolphins (Houser *et al.,* 2010a), common dolphins (Houser, Dankiewicz-Talmadge *et al.,* 2010), Atlantic bottlenose dolphins (Johnson, 1967), Indo-Pacific bottlenose dolphins (Houseret *et al.,* 2010a), Black Sea bottlenose dolphins (Popov *et al.,* 2007), striped dolphins (Kastelein *et al.,* 2003), white-beaked dolphins (Nachtigall *et al.,* 2008), Risso's dolphins (Nachtigall *et al.,* 2005), belugas (Finneran *et al.,* 2005; White *et al.,* 1977), long-finned pilot whales (Pacini *et al.,* 2010), false killer whales (Yuen *et al.,* 2005), killer whales (Szymanski *et al.,* 1999), Gervais' beaked whales (Finneran *et al.,* 2009), and Blainville's beaked whales (Pacini *et al.,* 2011).

Regarding the commenters' third point, the most recent publications by Dr. Kastelein are cited and were considered in the analysis presented in the NWTT FEIS/OEIS (see Kastelein *et al.,* 2014a, 2014b, 2105). In reference to the most recent publication involving non-pulse sources (sonar) from Kastelein *et al.* (2015), the authors found that the threshold shift criteria proposed by Southall *et al.* (2007) for cetaceans echolocating at high frequency (SEL 215

dB re 1 lPa2s) was too high for the harbor porpoise when considering high duty cycle sonars. Kastelein *et al.* (2015) documented fatiguing sounds at duty cycles of 10 percent (one sonar ping every 10 seconds) and 100 percent (one ping immediately followed by another). The high duty cycle sonar used in Kastelein's study were a different frequency (6–7 kHz) and produce sound at a higher rate than the Navy's hull-mounted mid-frequency anti-submarine sonar, which nominally produces one ping every 45 seconds. Therefore, the Kastelein (2015) study and its findings do not relate to the Navy's proposed action or the sonar sources proposed for use in the NWTT Study Area.

Additionally, TTS represents a physiological metric for a behavioral reaction and that an exposure resulting in TTS has been and is considered an MMPA Level B harassment take. As presented in Section 3.4.3.1.12.1 (Sonar and Other Active Acoustic Sources, Subsection ''Harbor Porpoises'') of the NWTT FEIS/OEIS, the Navy and NMFS are aware of the sensitivity of harbor porpoises and have established a sound pressure level of 120 dB re 1 μPa as a threshold for predicting behavioral responses in harbor porpoises and Level B takes pursuant to the MMPA.

The reference to Tougaard *et al.* (2014) cited by the commenters has been considered in the NWTT FEIS/OEIS. The point raised in that reference was that the Southall *et al.* (2007) weighting functions need updating given there have been new studies that have since become available. The Navy's analysis is in fact based on an update to Southall *et al.* (2007) as detailed in Finneran and Jenkins (2012). In the opinion of the authors, the net result from revisions to the weighting functions like that used by the Navy (Finneran and Jenkins, 2012) is that they are not guaranteed to be conservative enough specifically with regard to sound sources such as pile driving, ''seal scarers,'' and high-frequency pingers. With the exception of high frequency pingers, these sources are not part of the Navy's proposed action. As detailed in Section 3.4.3.1.11.2 (Hearing Loss—Temporary and Permanent Threshold Shift; see reference to Finneran (2015)) in the NWTT FEIS/OEIS, the Navy and NMFS are in the process of reviewing the latest and best available science to further refine future acoustic analyses using weighting functions.

Regarding the commenters' fourth point, NMFS and the Navy have incorporated empirical data on humans (see the NWTT FEIS/OEIS citations to Ward *et al.,* 1958, 1959a, b; and Miller *et al.,* 1963).

With regard to the references cited by the commenters: Kastak *et al.* (2008) reported PTS in a harbor seal after an exposure of 202 dB SEL at 4.1 kHz. This exposure level is 5 dB above the PTS onset criteria used by Navy analyses, and thus the Navy would have predicted PTS for this exposure. The Kastak *et al.* data are therefore in complete agreement with the criteria and thresholds used in the Navy's analysis and the proposed rule. Kujawa and Liberman (2009) reported TTS in mice of 40 dB measured 24 h after exposure. Thresholds were found to recover completely (thus there was no PTS) but other signs of auditory damage were found, such as neural degeneration and a decrease in suprathreshold evoked response amplitudes. A similar study by Lin *et al.* (2011) with guinea pigs found similar results after TTS of >50 dB measured 24 h after exposure. Since no lower level exposures were utilized, it is not known if the suite of auditory damage observed by Kujawa and Liberman (2009) and Lin *et al.* (2011) would have occurred with lesser exposures. Navy's analyses assumed PTS (and thus injury) would occur after exposures producing TTS of 40 dB or more measured ~4 minutes after exposure. Therefore, the exposures used by Kujawa and Liberman (2009) and Lin *et al.* (2011) would have been considered injurious by the Navy criteria. Therefore, both the Kastak *et al.* (2008) and Kujawa and Liberman (2009) studies are consistent with the Navy's use of TTS of 40 dB, measured ~4 min after exposure, as an indicator for auditory injury.

Comment 11: The Animal Legal Defense Fund *et al.* provided several comments, which were originally set forth in a detailed critique by Dr. David Bain, that were critical of the acoustic risk function used by the Navy and NMFS to estimate the probability of behavioral effects that NMFS would classify as harassment. The commenters assert that these risk functions are flawed and underestimate take.

Response: Dr. Bain's critique is not directly relevant to the proposed action in the NWTT Study Area. It is in reference to older Navy EISs (2007 Hawaii Range Complex (HRC) Navy DEIS/OEIS; 2006 Undersea Warfare Training Range (USWTR) DEIS/OEIS) that analyze different actions in another geographic location, and is no longer current as the science has evolved over the last seven years. The criteria and thresholds for determining potential effects on marine species used in the Navy's NWTT FEIS/OEIS and related consultation documents have been appropriately revised based on the best available science since the 2006 and 2007 Draft EISs which Dr. Bain reviewed (see Finneran and Jenkins (2012). Dr. Bain's critique is therefore dated and not directly relevant to the proposed rule or the Navy's analysis for the NWTT Study Area as presented in the NWTT FEIS/OEIS. Please also note that all comments from Dr. Bain's critique were previously responded to in the 2009 Hawaii Range Complex FEIS/OEIS. Particular aspects of Dr. Bain's critique highlighted by the commenters are discussed in Comments and Responses 12 through 19.

Comment 12: The Animal Legal Defense Fund *et al.* commented that NMFS and the Navy rely on studies of temporary threshold shift in captive animals for one of their primary source of data.

Response: The Navy's model uses the best available science to analyze impacts and often overestimates the potential effects of its activities by considering the worst case scenario (*e.g.,* modeling for the loudest sound source within a source bin); see the NWTT FEIS/OEIS Section 3.4.3.1.14.4 (Model Assumptions and Limitations) for details in this regard. The criteria and thresholds for determining potential effects on marine species used in the NWTT FEIS/OEIS and related consultation documents have been revised based on the best available science since the 2007 HRC DEIS/OEIS and the 2006 USWTR DEIS/OEIS. See Finneran and Jenkins (2012), which can be found at *http://www.nwtteis.com.*

NMFS and marine mammal scientists recognize the limitations of controlled experiments using captive animals, but there are no alternative scientific methods to document the onset of TTS, especially in wild animals. It is inaccurate to describe these limitations as deficiencies. Furthermore, commenters are incorrect that the TTS data used in the analysis is from only seven animals in the Navy's research program in the SPAWAR complex. Data used in the analysis and cited in the NWTT FEIS/OEIS also includes results from other species and non-Navy/SPAWAR animals—for example see Lucke *et al.* (2009); Kastelein *et al.* (2012b, 2012c); Kastak *et al.* (2005); Nachtigall, *et. al.* (2003); and Southall *et al.* (2007).

Comment 13: The Animal Legal Defense Fund *et al.* commented that NMFS and the Navy appear to have misused data garnered from the Haro Strait incident by including only those levels of sound received by the ''J'' pod

of killer whales when the USS Shoup was at its closest approach.

Response: Details of the analysis of the Haro Strait event were presented in the NWTT FEIS/OEIS Section 3.4.3.1.6. (Behavioral Reactions to Sonar and Other Active Acoustic Sources; subsection *Odontocetes*). The Navy and NMFS reviewed testimony, video, and all field notes from the time of the event, and have accurately used that documented data in the analysis for the NWTT activities. That data clearly indicated that the behaviors observed were within the species' normal range of behaviors and there were no immediate or general overt negative behavioral reactions observed at the time of the exposure. Furthermore, the presence of numerous small motor vessels maneuvering in close proximity to the orca further complicated any assessment of possible reactions related to sonar from a vessel.

Comment 14: The Animal Legal Defense Fund *et al.* commented that NMFS and the Navy exclude a substantial body of controlled exposure research and opportunistic studies on wild animals (and some research on other experimental animals as well, within a behavioral experimental protocol). For example, NMFS and the Navy fail to include data from the July 2004 Hanalei Bay event, in which 150–200 melon-headed whales were embayed for more than 24 hours during the Navy's Rim of the Pacific exercise.

Response: NMFS disagrees. The studies cited by the commenters are cited in the proposed rule and in the NWTT FEIS/OEIS and were fully considered in the analysis. Section 3.4 of the NWTT FEIS/OEIS contains citations to additional controlled exposure research on wild animals including, for example, DeRuiter *et al.* (2013a, b), Defence Science and Technology Laboratory (2007); Claridge and Durban (2009); McCarthy *et al.* (2011); Miller *et al.* (2012); Moretti *et al.* (2009); Southhall *et al.* (2011, 2012a, 2012b, 2013, 2014); Stimpert *et al.* (2014); and Tyack *et al.* (2011).

Regarding the Hanalei Bay event, NMFS included an extensive analysis of this event in the Potential Effects section of the proposed rule (80 FR 31738, June 3, 2015; pages 31764–31765. Please see that section for further information regarding NMFS' assessment and consideration of that event. It should be noted that NMFS considered active sonar transmissions a plausible, if not likely, contributing factor in the Hanalei stranding in what may have been a ''confluence of events,'' including a unique interaction of biological and physical factor—most of which are not expected to occur in the NWTT Study Area or during NWTT activities. The biological factors may have included the presence of an apparently uncommon, deep-diving cetacean species (and possibly an offshore, non-resident group), social interactions among the animals before or after they entered the Bay, and/or unknown predator or prey conditions. The physical factors may have included the presence of nearby deep water, multiple vessels transiting in a directed manner while transmitting active sonar over a sustained period, the presence of surface sound ducting conditions, and/or intermittent and random human interactions while the animals were in the Bay.

Comment 15: The Animal Legal Defense Fund *et al.* commented that NMFS and the Navy also fail to incorporate data on harbor porpoises and beaked whales in their dataset.

Response: NMFS disagrees with the commenters' assessment. The Navy and NMFS have used studies on harbor porpoises and beaked whales in the data sets used for analysis. Please see Section 3.4.3.1.12.1 (Sonar and Other Active Acoustic Source) of the NWTT FEIS/OEIS where this information is presented. The analysis includes, for example, data from both captive and wild harbor porpoises (see Kastelein *et al.* (2000, 2005b) and Johnston (2002)) and behavioral responses from a wild population of beaked whales as documented by Tyack *et al.* (2011). Please also refer to the cited Finneran and Jenkins (2012) for additional details. Finally, please see the discussions presented in Section 3.4.3.1.14.4 of the NWTT FEIS/OEIS (Model Assumptions and Limitations), which describes the numerous conservative assumptions incorporated into the Navy's model.

Comment 16: The Animal Legal Defense Fund *et al.* commented that the risk function should have taken into account the social ecology of some marine mammal species.

Response: The Navy and NMFS have taken these factors into account. As detailed in the NWTT FEIS/OEIS Section 3.4.3.1.14.3 (Navy Acoustic Effects Model) and the Navy's Determination of Acoustic Effects Technical Report (Marine Species Modeling Team 2013), group size is accounted for in the modeling of acoustic effects. Additionally, the behavioral response function includes observations of the J-pod in Haro Strait.

Comment 17: The Animal Legal Defense Fund *et al.* commented that NMFS' threshold is applied in such a way as to preclude any assessment of long-term behavioral impacts on marine mammals. It does not account, to any degree, for the problem of repetition: The way that apparently insignificant impacts, such as subtle changes in dive times or vocalization patterns, can become significant if experienced repeatedly or over time.

Response: NMFS disagrees. This analysis is presented in the NWTT FEIS/OEIS in Section 3.4.3.1.9 (Long-Term Consequences to the Individual and the Population) and Section 3.4.3 (Summary of Impacts (Combined Impacts of all Stressors) on Marine Mammals) where cumulative impacts are addressed, as well as in the Long-Term Consequences section of this rule. Assessment of long-term cumulative impacts to species and stocks is also represented by the discussion in Section 3.4.4.1 of the NWTT FEIS/OEIS (Summary of Monitoring and Observations During Navy Activities). NMFS finds that the vast majority of impacts expected from sonar exposure and underwater detonations are behavioral in nature, temporary and comparatively short in duration, relatively infrequent, and specifically not of the type or severity that would be expected to be additive for the small portion of the stocks and species likely to be exposed.

This analysis is further corroborated by the healthy, and in some locations, increasing marine mammal populations, where sonar use has been occurring for decades and is frequently in use on an annual basis, such as on instrumented ranges. As noted previously, there is no evidence that Navy activities have had or are having any long-term impact on marine mammal populations or stocks. For more information, see the Long-Term Consequences discussion in the Analysis and Negligible Impact Determination section of this rule.

Comment 18: The Animal Legal Defense Fund *et al.* commented that while NMFS and the Navy have assigned a specific threshold to beaked whales, in light of Tyack *et al.* (2011), it is clear that some beaked whales are taken on exposure to mid frequency sonar at levels below 140 decibels (SPL).

Response: The Navy and NMFS specifically considered the Tyack *et al.* (2011) study, which was cited in the NWTT FEIS/OEIS, and its findings were incorporated into the threshold for beaked whales (see the FEIS/OEIS Section 3.4.3.1.6 (Behavioral Reactions)). During Tyack *et al.*'s (2011) research at the Navy's fixed tracking range in the Bahamas, animals were observed to leave the immediate area of the anti-submarine warfare training exercise (avoiding the sonar acoustic

footprint at a distance where the received level was ''around 140 dB'' SPL. Further, Moretti *et al.* (2014) recently derived an empirical risk function for Blainville's beaked whale that predicts there is a 0.5 probability of disturbance at a received level of 150 dB SPL, suggesting that in some cases the current step function may over-estimate the effects of an activity using sonar on beaked whales. Therefore, NMFS has concluded that, based on the best available science, 140 dB re 1μPa (root mean square) is a conservative threshold for predicting potential behavioral effects on beaked whales from sonar signals.

Comment 19: The Animal Legal Defense Fund *et al.* commented that there are additional flaws in the Navy's acoustic effects modeling, which include: A lack of any indication that the Navy has accounted for reverberation effects in its modeling, or that its modeling sufficiently represents areas in which the risk of reverberation is greatest; and a failure to consider the possible synergistic effects on marine mammal physiology and behavior of using multiple acoustic sources in spatial and temporal proximity.

Response: NMFS disagrees. As presented in the Section 3.4.3.1.14.3 (Navy Acoustic Effects Model) of the NWTT FEIS/OEIS and in the referenced modeling technical report (Marine Species Modeling Team, 2013), the Navy's acoustic effects modeling incorporates the most up to date marine mammal density data and oceanographic data for the quantification of predicted acoustic impacts to marine mammals. Contrary to the assertions in the comment, the model does account for a fully three-dimensional environment in calculating sound propagation and exposures incorporating site-specific bathymetry, sound speed profiles, wind speed, and bottom properties into the propagation modeling process. As noted in the NWTT FEIS/OEIS, the modeling accounts for all sources within a scenario simultaneously, so this modeling approach specifically accounts for the combined (additive) effects from using multiple acoustic sources in spatial and temporal proximity (*i.e.,* the cumulative SEL is a composite of all sources received by the animat). Multiple conservative assumptions are incorporated into the model.

Vessel Strike

Comment 20: The Animal Legal Defense Fund *et al.* commented that the Navy and NMFS failed to evaluate ship collisions with large cetaceans, and recommended that the Navy model potential ship strikes in the same way it models acoustic harassment and injury. The Commission also recommended that NMFS require the Navy to use its spatially and temporally dynamic simulation models rather than simple probability calculations to estimate strike probabilities for specific activities (*i.e.,* movement of vessels, torpedoes, unmanned underwater vehicles and use of expended munitions, ordnance, and other devices).

Response: The potential for ship strikes is discussed in the NWTT FEIS/OEIS, Section 3.4.3.4.1 (Impact from Vessel Strikes), Chapter 6 of the LOA application (Section 6.7, Estimated Take of Large Whales by Navy Vessel Strike), and throughout this rule. There has never been a recorded vessel strike of a whale during any active training or testing activities in the NWTT Study Area. There has been only one whale strike in the Pacific Northwest by the Navy since such records have been kept (June 1994-present). In August 2012, a San Diego homeported DDG (destroyer) at-sea about 35 nm west of Coos Bay, Oregon struck a whale (believed to be a minke) while transiting to San Diego from Seattle. The whale (believed to be a minke whale) was last seen swimming away from the location. The fate of the animal is unknown and although no blood or other obvious indications of injury to the whale were detected, this does not negate the possibility that there may have been serious internal injury to the whale resulting from the encounter. It is important to note that the vessel strike mitigation procedures proposed for the NWTT activities (see Mitigation) were not employed during the August 12 ship strike incident that occurred during non-training activities (with the exception of ''safe speed'' protocols), and these measures are expected to effectively mitigate the potential impacts to marine mammals from vessel strike during the NWTT training and testing activities.

Any increase in vessel movement, as discussed in Section 3.4.3.4.1 (Impacts from Vessel Strikes) of the NWTT FEIS/OEIS, over the No Action Alternative is still well below areas such as Southern California and Hawaii where the density of large whales and the number of Navy activities is higher than that for the NWTT Study Area and yet strikes to large whales are still relatively rare in the SOCAL and Hawaii Range Complexes. Further, there are fewer Navy vessels for NWTT that are homeported in the Study Area than in the previous years included in the historical record. Additionally, while the number of training and testing activities is likely to increase, it is not expected to result in an appreciable increase in vessel use or transits since multiple activities usually occur from the same vessel. Finally, the Navy is not proposing substantive changes in the locations where vessels have been used over the last decade. In summary, neither the Navy nor NMFS anticipates vessel strikes to marine mammals during training or testing activities within the Study Area, and NMFS is not authorizing mysticete takes (by injury or mortality) from vessel strikes during the 5-year period of the NWTT regulations. However, the Navy has proposed measures (see Mitigation) to mitigate potential impacts to marine mammals from vessel strikes during training and testing activities in the Study Area.

The Navy considered using a dynamic simulation model to estimate strike probability. However, the Navy determined, and NMFS concurs, that the use of historical data was a more appropriate way to analyze the potential for strike. The Navy's strike probability analysis in the NWTT FEIS/OEIS is based upon actual data collected from historical use of vessels, in-water devices, and military expended materials, and the likelihood that these items may have the potential to strike an animal. This data accounts for real world variables over the course of many years, and any model would be expected to be less accurate than the use of actual data.

The suggestion to use the Navy's acoustic effects model to determine the probability of a strike would not provide a more reliable estimate of strike probability given that there are so many unknown but critical values which would be necessary as required inputs. There is no available science regarding the necessary functional parameters for a complex dynamic whale strike simulation model; there are large unknowns regarding the data that would be necessary such as the density, age classes, and behavior of large whales in the NWTT Study Area; and there are no means to validate the output of a model given there is no empirical data (not strikes) to ''seed the dynamic simulation.'' Therefore, use of historical data from identical activities elsewhere and additional use of a probability analysis remain a more reasonable analytical approach.

Mitigation and Monitoring

Comment 21: Some commenters suggested that the rule fails to include meaningful mitigation and monitoring measures that would ensure the ''least

practicable impact'' as obligated by the MMPA.

Response: NMFS disagrees. Under section 101(a)(5)(A) of the MMPA, NMFS must set forth the ''permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.'' NMFS' duty under this ''least practicable adverse impact'' standard is to prescribe mitigation reasonably designed to minimize, to the extent practicable, any adverse population-level impacts, as well as habitat impacts. While population-level impacts are minimized by reducing impacts on individual marine mammals, not all takes have a reasonable potential for translating to population-level impacts. NMFS' objective under the ''least practicable adverse impact'' standard is to design mitigation targeting those impacts on individual marine mammals that are reasonably likely to contribute to adverse population-level effects.

The mitigation measures required by this rule are discussed in the NWTT FEIS/OEIS and in the Mitigation section of this rule. In summary, the mitigation measures include the use of visual and acoustic methods to detect marine mammals, procedures to relocate or delay events where marine mammals have been detected, monitoring of event locations and marine mammals before, during, and after events, and the continued reporting of Navy activity and interactions with marine mammals as has been occurring since 2006. Please also note that the rule requires a robust adaptive management program that regularly addresses new information and allows for modification of mitigation and/or monitoring measures as appropriate. The mitigation measures are informed by years of experience and monitoring, which has shown them to be effective. NMFS has determined that the mitigation measures are adequate means of effecting the least practicable adverse impacts on marine mammals species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, while also considering personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Comment 22: The Commission recommended that NMFS require the Navy to provide the predicted average and maximum ranges for all impact criteria (*i.e.,* behavioral response, TTS, PTS, onset slight lung injury, onset slight gastrointestinal injury, and onset mortality), for all activities (*i.e.,* based on the activity category and representative source bins and including ranges for more than 1 ping), and for all functional hearing groups of marine mammals within the three NWTT areas (*i.e.,* offshore, inland waters, and Western Behm Canal).

Response: Ranges to effects for all criteria and functional hearing groups are provided for representative active sonars (Section 3.4.3.2.1.1, Range to Effects) and explosives (Section 3.4.3.2.2.1, Range to Effects) in the NWTT FEIS/OEIS. The representative sources include the most powerful active sonar source and the charge with the largest net explosive weight analyzed. NMFS believes that these representative sources provide adequate information to analyze potential effects on marine mammals. Because the Navy conducts training and testing in a variety of environments having variable acoustic propagation conditions, variations in acoustic propagation conditions are considered in the Navy's acoustic modeling and the quantitative analysis of acoustic impacts. Average ranges to effect are provided in the NWTT FEIS/OEIS to show the reader typical zones of impact around representative sources. The presentation of a maximum range based on a worst case analysis under extreme conditions would fail to be representative and therefore potentially confuse readers by presentation of a range to effects that are extremely unlikely to ever be present in actual real world conditions.

As explained in the NWTT FEIS/OEIS in Section 3.4.3.2.1.1 (Range to Effects), there is no reason to show a PTS range for more than one ping because of the short distances involved, even in the case of the most powerful hull mounted source. The ship moves beyond the PTS zone for each successive ping, and there is no difference in successive pings. Given all the science detailed in the NWTT FEIS/OEIS (see for example Section 3.4.3.2.1.2, Avoidance Behavior and Mitigation Measures as Applied to Sonar and Other Active Acoustic Sources) indicating that marine mammals will behaviorally avoid high levels of sound, the assumption that a marine mammal would not remain alongside a pinging vessel is a simple but reasonable assumption. As presented in the NWTT FEIS/OEIS, while 10 knots was the speed used in modeling the ship's speed of advance, a ship engaged in anti-submarine warfare training or testing would be moving at between 10 and 15 knots. For the majority of marine mammals, the distance to a PTS exposure is within 10 meters of the sonar dome, and that distance is not influenced significantly by differing ocean environments given that the calculated range to a PTS is almost entirely a function involving the physics of spreading loss. The comment's assumption that the distances provided in Tables 3.4–10 and 3.4–11 of the NWTT DEIS/OEIS do not apply to NWTT is incorrect.

Because the Navy conducts training and testing in a variety of environments having variable acoustic propagation conditions, variations in acoustic propagation conditions are considered in the Navy's acoustic modeling and the quantitative analysis of acoustic impacts. Although the Navy pointed out the complexity of acoustic modeling in inland waters, it would be incorrect to conclude that modeling therefore lacked precision. The Navy acoustic modeling makes use of the most accurate information and environmental data available, including the inland waters where these activities would take place.

The Navy's NWTT FEIS/OEIS and supporting technical documents provide the detail to make the analysis fully transparent. Details of this model's processes and the description and derivation of the inputs are presented in the Navy's Determination of Acoustic Effects Technical Report (Marine Species Modeling Team, 2013). As presented in Section 3.4.3.1.14.3 (Navy Acoustic Effects Model) of the NWTT FEIS/OEIS, the model incorporates actual site-specific bathymetric relief, sound speed profiles, wind speed, and bottom properties into the propagation analysis.

Comment 23: The Commission recommended that NMFS require the Navy to use a second clearance category of 60 minutes for beaked whales and sperm whales if the animal has not been observed exiting the mitigation zone.

Response: NMFS does not concur with the Commission's recommendation that the Navy should use a second clearance category of 60 minutes for deep-diving species for the following reasons:

- As described in the NWTT FEIS/OEIS in Chapter 5 (Standard Operating Procedures, Mitigation, and Monitoring), a 30-minute wait period more than covers the average dive times of most marine mammals.
- The ability of an animal to dive longer than 30 minutes does not mean that it will always do so. Therefore, the 60-minute delay would only potentially add value in instances when animals had remained under water for more than 30 minutes.
- Navy vessels typically move at 10–12 knots (5–6 m/sec) when operating

active sonar and potentially much faster when not. Fish *et al.* (2006) measured speeds of seven species of odontocetes and found that they ranged from 1.4–7.30 m/sec. Even if a vessel was moving at the slower typical speed associated with active sonar use, an animal would need to be swimming near sustained maximum speed for an hour in the direction of the vessel's course to stay within the safety zone of the vessel. Increasing the typical speed associated with active sonar use would further narrow the circumstances in which the 60-minute delay would add value.

- Additionally, the times when marine mammals are deep-diving (*i.e.,* the times when they are under the water for longer periods of time) are the same times that a large portion of their motion is in the vertical direction, which means that they are far less likely to keep pace with a horizontally moving vessel.
- Given that, the animal would need to have stayed in the immediate vicinity of the sound source for an hour, and considering the maximum area that both the vessel and the animal could cover in an hour, it is improbable that this would randomly occur. Moreover, considering that many animals have been shown to avoid both acoustic sources and ships without acoustic sources, it is improbable that a deep-diving cetacean (as opposed to a dolphin that might bow ride) would choose to remain in the immediate vicinity of the source.

Furthermore, the Navy was aware of the diving behaviors of marine mammals and integrated the data in Watwood and Buonantony (2012) into its modeling. In summary, NMFS believes that it is unlikely that a single cetacean would remain in the safety zone of a Navy sound source for more than 30 minutes, and therefore disagrees with the Commission that a second clearance category of 60 minutes for deep-diving species is necessary. The Navy's acoustic analysis predicts that that injury to deep-diving marine mammals (*e.g.,* sperm whales and beaked whales) are not expected to occur in the Study Area.

Comment 24: The Animal Legal Defense Fund *et al.* commented that NMFS should limit all Navy training and testing activities that use sonar and explosives that overlap biologically important areas identified along the Washington, Oregon, and Northern California coasts and off the coast of Southern Alaska. Time/Area closures were specifically recommended for NMFS-identified biologically important areas, Olympic Coast National Marine Sanctuary (OCNMS), Puget Sound, and Marine Protected Areas. Other commenters also recommended consideration of time/area limitations in biologically sensitive areas in the Study Area.

Response: The Navy and NMFS have fully considered area-specific mitigation measures for the Navy's low use of mid-frequency active sonar and other activities in areas of particular importance (*e.g.,* BIAs, OCNMS, MPAs, Puget Sound) to marine mammals. See the *Consideration of Time/Area Limitation* section of this rule for an assessment of Navy activities within these areas, along with clarification of, or updates to, mitigation measures within these areas. In addition, the analysis of mitigation measures in Chapter 5 (Standard Operating Procedures, Mitigation, and Monitoring) of the NWTT FEIS/OEIS provides an analysis of the activities in these BIAs, which has been incorporated into the analysis in Section 3.4 (Marine Mammals) of the NWTT FEIS/OEIS. Chapters 5 (see Section 5.3.4.12, Avoiding Marine Protected Areas) and 6 of the NWTT FEIS/OEIS include an analysis of the MPAs.

NMFS has determined that the mitigation measures required by this rule (especially when the adaptive management component is taken into consideration), including those clarified or updated above (see *Consideration of Time/Area Limitation*), are adequate means of effecting the least practicable adverse impacts on marine mammals species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, while also considering personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Comment 25: The Animal Legal Defense Fund *et al.* suggested the use of sonar and other active acoustic systems at the lowest practicable source level, with clear standards and reporting requirements for different testing and training scenarios.

Response: The Navy uses active sonar at the lowest practicable source level consistent with mission requirements. See Section 5.3.4.1.3 of the NWTT FEIS/OEIS (Reducing Sonar Source Levels and Total Number of Hours) for further information.

Comment 26: The Animal Legal Defense Fund *et al.* suggested expansion of the marine species ''safety zone'' to a 4 km shutdown, reflecting international best practice, or 2 km, reflecting the standard prescribed by the California Coastal Commission for similar activities in Southern California.

Response: Section 5.3.4.1.13 of the NWTT FEIS/OEIS (Increasing the Size of Observed Mitigation Zones) discusses mitigation zone expansion. See also Section 5.3.4.1.16 of the NWTT FEIS/OEIS (Adopting Mitigation Measures of Foreign Navies). There is no internationally recognized best practice with regard to mitigation zone distance. The Navy developed activity-specific mitigation zones based on the Navy's acoustic propagation model. Each recommended mitigation zone is intended to avoid or reduce the potential for onset of the lowest level of injury, PTS, out to the predicted maximum range. Mitigating to the predicted maximum range to PTS consequently also mitigates to the predicted maximum range to onset mortality (1 percent mortality), onset slight lung injury, and onset slight gastrointestinal tract injury, since the maximum range to effects for these criteria are shorter than for PTS. Furthermore, in most cases, the mitigation zone actually covers the TTS zone.

The mitigation zones contained in this final rule represent the maximum area the Navy can effectively observe based on the platform of observation, number of personnel that will be involved, and the number and type of assets and resources available. As mitigation zone sizes increase, the potential for reducing impacts decreases. For instance, if a mitigation zone increases from 1,000 to 4,000 yd. (914 to 3,658 m), the area that must be observed increases sixteen-fold, which is not practicable. The mitigation measures contained in this final rule balance the need to reduce potential impacts with the Navy's ability to provide effective observations throughout a given mitigation zone. Implementation of mitigation measures is most effective when the mitigation zone is appropriately sized to be realistically observed. The Navy does not have the resources to maintain additional Lookouts or observer platforms that would be needed to effectively observe mitigation zones of increased size.

Comment 27: The Animal Legal Defense Fund *et al.* suggested that the Navy delay or relocate activities when beaked whales are detected through passive acoustic monitoring and when significant aggregations of any species or particularly vulnerable or endangered species are detected by any means in the vicinity of an exercise, even if potentially occurring beyond the established mitigation zone.

Response: Mitigation will be implemented within the mitigation zone for all marine mammals regardless of species or numbers of animals if they

approach or enter a mitigation zone. NMFS disagrees that it is necessary to delay or relocate activities when beaked whales, other sensitive species or significant aggregations of marine mammals are detected outside the mitigation zones. For the NWTT activities, the Navy developed each recommended mitigation zone to avoid or reduce the potential for onset of the lowest level of injury, PTS, out to the predicted maximum range. Furthermore, in most cases, the predicted maximum range to PTS also consequently covers the predicted average range to TTS. The activity-specific mitigation zones are based on the longest range for all the functional hearing groups. The mitigation zone for a majority of activities is driven by either the high-frequency cetaceans or the sea turtle functional hearing groups. Therefore, the mitigation zones are even more protective for the remaining functional hearing groups (*i.e.,* low-frequency cetaceans, mid-frequency cetaceans, and pinnipeds). The predicted ranges are based on local environmental conditions and are unique to the NWTT Study Area.

With respect to passive acoustic monitoring, all passive acoustic detections will be reported to Lookouts to increase vigilance of the visual surveillance. However, as stated previously, passive acoustic monitoring can neither provide range or bearing to detected animals, and therefore cannot provide locations of these animals.

Comment 28: The Animal Legal Defense Fund *et al.* suggested use of simulated geography (and other work-arounds) to reduce or eliminate chokepoint exercises in near-coastal environments, particularly within canyons and channels, and use of other important habitat.

Response: There are no chokepoint exercises in the NWTT Study Area. Further, NMFS notes that the Navy has clarified that certain activities will not occur in the near-coastal environment. As explained previously in this rule, the Navy will conduct Missile Exercises using high explosives at least 50 nm from shore in the NWTRC Offshore Area, the Navy will conduct BOMBEX (high explosive munitions) events at least 50 nm from shore, and the Navy will conduct BOMBEX (non-explosive practice munitions) events at least 20 nm from shore.

As discussed in Section 2.5.1.4 (Simulated Training and Testing) and Section 5.3.4.1.2 (Replacing Training and Testing with Simulated Activities) of the NWTT FEIS/OEIS, the Navy uses computer simulation for training and testing whenever possible. However, training in near-coastal environments is an essential component to maintaining military readiness. Computer simulation can provide familiarity and complement live training; however, it cannot provide the fidelity and level of training necessary to prepare naval forces for deployment. Sound propagates differently in shallower water and operators must learn to train in this environment. Additionally, submarines have become quieter through the use of improved technology and have learned to hide in the higher ambient noise levels of the shallow waters of coastal environments. In real world events, it is highly likely Sailors would be working in, and therefore must train in, these types of areas. The littoral water space is also the most challenging area to operate in due to a diverse acoustic environment. It is not realistic or practicable to refrain from training in the areas that are the most challenging and operationally important. Operating in near-costal environments is essential in order to provide realistic training on real world combat conditions with regard to shallow water sound propagation.

The Navy will implement mitigation for all training and testing activities to minimize any potential effects. Further, the Navy does have a particular set of monitoring measures (intended to help reduce the chance of a stranding) that would be applied if a combination of circumstances exist that are thought to make a stranding more likely (*e.g.,* steep bathymetry, multiple vessels using sonar in a single area over an extended period of time, constricted channels or embayments). However, a combination of these environmental and operational features is not present in the NWTT Study Area.

Comment 29: The Animal Legal Defense Fund *et al.* suggested avoidance or reduction of training during months with historically significant surface ducting conditions; delay of activities or use of power-downs during significant surface ducting conditions; and use of additional power-downs when significant surface ducting conditions coincide with other conditions that elevate risk.

Response: The mitigation measures required by this rule, which have proven effective over years of monitoring and reporting, apply to activities conducted during surface ducting conditions. Avoiding or reducing active sonar during surface ducts for the purpose of mitigation would increase safety risks to personnel, be impractical with regard to implementation of military readiness activities, and result in unacceptable impacts on readiness for the following reasons: The Navy must train in the same manner as it will fight. Submarines have long been known to exploit the phenomena associated with surface ducting. Therefore, training in surface ducting conditions is a critical component to military readiness because sonar operators need to learn how sonar transmissions are altered due to surface ducting, how submarines may take advantage of them, and how to operate sonar effectively in this environment. Avoiding activities during periods with surface ducting conditions or requiring the use of power-downs during surface ducting conditions would reduce a sonar operator's ability to effectively operate in a real world combat situation, thereby resulting in an unacceptable increased risk to personnel safety and the ability to achieve military readiness. Furthermore, avoiding surface ducting would be impractical to implement because ocean conditions contributing to surface ducting change frequently, and surface ducts can be of varying duration. See section 5.3.4.1.9 of the NWTT FEIS/OEIS for more information on avoiding or reducing activities during surface ducting conditions.

Comment 30: The Animal Legal Defense Fund *et al.* suggested that the Navy plan their ship tracks to avoid embayments and provide escape routes for marine mammals.

Response: First, NMFS notes that the Navy has particular set of monitoring measures (intended to help reduce the chance of a stranding) that would be applied if a combination of circumstances exist that are thought to make a stranding more likely (*e.g.,* steep bathymetry, multiple vessels in a single area over an extended period of time, and in areas of constricted channels or embayments). However, a combination of these environmental and operational features is not present in the NWTT Study Area. Further, the majority of Navy training activities involving ''ship tracks'' would occur in the offshore portion of the Study Area and therefore not involve embayments. In inland waters where there may be areas that could be considered embayments, ship tracks are generally constrained by the vessel traffic separation scheme, safety of operation, and mission requirements. See Section 5.3.4.1.6 of the NWTT FEIS/OEIS (Limiting Activities to a Few Specific Locations) for further information regarding limiting the location of activities.

Comment 31: Several commenters suggested that the Navy limit their activities to periods of good visibility. More specifically, the Animal Legal

Defense Fund *et al.* suggested that all weapons firing in missile and bombing exercises involving detonations exceeding 20 lb. net explosive weight take place during the period 1 hour after sunrise to 30 minutes before sunset.

Response: NMFS believes that effective mitigation measures are already in place to address missile and bombing exercises. The Navy must train at night and in low-visibility conditions to ensure personnel may operate in similar conditions when required for actual operations. After sunset and prior to sunrise, watch personnel employ night visual search techniques, which could include the use of night vision devices. Please see the Mitigation section of the rule for further information. Section 5.3.4.1.8 of the NWTT FEIS/OEIS (Avoiding or Reducing Active Sonar at Night and During Periods of Low Visibility) also discusses activities conducted during varying environmental conditions.

NMFS clarifies that historically, Navy bombing exercises in the NWTT Study area are very infrequent and have occurred greater than 50 nm from shore in order to avoid other users and for marine safety purposes. Conducting these exercises greater than 50 nm from shore has the practical effort of affording environmental protections to certain species such as southern resident killer whale, salmonids, and harbor porpoise that generally are not in these areas. The Navy proposes to continue to conduct bombing and missile exercises with high explosives at least 50 nm off shore in the NWTT study area. In addition, Bombex and other events using non-explosive practice munitions are not anticipated to occur within 20 nm of shore in NWTT Study area, and SINKEX are not proposed to occur in the NWTT Study area.

Comment 32: The Animal Legal Defense Fund *et al.* suggested suspension or postponement of chokepoint exercises during surface ducting conditions and scheduling of such exercises during daylight hours.

Response: There are no chokepoint exercises in the NWTT Study Area. See our Responses to Comment 29 regarding avoiding or reducing activities during surface ducting conditions. See our Response to Comment 31 regarding avoidance of activities at night.

Comment 33: The Animal Legal Defense Fund *et al.* suggested use of dedicated aerial monitors during chokepoint exercises, major exercises, and near-coastal exercises.

Response: There are no chokepoint or Major Training Exercises proposed for the NWTT Study Area. Please refer to Section 2 of the NWTT FEIS/OEIS for a detailed description of the action. As described throughout Chapter 5 of the NWTT FEIS/OEIS and in this rule (see ''Mitigation'' section), visual observation (aerial and vessel-based) would be conducted in association with Navy activities. Specific aerial monitoring is not typically feasible given the limited duration of typical monitoring flights (less than 4 hours). In addition, there are significant flight safety considerations and airspace restrictions during many Navy exercises when larger groups of military aircraft are present in high numbers at various altitudes.

Comment 34: The Animal Legal Defense Fund *et al.* suggested use of dedicated passive acoustic monitoring to detect vocalizing species, through established and portable range instrumentation and the use of hydrophone arrays off instrumented ranges. The Commission also recommended that NMFS require the Navy to use passive and active acoustics, whenever practicable, to supplement visual monitoring during the implementation of its mitigation measures for all activities that could cause PTS, injury, or mortality beyond those explosive activities for which passive acoustics already was proposed. The Commission questioned why passive and active acoustic monitoring used during the Navy's Surveillance Towed Array Sensory System Low Frequency Active (SURTASS LFA) activities is not applied here.

Response: As described in Section 5 of the NWTT FEIS/OEIS and this rule, the Navy will conduct passive acoustic monitoring during several activities. The Navy will use passive acoustic monitoring to supplement visual observations during IEER sonobuoy activities, explosive sonobouys using >0.5–2.5 lb net explosive weight, and torpedo (explosive) testing exercises, to detect marine mammal vocalizations. The Navy does not have the resources to construct and maintain passive acoustic monitoring systems for each training and testing activity. See Section 5.3.4.1.13 of the NWTT FEIS/OEIS (Increasing Visual and Passive Acoustic Observations) for more information regarding the use of passive sensors. For additional information on the Navy's marine mammal monitoring efforts, see *http://www.navymarinespecies monitoring.us/*.

The active sonar system used by SURTASS LFA is unique to the platforms that use SURTASS LFA. Moreover, this system requires the platforms that carry SURTASS LFA to travel at very slow speeds for the system to be effective. For both of these reasons it is not possible for the Navy to use this system for the platforms analyzed in the NWTT FEIS/OEIS.

Comment 35: The Animal Legal Defense Fund *et al.* suggested modification of sonobuoys for passive acoustic detection of vocalizing species.

Response: Modifying sonobuoys to increase their bandwidth is considered impractical for the Navy because it would require significant modification to the sonobuoy receiving equipment at a substantial cost and reduce the effectiveness of the sonobuoy system's ability to detect submarines. See section 5.3.4.1.13 of the NWTT FEIS/OEIS (Increasing Visual and Passive Acoustic Observations) for further information regarding the use of passive sensors.

Comment 36: The Animal Legal Defense Fund *et al.* suggested use of aerial surveys and ship-based surveys before, during, and after multi-unit exercises.

Response: There are no Major Training Exercises proposed for NWTT. See Chapter 2 of the NWTT FEIS/OEIS for a discussion of the Proposed Action and a description of events that may involve more than one unit, such as a helicopter coordinating with a surface vessel. As described throughout Chapter 5 of the NWTT FEIS/OEIS and this rule, visual observation (aerial and vessel-based) would be conducted in association with Navy activities. Specific aerial monitoring is not typically effective or feasible given the limited duration of typical monitoring flights (less than 4 hours). In addition, there are significant flight safety considerations and airspace restrictions during Navy training when military aircraft are present in high numbers at various altitudes. Ship-based surveys before, during, and after multi-unit exercises are impractical due to the large amount of resources required and the significant impact such a requirement would have on readiness. In addition to the mitigation and monitoring required by this rule, which have proven to be effective, the Navy is also committed to a robust marine mammal monitoring program designed to answer specific questions about the effects of the Navy's activities on marine mammals.

Comment 37: The Animal Legal Defense Fund *et al.* suggested use of all available range assets for marine mammal monitoring.

Response: NMFS has worked with the Navy over the years to help develop the most effective mitigation protocols using the platforms and assets that are available for monitoring. The required mitigation measures in this document represent the maximum level of effort

(*e.g.,* numbers of Lookouts and passive sonobuoys) that the Navy can commit to observing mitigation zones given the number of personnel that will be involved and the number and type of assets and resources available.

Comment 38: Some commenters believe that using Lookouts as the primary strategy for limiting potential impacts from Navy activities is inadequate. The Animal Legal Defense Fund *et al.* suggested the use of additional Lookouts, and the use of NMFS-certified observers for marine mammal detection. Several commenters requested further information on the Navy's Lookout effectiveness study. More specifically, the Animal Legal Defense Fund *et al.* suggested that the Navy complete a Lookout effectiveness study comparing the abilities of Navy vessel-based Lookouts and third-party protected species observers.

Response: One key component of the monitoring and mitigation required by this rule is the shipboard Lookouts (also known as watchstanders), who are part of the standard operating procedure that ships use to detect objects (including marine mammals) within a specific area around the ship during events. The Lookouts are an element of the Navy's monitoring plan, as required by NMFS and specified in the LOAs. The goal of Lookouts is to detect marine mammals entering ranges of 200, 500, and 1,000 yd (183, 457, and 914 m) around the vessel, which correspond to distances at which various mitigation actions should be performed. In addition to the Lookouts, officers on the bridge search visually and sonar operators listen for marine mammal vocalizations.

NMFS disagrees that using Lookouts as the primary strategy for limiting potential impacts from Navy activities is inadequate. Navy Lookouts are qualified and experienced observers of the marine environment. All Lookouts take part in Marine Species Awareness Training so that they are better prepared to spot marine mammals. Their duties require that they report all objects sighted in the water to the Office of the Deck (OOD) and all disturbances that may be indicative of a threat to the vessel and its crew. Lookouts are on duty at all times, day and night, when a ship or surfaced submarine is moving through the water. Visual detections of marine mammals would be communicated immediately to a watch station for information disseminations and appropriate mitigation action. The number of Lookouts required for each activity represents the maximum level of effort (*e.g.,* numbers of Lookouts and passive sonobuoys) that the Navy can commit to observing mitigation zones given the number of personnel that will be involved in an activity and the number and type of assets and resources available. The number of Lookouts that the Navy uses for each activity often represents the maximum capacity based on limited resources (*e.g.,* space and manning restrictions). NMFS has carefully considered Navy's use of Lookouts and determined that, in combination with the other mitigation measures identified, the Navy's mitigation plan will effect the least practicable adverse impacts on marine mammal species or stocks and their habitat.

The Navy has determined that the use of third-party observers (*e.g.,* NMFS-certified protected species observers) in air or on surface platforms in lieu of or in addition to existing Navy Lookouts for the purposes of mitigation is impractical for the following reasons: The use of third-party observers would compromise security for some activities involving active sonar due to the requirement to provide advance notification of specific times and locations of Navy platforms; reliance on the availability of third-party personnel could impact training and testing flexibility; the presence of additional aircraft in the vicinity of naval activities would raise safety concerns; and there is limited space aboard Navy vessels. Furthermore, Navy personnel are extensively trained in spotting items on or near the water surface and receive more hours of training than many third-party personnel.

In 2010, the Navy initiated a study designed to evaluate the effectiveness of the Navy Lookout team. The University of St. Andrews, Scotland, under contract to the Navy, developed an initial data collection protocol for use during the study. Between 2010 and 2012, trained Navy marine mammal observers collected data during nine field trials as part of a ''proof of concept'' phase. The goal of the proof of concept phase was to develop a statistically valid protocol for quantitatively analyzing the effectiveness of Lookouts during Navy training exercises. Field trials were conducted in the HRC, SOCAL Range Complex, and Jacksonville Range Complex onboard one frigate, one cruiser, and seven destroyers. Preliminary analysis of the proof of concept data is ongoing. The Navy is also working to finalize the data collection process for use during the next phase of the study. While data was collected as part of this proof of concept phase, those data are not fairly comparable because protocols were being changed and assessed, nor are those data statistically significant. Therefore, it is improper to use these data to draw any conclusions on the effectiveness of Navy Lookouts at this time.

Comment 39: The Animal Legal Defense Fund *et al.* suggested the use of dedicated aerial monitoring for all Navy explosive activities using time-delay firing devices and/or all activities involving explosives greater than 20 lb net explosive weight.

Response: There are no time-delay devices proposed for use in the NWTT Study Area. Further, the largest charge weight (NEW) proposed for use in the NWTT Study Area during Mine Warfare training exercises is a 2.5 lb. charge. Please see Chapter 2 of the NWTT FEIS/OEIS for a detailed description of the action.

Comment 40: The Animal Legal Defense Fund *et al.* suggested the use of gliders or other platforms for pre-activity monitoring to avoid significant aggregations of marine mammals.

Response: The development of passive acoustic detectors on gliders and other platforms is still in the research and development stages under funding from the Office of Naval Research and the Navy's Living Marine Resources programs. While promising, many of the various technologies are still being tested and not ready for transition to compliance monitoring where a higher degree of performance is needed. Gliders, even if able to report in real-time or delayed near real-time, would only be able to document the presence of marine mammals, not the distance of the marine mammals from the glider or individual animal movement. Moreover, gliders would only provide an indication that animals are in the area, but these same animals could easily move substantial distances over the course of just a few hours. In some cases, use of gliders in and around where Navy submarines also operate is an underwater safety hazard to the submarine and to the glider. Gliders and other passive acoustic platforms, therefore, are more appropriate for broad area searches within Navy ranges to document marine mammal seasonal occurrence, but are not practical as a mitigation tool.

Comment 41: The Animal Legal Defense Fund *et al.* recommended that the Navy comply with underwater detonation and gunnery exercise mitigation measures as set forth in NMFS' 2009 final rule for the SOCAL Range Complex.

Response: The commenters do not elaborate on why the mitigation measures for underwater explosives and gunnery exercises—which are unrelated

activities—for the SOCAL Range Complex would be more protective than those currently proposed for similar activities in the NWTT Study Area. Moreover, mitigation measures designed for training and testing activities in the SOCAL Range Complex are not directly applicable to NWTT activities. Mitigation measures for underwater detonations and gunnery exercises for NWTT are described in the Mitigation section and regulatory text of this rule. NMFS has determined that these mitigation measures are adequate means of effecting the least practicable adverse impacts on marine mammal species or stocks and their habitat.

Comment 42: The Animal Legal Defense Fund *et al.* recommended avoidance and reduction in the use of timer delays in favor of explosives with positive controls.

Response: There are no time-delay devices proposed for use in the NWTT Study Area. Please see Chapter 2 of the NWTT FEIS/OEIS for a detailed description of the action.

Comment 43: The Animal Legal Defense Fund *et al.* recommended application of ship-speed restriction (*e.g.,* of 10 knots) for support vessels and/or other vessels while transiting high-value habitat for baleen whales and endangered species, or other areas of biological significance, and/or shipping lanes.

Response: The Navy typically chooses to run vessels at slower speeds for efficiency to conserve fuel when possible, which may include speeds less than 5 knots or completely stopped for launching small boats, certain tactical maneuvers, target launch, or retrievals of unmanned underwater vehicles, etc. However, some operational requirements mean that Navy vessels must exceed 10 knots due to unique training, testing, or safety requirements for a given event. Further, imposing an artificial speed restriction only on Navy vessels, which represent an extremely small percentage of ship traffic, particularly in areas of high commercial traffic where no other limits exist, could create safety or navigation concerns where Navy vessels are not traveling at speeds consistent with surrounding traffic.

As discussed earlier in this rule in the Mitigation section, the Navy is clarifying its existing speed protocol: While in transit, Navy vessels shall be alert at all times, use extreme caution, and proceed at a ''safe speed'' so that the vessel can take proper and effective action to avoid a collision with any sighted object or disturbance, including any marine mammal or sea turtle and can be stopped within a distance appropriate to the prevailing circumstances and conditions. Other mitigation measures will be implemented to avoid vessel strikes, such as maneuvering to keep at least 500 yards from whales observed in a vessel's path, and not approaching whales head-on, provided it is safe to do so. The Navy will also be required to report any vessel strike.

Navy ship speed has not been implicated in impacts to marine mammals in the NWTT Study Area. As discussed in the Take Request section and elsewhere in this rule, there has never been a recorded vessel strike of marine mammals during any training or testing activities in the Study Area. There has been only one whale strike in the Pacific Northwest by the Navy since such records have been kept (June 1994–present). In August 2012, a San Diego homeported DDG (destroyer) at-sea about 35 nm west of Coos Bay, Oregon struck a whale (believed to be a minke) while transiting to San Diego from Seattle. A detailed analysis of strike data is contained in Section 6.7 (Estimated Take of Large Whales by Navy Vessel Strike) of the LOA application. The Navy's proposed actions would not result in any appreciable changes in locations or frequency of vessel activity, and there have been no recorded whale strikes during any training and testing activities in the Study Area. The manner in which the Navy has trained would remain consistent with the range of variability observed over the last decade so the Navy does not anticipate vessel strikes would occur within the Study Area during training events.

Navy vessel transit potentially occurring within biologically important areas in the NWTT Study Area is discussed in the *Consideration of Time/Area Limitations* section of this rule. In general, there is a very small likelihood of Navy vessel movement in the gray whale feeding area mapped along the northern coast of Washington as ships transit to the offshore training and testing areas. Where there is overlap between vessel movement and gray whale feeding areas in the Study Area (Northern Puget Sound), the potential for Navy vessels to interact with feeding gray whales within this area is low, especially given the proportion of Navy vessels and the short time period (March–May) that whales will be present. Navy vessel traffic is extremely minimal in comparison to commercial ship traffic within the Northern Washington humpback whale feeding area, and there is an extremely low likelihood of any Navy vessel movements occurring within the two southern humpback whale feeding areas.

Comment 44: The Animal Legal Defense Fund *et al.* recommended application of mitigation prescribed by state regulators, by the courts, by other navies or research centers, or by the U.S. Navy in the past or in other contexts.

Response: NMFS and the Navy worked together on developing a comprehensive suite of mitigation measures to reduce the impacts from Navy training and testing activities on marine mammal species or stocks and their habitat. During the process of developing mitigation measures, NMFS and the Navy considered all potentially applicable mitigation measures. Evaluation of past and present Navy mitigation measures, alternative mitigation measures, and mitigation measures of foreign navies is discussed Chapter 5 of the NWTT FEIS/OEIS. As discussed in the Mitigation section, NMFS has determined that the mitigation measures required by this rule are adequate means of effecting the least practicable adverse impacts on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, while also considering personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Comment 45: The Animal Legal Defense Fund *et al.* recommended avoidance of fish spawning grounds and of important habitat for fish species potentially vulnerable to significant behavioral change, such as wide-scale displacement within the water column or changes in breeding behavior.

Response: NMFS considered impacts to prey species as a component of marine mammal habitat. Please see the ''Marine Mammal Habitat'' section of the proposed rule, which included an extensive discussion of the potential impact of the Navy's activities on fish. In summary, long-term consequences to fish populations are not expected. Impacts to fish spawning grounds and habitat use are also considered under the Magnuson-Stevens Fishery Conservation and Management Act (MSFCMA) as it relates to Essential Fish Habitat (EFH). The effect of the Navy's activities on threatened and endangered fish was also addressed in NMFS' Biological Opinion, which concluded that the Navy's activities would not reasonably be expected to reduce appreciably the likelihood of the survival and recovery of any listed fish species.

Section 5.3.4.1.11 of the NWTT FEIS/OEIS (Avoiding Marine Species

Habitats) discusses habitat avoidance. Section 3.9 of the NWTT FEIS/OEIS (Fish) provides the effects determinations on fish. As noted in Chapter 3.9 of the NWTT FEIS/OEIS, the current science regarding behavioral impacts to fish from sonar is that the potential for effects within the near field (within few tens of meters of the source), intermediate, or far distances is low (Popper *et al.,* 2014). For explosives, the potential for behavioral effects is high within a few tens of meters from the source, moderate to high within intermediate distances (100s of meters from the source), and low within the far field (thousands of meters from the source) (Popper *et al.,* 2014). Therefore, the type of wide-scale displacement being described by the commenter is unlikely to occur based on the current state of the science.

Comment 46: The Animal Legal Defense Fund *et al.* recommended evaluating before each multi-unit exercise whether reductions in sonar use are possible, given the readiness status of the units involved.

Response: There are no MTEs in the NWTT Study Area. The Navy uses active sonar at the lowest practicable source level consistent with mission requirements. See Section 5.3.4.1.3 of the NWTT FEIS/OEIS (Reducing Sonar Source Levels and Total Number of Hours) for more information.

Comment 47: The Animal Legal Defense Fund *et al.* recommended dedicated research and development of technology to reduce impacts of active acoustic sources on marine mammals.

Response: The Navy has provided a significant amount of funding for marine mammal research. For example, from 2004 to 2012, the Navy provided over $230 million for marine species research and currently sponsors 70 percent of all U.S. research concerning the effects of human-generated sound on marine mammals and 50 percent of such research conducted worldwide. The Navy's research and development efforts have significantly improved our understanding of the effects of Navy-generated sound in the marine environment. These studies have supported the modification of acoustic criteria to more accurately assess behavioral impacts to beaked whales and the thresholds for auditory injury for all species, and the adjustment of mitigation zones to better avoid injury. In addition, Navy scientists work cooperatively with other government researchers and scientists, universities, industry, and non-governmental conservation organizations in collecting, evaluating, and modeling information on marine resources. Navy scientists work cooperatively with other government researchers and scientists, universities, industry, and nongovernmental conservation organizations in collecting, evaluating, and modeling information on marine resources. Further, the adaptive management process required by this rule regularly considers and evaluates the development and use of new science and technologies for Navy applications. For additional information on the Navy's marine mammal monitoring efforts, see *http://www.navymarine speciesmonitoring.us/*. For the Navy's Living Marine Resources Applied Research Program see *http://www.lmr.navy.mil.* For the Office of Naval Research's Marine Mammals and Biology Basic Research Program see *http://www.onr.navy.mil/Science-Technology/Departments/Code-32/All-Programs/Atmosphere-Research-322/Marine-Mammals-Biology.aspx.*

Comment 48: The Animal Legal Defense Fund *et al.* recommended establishment of a plan and a timetable for maximizing synthetic training in order to reduce the use of active sonar training.

Response: Section 5.3.4.1.2 of the NWTT FEIS/OEIS (Replacing Training and Testing with Simulated Activities) discusses simulated activities. As described in the NWTT FEIS/OEIS, the Navy currently uses computer simulation for training and testing whenever possible. Computer simulation can provide familiarity and complement live training and testing; however, it cannot provide the fidelity and level of training necessary to prepare naval forces for deployment. The Navy is required to provide a ready and capable force. In doing so, the Navy must operationally test major platforms, systems, and components of these platforms and systems in realistic combat conditions before full-scale production can occur. Substituting simulation for live training and testing fails to meet the Navy's statutory requirement to properly prepare forces for national defense.

Comment 49: The Animal Legal Defense Fund *et al.* recommended prescription of specific mitigation requirements for individual classes (or sub-classes) of testing and training activities, in order to maximize mitigation given varying sets of operational needs.

Response: The Navy and NMFS have already developed mitigation requirements by activity type to reduce potential impacts from the proposed training and testing activities while not causing an unacceptable impact on readiness. Chapter 5 of the NWTT FEIS/OEIS and the Mitigation section of this final rule discuss these mitigation measures.

Comment 50: The Animal Legal Defense Fund *et al.* recommended timely, regular reporting to NOAA, state coastal management authorities, and the public to describe and verify use of mitigation measures during testing and training activities.

Response: NMFS has long required the Navy to submit timely, regular reports regarding the use of mitigation measures during training and testing activities. Section 3.4.4.1 of the NWTT FEIS/OEIS (Summary of Monitoring and Observations During Navy Activities) provides the results from regular reporting that has occurred since 2006. These reports are publically available at the Navy Web site *(http://www.navy marinespeciesmonitoring.us/*) and from the NMFS Office of Protected Resources Web site (*www.nmfs.noaa.gov/pr/permits/incidental/military.htm*). Navy reporting requirements, including exercise and monitoring reporting, are described in the Monitoring and Reporting section of this final rule and in Section 5.5 of the NWTT FEIS/OEIS (Monitoring and Reporting).

Comment 51: The Animal Legal Defense Fund *et al.* recommended that the Navy agree to additional clean-up and retrieval of discarded debris and expended materials associated with its proposed activities.

Response: The Navy conducted a full analysis of the potential impacts of military expended materials on marine mammals and will implement several mitigation measures to help avoid or reduce those impacts. This analysis is contained throughout Chapter 3 (Affected Environment and Environmental Consequences) of the NWTT FEIS/OEIS. The Navy determined that military expended materials related to training exercises under a worst-case scenario will have no more than a negligible impact on the available soft bottom habitat annually within any of the range complexes. The Navy has standard operating procedures in place to reduce the amount of military expended materials to the maximum extent practical, including recovering targets and associated parachutes.

Comment 52: Some commenters suggested that NMFS did not propose any additional mitigation measures beyond what the Navy included in their LOA application.

Response: NMFS worked closely with the Navy to develop mitigation measures for the Navy's training and testing activities in the NWTT Study Area. The measures that the Navy

proposed reflect years of experience and consideration of extensive monitoring results. NMFS and the Navy considered mitigation additional measures, both before and after the public comment period. A description of some of the additional measures that were considered, and how they were analyzed in the context of the ''least practicable adverse impact on the species and/or stock'' finding, is included in this document as well as the Navy's NWTT FEIS/OEIS. As described, NMFS has determined that the Navy's proposed mitigation measures (especially when the adaptive management component is taken into consideration (see previous Adaptive Management discussion)), along with the additional requirements detailed in the Mitigation section, are adequate means of effecting the least practicable adverse impacts on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, while also considering personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Effects Analysis/Takes

Comment 53: The Commission recommended that NMFS require the Navy to request the total numbers of model-estimated Level A harassment (PTS and slight lung and gastrointestinal tract injuries) and mortality takes rather than reducing the estimated numbers of Level A harassment and mortality takes based on the Navy's proposed post-model analysis and base the negligible impact determination analyses on those adjusted takes. Other commenters, including Animal Legal Defense Fund *et al.,* were also critical of the Navy's post-model analysis, claiming that post-model adjustments in takes resulted in underrepresented total takes. Animal Legal Defense Fund *et al.* and other commenters requested further explanation of, or more information on, the post-model reduction process. Both the Commission and the Animal Legal Defense Fund *et al.* expressed concern with observer effectiveness in the Navy's development of mitigation effectiveness scores or g(0) values.

Response: See Section 3.4.3.1.15 (Marine Mammal Avoidance of Sound Exposures) of the NWTT FEIS/OEIS for the discussion of the science regarding the avoidance of sound sources by marine mammals. In addition, the Post-Model Quantitative Analysis of Animal Avoidance Behavior and Mitigation Effectiveness for Northwest Training and Testing Technical Report, available at *http://www.nwtteis.com,* provides additional details regarding how the avoidance and mitigation factors were used and provides scientific support from peer-reviewed research. A comprehensive discussion of the Navy's quantitative analysis of acoustic impacts, including the post-model analysis to account for mitigation and avoidance, is also presented in Chapter 6 of the LOA application, which is available on NMFS' Web site at *http://www.nmfs.noaa.gov/pr/permits/incidental/military.htm.*

NMFS believes that the post-modeling analysis is an effective method for quantifying the implementation of mitigation measures to reduce impacts on marine mammals and the science regarding the avoidance of sound sources by marine mammals which cannot be captured within the modeling process itself, and that the resulting exposure estimates are, nevertheless, a conservative estimate of impacts on marine mammals from the Navy's proposed activities. As explained in the above-referenced documents, as part of the post-modeling analysis the Navy reduced some predicted Level A (PTS) exposures based on the potential for marine mammals to be detected and mitigation implemented, and the potential for marine mammals to avoid a sound source. Given this potential, not taking into account some possible reduction in Level A exposures would result in a less realistic, overestimation of possible Level A takes, as if there were no mitigation measures implemented. For example, with respect to mitigation effectiveness, the period of time between clearing the impact area of any non-participants or marine mammals and weapons release is on the order of minutes, making it highly unlikely that a marine mammal would enter the mitigation zone. Information provided in Section 3.4.3.1.16 (Implementing Mitigation to Reduce Sound Exposures) of the NWTT FEIS/OEIS indicates how much of a reduction each factor represents for specific activities. As explained in the documents referenced above, the adjustments move a percentage of the model predicted Level A (PTS) effects at close range to more likely behavioral effects (Level B harassment) and do not conclude that all modeled mortalities or non-PTS injuries will be avoided. This process represents peer-reviewed and accepted scientific process.

The assignment of mitigation effectiveness scores and the appropriateness of consideration of sightability using detection probability, g(0), when assessing the mitigation in the quantitative analysis of acoustic impacts is discussed in the NWTT FEIS/OEIS (Section 3.4.3.1.16, Implementing Mitigation to Reduce Sound Exposures). Additionally, the activity category, mitigation zone size, and number of Lookouts are provided in the proposed rule (80 FR 31738, June 3, 2015, pages 31772–31773) and NWTT FEIS/OEIS (Section 5, Tables 5.3–2 and 5.4–1). In addition to the information already contained within the NWTT FEIS/OEIS, the Post-Model Quantitative Analysis of Animal Avoidance Behavior and Mitigation Effectiveness for the Northwest Training and Testing Technical Report (*http://www.nwtteis.com*) and Chapter 6 of the Navy's LOA application describe the process for the post-modeling analysis in further detail. There is also information on visual detection leading to the implementation of mitigation in the annual exercise reports provided to NMFS and briefed annually to NMFS and the Commission. These annual exercise reports have been made available and can be found at *http://www.navymarinespeciesmonitoring.us/* in addition to *http://www.nmfs.noaa/pr/permits/incidental.*

The Navy is in the process of assessing Lookout effectiveness at detecting marine mammals during Navy exercises. Lookouts will not always be effective at avoiding impacts on all species. However, Lookouts are expected to increase the overall likelihood that certain marine mammal species and some sea turtles will be detected at the surface of the water, when compared to the likelihood that these same species would be detected if Lookouts are not used. The continued use of Lookouts contributes to helping reduce potential impacts on these species from training and testing activities. Results from the Lookout effectiveness study will be reviewed and any recommendations for improving Lookout effectiveness will be considered at that time. In summary, NMFS and the Navy believe that consideration of marine mammal sightability and activity-specific mitigation effectiveness is appropriate in the Navy's quantitative analysis in order to provide decision makers a reasonable assessment of potential impacts from the Navy's proposed activities.

Comment 54: The Commission recommended that NMFS require the Navy to round its takes based on model-estimated takes to the nearest whole number or zero in all of its take tables.

Response: The exposure numbers presented in the NWTT FEIS/OEIS Criteria and Thresholds Technical

Report are raw model outputs that have not been adjusted by post-processing to account for likely marine mammal behavior or the effect from implementation of mitigation measures. All fractional post-processed exposures for a species across all events within each category subtotal (Training, Testing, Impulse, and Non-Impulse) are summed to provide an annual total predicted number of effects. The final exposure numbers presented in the LOA application and the NWTT FEIS/OEIS incorporate post-processed exposures numbers that have been rounded down to the nearest integer so that subtotals correctly sum to total annual effects rather than exceed the already conservative total exposure numbers.

Comment 55: Some commenters recommended that NMFS fully examine the impacts from sonar, underwater detonations, and other stressors on all organisms (*e.g.,* salmonids and other fish) living within the Study Area.

Response: NMFS considered impacts to marine mammal prey species as a component of their habitat. The effects of the Navy's activities on threatened and endangered fish was also addressed in NMFS' Biological Opinion, which concluded that the Navy's activities would not reasonably be expected to reduce appreciably the likelihood of the survival and recovery of any listed fish species. Impacts to fish spawning grounds and habitat are also addressed under the Magnuson-Stevens Fishery Conservation and Management Act (MSFCMA) as it relates to Essential Fish Habitat (EFH). The Navy consulted with NMFS under the MSFCMA.

Comment 56: The Animal Legal Defense Fund *et al.* commented that the Navy and NMFS failed to adequately assess the impacts of stress on marine mammals.

Response: NMFS fully considered in the proposed rule the potential for physiological responses, particularly stress responses, that could potentially result from exposure to MFAS/HFAS or underwater explosive detonations (see *Stress Response* in the Potential Effects section). NMFS' analysis identifies the probability of lethal responses, physical trauma, sensory impairment (permanent and temporary threshold shifts and acoustic masking), physiological responses (including stress responses), behavioral disturbance (that rises to the level of harassment), and social responses (effects to social relationships) that would be classified as a take and whether such take would have a negligible impact on such species or stocks. This analysis is included in the Analysis and Negligible Impact Determination in this final rule, and results of the analysis of physiological stress responses are summarized below. The Navy's analysis also considered secondary and indirect impacts, including impacts from stress (see the NWTT FEIS/OEIS Section 3.4 (Marine Mammals)). See for example, Section 3.4.3.1.5 (Physiological Stress), Section 3.4.3.1.9 (Long-Term Consequences to the Individual and the Population), and Section 3.4.3.7 (Impacts from Secondary Stressors). For a discussion of biotoxins, see Section 3.4.2.4 (General Threats).

The studies referenced by the commenters of North Atlantic right whales (*e.g.,* Rolland *et al.,* 2012) impacted by chronic noise were cited and considered in the Navy's and NMFS' analysis, as well as similar studies such as Hatch *et al.* (2012) and Parks *et al.* (2007) (see Section 3.4.3.1, Acoustic Stressors in the NWTT FEIS/OEIS; see Potential Effects of Specified Activities on Marine Mammals in the proposed rule). Similar findings for blue whales from the Pacific (Melcon *et al.,* 2012) were also considered for mysticetes, as well as similar findings for other marine mammals groups with regard to potential chronic stressors. Note, however, that these studies (and similar studies from the Pacific Northwest such as Williams *et al.* (2013)) involve chronic noise resulting from the pervasive presence of commercial vessels. The Navy activities in the NWTT Study Area involving active sonar or underwater detonations are infrequent, short-term, and generally unit level. Unit level events occur over a small spatial scale (one to a few 10s of square miles) and with few participants (usually one or two). Single-unit unit level training would typically involve a few hours of sonar use, with a typical nominal ping of every 50 seconds (duty cycle). Even though an animal's exposure to active sonar may be more than one time, the intermittent nature of the sonar signal, its low duty cycle, and the fact that both the vessel and animal are moving provide a very small chance that exposure to active sonar for individual animals and stocks would be repeated over extended periods of time. Since the impact from noise exposure and the Navy's training and testing events in general should be transitory given the movement of the participants, any stress responses should be short in duration and have less than biologically significant consequences. Consequently, NMFS has determined that the Navy's activities in the NWTT Study Area do not create conditions of chronic, continuous underwater noise and are unlikely to lead to habitat abandonment or long-term hormonal or physiological stress responses in marine mammals.

Comment 57: The Animal Legal Defense Fund *et al.* commented that the Navy would release a host of toxic chemicals, hazardous materials and waste into the marine environment that could pose a threat to marine mammals over the life of the range. They also commented that the Navy plans to abandon cables, wires, and other items that could entangle marine wildlife, including parachutes. The Sun'aq Tribe of Kodiak also commented that the analysis of these materials in the NWTT DEIS/OEIS was inadequate.

Response: The Navy is not proposing to release toxic chemicals, hazardous material, or waste into the marine environment. The NWTT FEIS/OEIS analysis concluded that material expended during training and testing would not result in water or sediment toxicity, and that no adverse effects on marine organisms would be expected.

In the course of training and testing activities, military expended material is released into the marine environment as detailed in the NWTT FEIS/OEIS Chapter 3.1 (Sediments and Water Quality). The NWTT FEIS/OEIS presents a thorough description and analysis in Section 3.1.3 (Environmental Consequences) of amounts and types of specific training materials as well as chemical composition and breakdown processes of expended materials. The analysis concludes that chemical, physical, or biological changes to sediment or water quality, while measurable, are below applicable standards, regulations, and guidelines, and would be within existing conditions or designated uses. Neither state nor federal standards or guidelines would be violated. Further, as discussed in Section 3.4 of the NWTT FEIS/OEIS, military expended materials are not expected to result in mortality, Level A, or Level B harassment of marine mammals. This conclusion is supported by studies referenced in the NWTT FEIS/OEIS that have investigated the fate of the constituents of military expended materials; see for example the discussion presented in Section 3.4.3.7 (Explosion By-Products and Unexploded Ordnance) and citations to Rosen and Lotufo (2010) and University of Hawaii at Manoa (2010).

In addition, Section 3.1 of the NWTT FEIS/OEIS analyzed the impact from explosives, explosive byproducts, and metals using the best available science. The analysis concluded that the impact of explosives, explosion byproducts, and metals on sediment and water quality would be both short- and long-term, and localized. As above, chemical,

physical, or biological changes in sediment or water quality would be measurable, but below applicable standards and guidelines, and would be below or within existing conditions or designated uses. Further, as discussed in Section 3.4 of the NWTT FEIS/OEIS, secondary stressors are not expected to result in mortality, Level A, or Level B harassment of marine mammals.

Finally, the NWTT FEIS/OEIS analyzed other potential stressors, such as entanglement in cables, wires, and parachutes, in Section 3.4.3.5 (Entanglement Stressors). As discussed in that section, the chance that an individual animal would encounter expended cables or wires is likely low, and it is unlikely that an animal would get entangled even if it encountered a wire. For example, the majority of the ''parachutes'' expended are 18-inch (in.) diameter cruciform (''X'' shaped) decelerators attached with short lines to the top of sonobuoys. These are designed to sink and, given their small size, are very unlikely entanglement hazards for most marine mammals.

Comment 58: The Animal Legal Defense Fund *et al.* commented that the Navy does not adequately analyze the potential for and impact of oil spills (the Commenters make reference to the Exxon Valdez and Cosco Busan oil spill incidents).

Response: The analysis presented in the NWTT FEIS/OEIS is limited to the activities and reasonable outcomes of such activities. As accidents involving large oil spills from commercial oil tankers are not reasonably foreseeable outcomes of proposed Navy training or testing, this scenario is not addressed or analyzed. It is noteworthy that the two examples provided by the comment did not occur in the NWTT Action Area, and neither had any connection to Navy training or testing, nor does the commenter offer any example of large oil spills related to Navy training or testing activities. The Exxon Valdez spilled occurred in Alaska as a result of improper ship manning and handling, and the Cosco Busan incident that occurred in San Francisco resulted from an impaired pilot. Neither incident is connected to Navy training and testing.

Comment 59: The Animal Legal Defense Fund *et al.* commented that the Navy's analysis cannot be limited only to direct effects, *i.e.,* effects that occur at the same time and place as the training exercises that would be authorized, but must also take into account the activity's indirect effects. The commenters assert that this requirement is critical given the potential for sonar exercises to cause significant long-term impacts not clearly observable in the short term.

Response: NMFS and the Navy analyzed both direct and indirect effects from Navy training and testing activities. A discussion of potential indirect effects may be found in the proposed rule (see Potential Effects of Specified Activities on Marine Mammals) and this rule (see Analysis and Negligible Impact Determination). As depicted in the NWTT FEIS/OEIS Figure G–1 in Appendix G (Biological Resource Methods), the Navy's analysis also considers all potential impacts resulting from exposure to acoustic sources, including indirect effects. In Figure G–1, the effects are shown in terms of physiological responses, behavioral responses, potential costs to the animal, recovery, and long-term consequences.

With respect to long-term impacts, see the discussion in Section 3.4.3.1.9 of the NWTT FEIS/OEIS (Long-Term Consequences to the Individual and the Population) and the *Long-Term Consequences* section of this rule. Also see Section 3.4.4.1 (Summary of Monitoring and Observations During Navy Activities) of the NWTT FEIS/OEIS presenting the evidence collected from the intensive monitoring of Navy training and testing at range complexes nationwide since 2006 which provides support for the conclusions that it is unlikely there would be any population level or long-term consequences resulting from the proposed training and testing activities and implementation of this final rule. The scientific authorities presented in the comment (the National Research Council) are discussed in the NWTT FEIS/OEIS, and do not support the contention that there is a link between the use of sonar and any population-level effects. For example, the number of blue whales has been increasing at 3% annual rate in the Southern California waters where the most frequent and intensive sonar use occurs in the Pacific (Calambokidis *et al.,* 2009a). For further examples see our Response to Comment 61.

Comment 60: The Animal Legal Defense Fund *et al.* commented that NMFS failed to adequately assess the cumulative impacts of the Navy's activities in its negligible impact determination. More specifically, see the commenters' four comments in Comments 61 to 64 below.

Response: Section 101(a)(5)(A) of the MMPA requires NMFS to make a determination that the take incidental to a specified activity will have a negligible impact on the affected species or stocks of marine mammals, and will not result in an unmitigable adverse impact on the availability of marine mammals for taking for subsistence uses. Neither the MMPA nor NMFS' implementing regulations specify how to consider other activities and their impacts on the same populations. However, consistent with the preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into the negligible impact analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the density/distribution and status of the species, population size and growth rate, and ambient noise).

As discussed in the Analysis and Negligible Impact determination section of this final rule, Chapter 4 of the NWTT FEIS/OEIS contains a comprehensive assessment of potential cumulative impacts, including analyzing the potential for cumulatively significant impacts to the marine environment and marine mammals. The Navy used the best available science and a comprehensive review of past, present, and reasonably foreseeable actions to develop a robust cumulative impacts analysis. The cumulative impacts analysis focused on impacts that are ''truly meaningful.'' This was accomplished by reviewing the direct and indirect impacts that have the potential to occur on each resource under each of the alternatives. Key factors considered were the current status and sensitivity of the resource and the intensity, duration, and spatial extent of the impacts of each potential stressor. In general, long-term rather than short-term impacts and widespread rather than localized impacts were considered more likely to contribute to cumulative impacts. Those impacts to a resource that were considered to be negligible were not considered further in the analysis. As required under NEPA, the level and scope of the analysis are commensurate with the potential impacts of the action as reflected in the resource-specific discussions in Chapter 3 of the NWTT FEIS/OEIS (Affected Environment and Environmental Consequences). The NWTT FEIS/OEIS considered its activities alongside those of other activities in the region whose impacts are truly meaningful to the analysis.

In addition, NMFS' Biological Opinion concludes that NMFS' proposed rulemaking and LOAs and any take associated with activities authorized by the rulemaking and LOAs are not likely to jeopardize the continued existence of threatened or endangered species (or species proposed for listing) in the action area during any

single year or as a result of the cumulative impacts of a 5-year authorization. The Biological Opinion includes an explanation of how the results of NMFS' baseline and effects analyses in Biological Opinions relate to those contained in the cumulative impact section of the NWTT FEIS/OEIS.

Comment 61: The Animal Legal Defense Fund *et al.* assert that there is a lack of any population analysis or quantitative assessment of long-term effects in the proposed rule. Several other commenters also suggested that NMFS and the Navy underestimate the effects of the Navy's activities and fail to consider longer term effects or conduct a population-level analysis.

Response: NMFS disagrees that impacts to marine mammals from the Navy's training and testing activities are underestimated. The Navy's model uses the best available science to analyze impacts and often overestimates the potential effects of their activities by considering the worst case scenario (*e.g.,* modeling for the loudest sound source within a source bin). Further, NMFS and the Navy fully considered potential long-term and population-level effects. Analysis of these effects is presented in the NWTT FEIS/OEIS in Section 3.4.3.1.9 (Long-Term Consequences to the Individual and the Population) and in the Analysis and Negligible Impact Determination in this final rule (*see Long-Term Consequences* and *Final Determination* sections). NMFS' assessment is that the Navy training and testing activities involving active sonar or underwater detonations are infrequent, short-term, and generally unit level. Unit level events occur over a small spatial scale (one to a few 10s of square miles) and with few participants (usually one or two). Consequently, the Navy's activities do not create conditions of chronic, continuous underwater noise and are unlikely to lead to habitat abandonment or long-term hormonal or physiological stress responses in marine mammals. Based on the findings from surveys in Puget Sound and research efforts and monitoring before, during, and after training and testing events across the Navy since 2006, NMFS' assessment is that it is unlikely there would be impacts to populations of marine mammals having any long-term consequences as a result of the proposed continuation of training and testing in the ocean areas historically used by the Navy, including the Study Area. NMFS concludes that exposures to marine mammal species and stocks due to NWTT activities would result in primarily short-term (temporary and short in duration) and relatively infrequent effects to most individuals exposed, and not of the type or severity that would be expected to be additive for the portion of the stocks and species likely to be exposed.

Additionally, NMFS notes that, even in areas where the Navy uses sonar frequently, such as instrumented ranges, marine mammal populations are present, not diminishing, and in some cases, thriving. NMFS and the Navy relied on actual trends in marine mammal populations and the best available science regarding marine mammals, including behavioral response studies and the satellite tracking of tagged marine mammals in areas of higher sonar use.

NMFS has reporting and monitoring data from the Navy on training and testing events occurring around the U.S. since 2006. For example, results from 2 years (2009–2010) of intensive monitoring by independent scientists and Navy observers in Southern California Range Complex and Hawaii Range Complex recorded an estimated 161,894 marine mammals with no evidence of distress or unusual behavior observed during Navy activities. Additional information and data summarized in the NWTT FEIS/OEIS Section 3.4.4.1 (Summary of Monitoring and Observations During Navy Activities) provide support for the conclusions that it is unlikely there would be any population level or long-term consequences resulting from implementation of final rule.

Comment 62: The Animal Legal Defense Fund *et al.* commented that NMFS does not consider the potential for acute synergistic effects from multiple Navy activities taking place at one time, or from Navy activities in combination with other actions. As an example, the Commenters state that NMFS does not consider the greater susceptibility to vessel strike of animals that have been temporarily harassed or disoriented. The commenters cite a Nowacek *et al.* (2004) study in which exposure to a mid-frequency sound source provoked interruption of foraging dives and the surfacing of five North Atlantic right whales and presumably increased risk of vessel strike.

Response: The Navy's and NMFS' analysis and acoustic impact modeling does consider and quantify the potential for additive effects from multiple activities involving acoustic stressors. Unlike the method used previously that modeled acoustic sources individually, the Navy's acoustic effects model (NAEMO) has the capability to run all sound sources within a scenario simultaneously, which accounts for accumulative sound and provides a more realistic depiction of the potential effects of an activity (See Section 3.4.3.1.14.3 (Navy Acoustic Effects Model) of the NWTT FEIS/OEIS).

In addition, there is no scientific basis for the suggestion that animals taken by harassment would have ''greater susceptibility to vessel strike.'' NMFS considered Nowacek *et al.* (2004), cited by the commenters, which is discussed in the NWTT FEIS/OEIS (Section 3.4.3.1.6.2, Behavioral Reactions to Sonar and Other Active Acoustic Sources). Unlike Navy sonar, the sound source used in the Nowacek *et al.* (2004) study was intended to be an alarm signal that lasted several minutes in duration, and was purposely designed to elicit a reaction from the animals as a prospective means to protect them from ship strikes. In contrast, Navy sonar is used intermittently for short durations, and is not aimed at or designed to be an alarm signal for low frequency mysticetes. In addition, the experimental sound source used in the Nowacek study had an extremely different frequency, duration, and temporal pattern of signal presentation from anything used by or proposed for use by the Navy. Of note, and in contrast to the comment's assertion, an equally plausible interpretation of the study is that an active mid-frequency sound source could potentially alert marine mammals to the presence of a Navy vessel and therefore reduce the potential for ship strikes.

Regarding ship strike generally, see the Response to Comment 20.

Comment 63: The Animal Legal Defense Fund *et al.* commented that proposed rule makes no attempt to analyze the cumulative and synergistic effects of the Navy's proposed activities or for the Navy's activities combined with other activities affecting the same marine mammal species and populations, and NMFS makes no attempt to incorporate the effects of reasonably foreseeable activities impacting the same species and populations into its impact analysis.

Response: As described in the Response to Comment 62, the Navy's acoustic impact modeling does consider and quantify the potential for additive effects from multiple activities involving acoustic stressors by modeling all sound sources within a scenario simultaneously, which accounts for accumulative sound and provides a more realistic depiction of the potential effects of an activity. Further, as explained throughout this rule, NMFS' assessment is that the cumulative impacts of active sonar would be extremely small because the exercises would occur for relatively short periods

of time; the sources of active sonar would most often not be stationary; and the effects of any LF/MFAS/HFAS exposure would stop when transmissions stop. Additionally, the vast majority of impacts expected from sonar exposure and underwater detonations are behavioral in nature, temporary and comparatively short in duration, relatively infrequent, and not of the type or severity that would be expected to be additive for the portion of the stocks and species likely to be exposed. NMFS' final rule is specifically designed to reduce the effects of the Navy's activity on marine mammal species and stocks to the least practicable impact, through the inclusion of appropriate mitigation and monitoring measures, and the issuance of an Authorization with those conditions does not result in significant cumulative impacts when considered with all other past, present, and reasonably foreseeable projects.

Chapter 4 of the NWTT FEIS/OEIS contains a comprehensive assessment of potential cumulative impacts, including analyzing the potential for cumulatively significant impacts to the marine environment and marine mammals. Specifically, the Navy concluded, and NMFS concurs, that their proposed action is likely to result in generally no more than temporary changes to the noise environment and sediment and water quality. Therefore, there is limited potential for those effects to interact cumulatively with the effects of other past, present, and reasonably foreseeable projects. Implementation of the proposed action, in conjunction with other past, present, and reasonably foreseeable future actions, would not be expected to result in significant cumulative impacts to the environment. As such, the proposed action will not result in cumulative adverse effects that could have a substantial effect on species and populations in the action area.

In addition, we note that the Navy has been training in the same relative area for decades using substantially similar training and testing systems for decades, and coupled with the multitude of other activities taking place in the area, there is no evidence of long term consequences to marine mammal populations or stocks.

Comment 64: The Animal Legal Defense Fund *et al.* commented that NMFS must account for the additive impact of its activities in light of changing ocean conditions.

Response: NMFS and the Navy have considered changing ocean conditions. As discussed in the NWT FEIS/OEIS (Section 3.4, Marine Mammals), NMFS and the Navy are aware that marine mammals will shift their habitat based on changing ocean conditions. Please see specifically Section 3.4.2.5 (Marine Mammal Density Estimates) of the NWTT FEIS/OEIS discussing the integration of habitat modeling into the analysis; also see the Navy's Pacific Marine Species Density Database Technical Report. The predictive habitat models reflect the interannual variability and associated redistribution of marine mammals as a result of changing environmental conditions during the survey years used to develop the models. The analysis presented in the Navy Marine Species Density Database includes density data for periods of warmer water and potentially shifting ranges of marine mammals as a result of those conditions.

While climate change may result in changes in the distribution of marine mammals, it is currently not possible to predict how or under what conditions such changes might occur without engaging in unsupported conjecture. Therefore, it is not possible to reasonably determine what hypothetical future marine mammal distributions may look like as a result of climate change or otherwise factor such changes into an analysis of resulting potential effects and impacts from Navy activities.

Comment 65: The Animal Legal Defense Fund *et al.,* and other commenters, commented that NMFS failed to properly analyze the potential for serious injury and mortality, particularly with regard to sonar-related injury and mortality (*i.e.,* strandings) during the Navy's use of mid-frequency active sources and other sources. The commenters cited several stranding events (*e.g.,* Bahamas, 2000; Washington State, 2003) that they assert occurred coincident with military mid-frequency sonar use. The Animal Legal Defense Fund *et al.* commented that beaked whales ''seem to be particularly vulnerable to the effects of active sonar'' and that beaked whale mortalities are likely to go undetected.

Response: NMFS uses best available science to analyze the Navy's activities. The Stranding and Mortality section of the proposed rule (80 FR 31738, June 3, 2015; pages 31761–31767) summarized the stranding events referenced in the Animal Legal Defense Fund *et al.'s* comment, including the association between stranding events and exposure to MFAS. Also, see the NWTT FEIS/OEIS Section 3.4.1.8 (Stranding) and the U.S. Department of the Navy (2013c) ''Marine Mammal Strandings Associated with U.S. Navy Sonar Activities'' technical report available at *http://www.nwtteis.com.* The modeling of acoustic effects takes into consideration all applicable environmental factors and all applicable sound sources to predict the likely effects to beaked whales and all other species. Please also see Southall *et al.* (2007), Finneran and Jenkins (2012), and the NWTT FEIS/OEIS Section 3.4.3.1.11 (Frequency Weighting) to understand the implementation of frequency weighting as it applies to the analysis of effects from mid-frequency and high frequency sound sources.

The environmental conditions in the NWTT Study Area and the types of activities proposed in the NWTT FEIS/OEIS have no relationship to those present in the Bahamas incident fourteen years ago in unique and warm tropical waters. The environmental conditions otherwise differentiating the Atlantic tropical Bahamas environment present in 2000 from the Pacific Northwest NWTT Study Area include the unique bathymetry of the Bahamas Providence Channels that are steep sided, narrow, and very deep—ranging from approximately 2,000 to 12,000 in depth. On that day in 2000 in the Bahamas, there was also a 200 meter thick layer of near constant water temperature, calm seas, as well as the presence of beaked whales. The Strait of Juan de Fuca, by comparison, is not steep sided, is relatively shallow (approximately 600 feet depth), is unlikely to ever have a uniformly mixed thermocline, and beaked whales are not known to inhabit its waters. Additionally and also unlike the Bahamas, there will be no Navy training or testing activities involving multiple ships using hull mounted tactical mid-frequency active sonar over an extended period of time in a single area.

With regard to the harbor porpoise strandings in Washington State (2003), NMFS has since determined that these strandings were unrelated to Navy sonar use. There was a lack of evidence of any acoustic trauma among the harbor porpoises, and the identification of probable causes (*e.g.,* entanglement in a fishing net, disease processes) of stranding or death in several animals supports the conclusion that the harbor porpoise strandings were unrelated to the sonar activities by the USS SHOUP. Refer to the discussion in the NWTT FEIS/OEIS Section 3.4.1.8 (Stranding) and the U.S. Department of the Navy (2013c) ''Marine Mammal Strandings Associated with U.S. Navy Sonar Activities'' technical report for a discussion of other previous strandings and note that the other stranding events in this comment did not occur in, and were not associated with, the NWTT Study Area and did not involve any of

the training or testing scenarios proposed for the NWTT Study Area.

Lastly, while not referenced by the commenters and not related to active sonar exposure, NMFS considered an investigation into a long-finned pilot whale mass stranding event at Kyle of Durness, Scotland on July 22, 2011 (Brownlow *et al.,* 2015). The investigation considered unexploded ordnance detonation activities at a Ministry of Defense bombing range, conducted by the Royal Navy prior to and during the strandings, as a plausible contributing factor in the mass stranding event. While Brownlow *et al.* (2015) concluded that the serial detonations of underwater ordnance were an influential factor in the mass stranding event (along with presence of a potentially compromised animal and navigational error in a topographically complex region) they also suggest that mitigation measures—which included observations from a zodiac only and by personnel not experienced in marine mammal observation, among other deficiencies—were likely insufficient to assess if cetaceans were in the vicinity of the detonations. The authors also cite information from the Ministry of Defense indicating ''an extraordinarily high level of activity'' (*i.e.,* frequency and intensity of underwater explosions) on the range in the days leading up to the stranding.

The NWTT FEIS/OEIS provides an analysis of potential impacts occurring in the NWTT Study Area. While most of the world's coastlines lack coverage by a stranding network, the Navy's analysis of impacts has focused on scientific data collected in and around the Navy range complexes, which are the proposed locations for the continuation of historically occurring training and testing activities including the use of sonar. A summary of the compendium of the research in that regard is presented in NWTT FEIS/OEIS in Section 3.4.4.1 (Summary of Monitoring and Observations During Navy Activities). Unlike the rest of the world's oceans, there has not been an absence of observation where the U.S. Navy has been routinely training and testing for years. In particular and as ongoing for approximately the last 8 years, the Navy, NMFS, and an independent group of scientists have been engaged in implementing a comprehensive monitoring program and associated research that includes monitoring before, during, and after Navy activities on U.S. Navy range complexes. In short, the research and monitoring associated with Navy training and testing activities makes the Navy range complexes different than the remainder of the world's oceans.

For beaked whales in particular, not only have there been no mortalities or strandings associated with Navy sonar use during the past approximately 8 years of monitoring, but to the contrary there has been overwhelming evidence from research and monitoring indicating the continued presence or residence of individuals and populations in Navy range complexes and no clear evidence indicating long-term effects from Navy training and testing in those locations. For example, photographic records spanning more than 2 decades demonstrated re-sightings of individual beaked whales (from two species: Cuvier's and Blainville's beaked whales), suggesting long-term site fidelity to the area west of the Island of Hawaii where intensive swept-channel exercises historically occurred (McSweeney *et al.,* 2007). In the most intensively used training and testing ranges in the Pacific, photo identification of animals associated with the SOCAL Range Complex have identified approximately 100 individual Cuvier's beaked whale individuals with 40 percent having been seen in one or more prior years, with re-sightings up to 7 years apart (Falcone and Schorr, 2014). Data from visual surveys documenting the presence of Cuvier's beaked whales for the ocean basin west of San Clemente Island (Falcone *et al.,* 2009; Falcone and Schorr, 2012, 2014; Smultea and Jefferson, 2014) is also consistent with concurrent results from passive acoustic monitoring that estimated regional Cuvier's beaked whale densities were higher than indicated by NMFS's broad scale visual surveys for the United States west coast (Hildebrand and McDonald, 2009). Falcone and Schorr (2012) suggested that these beaked whales may have population sub-units with higher than expected residency to the Navy's instrumented Southern California Anti-Submarine Warfare Range in particular. For over 3 decades, this ocean area west of San Clemente has been the location of the Navy's instrumented training range and is one of the most intensively used training and testing areas in the Pacific, given the proximity to the Naval installations in San Diego. In summary, the best available science indicates the Navy's continued use of Navy range complexes have not precluded beaked whales from also continuing to inhabit areas where sonar use has been occurring, and there is no evidence to suggest that undocumented mortalities are occurring in the NWTT Study Area or on the range complexes where the U.S. Navy routinely conducts training and testing activities.

In the NWTT FEIS/OEIS, the sensitivity of beaked whales is taken into consideration both in the application of Level B harassment thresholds and in how beaked whales are expected to avoid sonar sources at higher levels. No beaked whales were predicted in the acoustic analysis to be exposed to sound levels associated with PTS, other injury, or mortality (note: There is no data from which to develop or set a mortality criterion and there is no evidence that sonar can lead to a direct mortality due to lack of a shock wave). After decades of the Navy conducting similar activities in the NWTT Study Area without incident, NMFS does not expect strandings, injury, or mortality of beaked whales or any other species to occur as a result of training and testing activities. Additionally, through the MMPA rulemaking (which allows for adaptive management), NMFS and the Navy will determine the appropriate way to proceed in the event that a causal relationship were to be found between Navy activities and a future stranding.

Comment 66: The Animal Legal Defense Fund *et al.* commented that NMFS dismisses the leading explanation about the mechanism of sonar-related injuries—that whales suffer from bubble growth in organs that is similar to decompression sickness, or ''the bends'' in human divers—as one of several controversial hypotheses. They cite numerous papers in support of this explanation.

Response: The comment assumes injury from sonar use, and discounts the best available science. The publications cited for this comment are generally old and do not constitute the most recent best available science in this subject area. Please see the Navy's NWTT FEIS/OEIS Section 3.4.3.1.2.1 (Direct Injury) in general and specifically Section 3.4.3.1.2.2 (Nitrogen Decompression) where the latest scientific findings have been presented.

NEPA

Comment 67: The Animal Legal Defense Fund *et al.* commented that NMFS cannot rely on adoption of the Navy's NWTT FEIS/OEIS to fulfill its obligation under NEPA due to the inadequacy of the document. The Sun'aq Tribe of Kodiak commented that NMFS has not independently fulfilled its NEPA obligations. Some of the commenters also submitted or referenced comments on the NWTT DEIS/OEIS that were submitted to the Navy during the public comment period on that document.

Response: NMFS disagrees with the commenters' assertion that the NWTT FEIS/OEIS is inadequate for our adoption and to meet our responsibilities under NEPA for the issuance of regulations and LOAs, or that NMFS has not fulfilled its NEPA obligations. NMFS notes that comments submitted on the NWTT DEIS/OEIS during its public comment period are addressed by the Navy in Appendix I of the NWTT FEIS/OEIS.

NMFS' Office of Protected Resources has thoroughly reviewed the Navy's NWTT FEIS/OEIS and concluded that the impacts evaluated by the Navy are substantially the same as the impacts of NMFS' proposed action to issue regulations (and associated LOAs) governing the take of marine mammals incidental to Navy training and testing activities in the NWTT Study Area from November 2015 through November 2020. In addition, the Office of Protected Resources has evaluated the NWTT FEIS/OEIS and found that it includes all required components for adoption by NOAA including: a discussion of the purpose and need for the action; a listing of the alternatives to the proposed action; a description of the affected environment; a succinct description of the environmental impacts of the proposed action and alternatives, including cumulative impacts; and a listing of agencies and persons consulted, and to whom copies of the FEIS are sent.

Per the cooperating agency commitment, the Navy provided NMFS with early preliminary drafts of the NWTT DEIS/OEIS and the FEIS/OEIS and a designated (and adequate) timeframe within which NMFS could provide comments. The Office of Protected Resources circulated the Navy's preliminary NEPA documents to other interested NOAA line offices and NMFS' regional and science center offices, compiled any comments received, and submitted them to the Navy. Subsequently, the Navy and NMFS participated in comment resolution meetings, in which the Navy addressed NMFS' comments, and in which any outstanding issues were resolved. The Navy has incorporated the majority of NMFS' comments into the FEIS, and adequately addressed those comments that were not incorporated. As a result of this review, the Office of Protected Resources has determined that it is not necessary to prepare a separate Environmental Assessment or EIS to issue regulations or LOAs authorizing the incidental take of marine mammals pursuant to the MMPA, and that adoption of the Navy's NWTT FEIS/OEIS is appropriate. Based on NMFS' review of the FEIS, NMFS has adopted the FEIS under the Council on Environmental Quality's Regulations for Implementing the National Environmental Policy Act (40 CFR 1506.3). Furthermore, in accordance with NEPA, its implementing regulations, and the NOAA's Administrative Order (NAO) 216–6 ''Environmental Review Procedures for Implementing the National Environmental Policy Act,'' we have prepared a Record Decision (ROD) which addresses NMFS' determination to issue regulations and LOAs to the Navy pursuant to section 101(a)(5)(A) of the MMPA, for the taking of marine mammals incidental to the conduct of Navy's training and testing activities.

Comment 68: Several commenters felt that the Navy should wait until after the NEPA process is complete and a Record of Decision (ROD) signed before requesting an incidental take authorization from NMFS.

Response: The Navy prepared the NWTT FEIS/OEIS in accordance with the President's CEQ regulations implementing NEPA (40 CFR parts 1500–1508). NEPA (42 U.S.C. 4321–4347) requires federal agencies to prepare an EIS for a proposed action with the potential to significantly affect the quality of the human environment, disclose significant environmental impacts, inform decision makers and the public of the reasonable alternatives to the proposed action, and consider comments to the EIS. The Navy initiated (*i.e.,* submitted a request for regulations and Letters of Authorization) MMPA consultation with NMFS early on in the NEPA process, so that development of both the FEIS/OEIS, of which NMFS is a cooperating agency because of its expertise and regulatory authority over marine resources, and the rule could occur concurrently. Moreover, because the FEIS/OEIS must also be prepared in accordance with the applicable regulations of the MMPA (and ESA) to evaluate all components of the proposed training and testing activities that have the potential to take marine mammals, the Navy cannot select its preferred alternative, or issue its final decision through the ROD, until all the regulatory requirements of the MMPA have been met and the regulations to take marine mammals incidental to the proposed activities has been issued. Note that NMFS did not issue these regulations until the Navy released the NWTT FEIS/OEIS to the public and allowed the public to comment on the notice of availability (NOA). Further, NMFS fully considered any relevant comments on the NOA prior to the finalization of this rule and the issuance of regulations.

Comment 69: One commenter questioned why the Navy's NWTT DEIS/OEIS would include an assessment of the effects on the human environment.

Response: An EIS is required when there is the potential for a proposed action to have a significant impact on the human environment (40 CFR 1508.18). NEPA requires that the human environment shall be interpreted comprehensively to include the natural and physical environment and the relationship of people with that environment (40 CFR 1508.14). When an EIS is prepared and economic or social and natural or physical environmental effects are interrelated, then the environmental impact statement will discuss all of these effects on the human environment.

General Opposition

Comment 70: The vast majority of comments received by NMFS were from commenters expressing general opposition to Navy training and testing activities and NMFS' issuance of an MMPA authorization. Many commenters claimed that the Navy's activities would result in the ''killing of marine mammals'' or the ''deaths of thousands of marine mammals'' during NWTT training and testing activities using sonar.

Response: NMFS appreciates the commenters' concern for the marine environment. However, the commenters' assertion that the Navy's activities in the NWTT Study Area will result in the deaths of thousands of marine mammals is incorrect. As discussed throughout this rule and in the NWTT FEIS/OEIS, the vast majority of predicted takes are by behavioral harassment (behavioral reactions and TTS), and there are no mortality takes predicted or authorized for any training or testing activities in the NWTT Study area. Further, any impacts from the Navy's activities are expected to be short term and would not result in significant changes in behavior, growth, survival, annual reproductive success, lifetime reproductive success (fitness), or species recruitment. The Navy has conducted active sonar training and testing activities in the Study Area for decades, and there is no evidence that routine Navy training and testing has negatively impacted marine mammal populations in the Study Area or at any Navy Range Complex. Based on the best available science, NMFS has determined that the Navy's training and testing activities will have a negligible impact on the affected species or stocks and, therefore, we plan to issue the requested MMPA authorization.

Comment 71: Several commenters opposed the Navy's activities within Olympic National Park.

Response: The Navy does not conduct any ship or submarine activities, including active sonar or explosives training and testing, within Olympic National Park. Other Navy activities within the Park would not impact marine resources. As such, these concerns are outside the scope of this rulemaking.

General

Comment 72: Some commenters requested access to, or copies of, NMFS' response to public comments on the proposed rule. Other commenters voiced concerns with the difficulty of viewing documents in person at NMFS headquarters in Silver Spring, MD.

Response: As stated in the Addresses section of the proposed rule, all comments received on the proposed rule are part of the public record and are posted for public viewing on *www.regulations.gov* without change. NMFS' responses to these comments are set forth in this **Federal Register** document. All documents prepared as part of the rulemaking, including the Navy's LOA application, **Federal Register** proposed and final rules, the issued LOAs, and related NMFS NEPA documents, may be obtained by visiting the Internet at: *http://nmfs.noaa.gov/pr/permits/incidental/military.htm.* The Navy's NWTT FEIS/OEIS and supporting technical documents (*e.g.,* Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis Technical Report) are available at *http://www.nwtteis.com.*

Comment 73: One commenter requested that NMFS provide a ''master list'' of all species-specific takes currently authorized by NMFS for all activities, whether military or non-military, occurring annually in the Atlantic and Pacific oceans and Gulf of Mexico. The same commenter requested that NMFS assess the cumulative effects of all military and non-military activities in the Atlantic and Pacific oceans and Gulf of Mexico for which an MMPA authorization has been issued.

Response: This request is beyond the scope of this rulemaking; however, all currently active MMPA authorizations issued by NMFS, and associated NEPA documents, may be obtained by visiting the Internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.* Each incidental take authorization provides a list of annual takes for each species authorized to be taken for a given activity.

Comment 74: Several people commented on other active rulemakings and LOAs for Navy training and testing activities, including HSTT, NWTRC, and AFTT.

Response: These comments are beyond the scope of this rulemaking. Commenters with concerns or questions regarding other Navy training and testing activities and related MMPA authorizations should visit NMFS' Web site at: *http://www.nmfs.noaa.gov/pr/permits/incidental/military.htm.*

Comment 75: One commenter suggested that Navy training and testing activities could be significantly reduced while still maintaining military readiness.

Response: The Navy has identified the level of training and testing activities necessary to meet its legally mandated requirements. As described in Section 5.3.4.1.1 of the NWTT FEIS/OEIS, the Navy's proposed training activities do not include training beyond levels required for maintaining satisfactory levels of readiness due to the need to efficiently use limited resources (*e.g.,* fuel, personnel, and time). Section 101(a)(5)(A) of the MMPA directs the Secretary of Commerce to allow, upon request, the incidental taking of small numbers of marine mammals if certain findings are made and regulations are issued. NMFS has made the requisite findings and therefore must issue regulations and LOAs for the Navy's activities.

Estimated Take of Marine Mammals

In the Estimated Take of Marine Mammals section of the proposed rule, NMFS described the potential effects to marine mammals from active sonar and underwater detonations in relation to the MMPA regulatory definitions of Level A and Level B harassment (80 FR 31738, June 3, 2015, pages 31785–31790). That information has not changed and is not repeated here. It is important to note that, as Level B Harassment is interpreted here and quantified by the behavioral thresholds described below, the fact that a single behavioral pattern (of unspecified duration) is abandoned or significantly altered and classified as a Level B take does not mean, necessarily, that the fitness of the harassed individual is affected either at all or significantly, or that, for example, a preferred habitat area is abandoned. Further analysis of context and duration of likely exposures and effects is necessary to determine the impacts of the estimated effects on individuals and how those may translate to population-level impacts, and is included in the Analysis and Negligible Impact Determination.

Tables 11 and 12 provide a summary of non-impulsive and impulsive thresholds to TTS and PTS for marine mammals. Behavioral thresholds for impulsive sources are summarized in Table 13. A detailed explanation of how these thresholds were derived is provided in the NWTT FEIS/OEIS Criteria and Thresholds Technical Report (*http://www.nwtteis.com*) and summarized in Chapter 6 of the LOA application (*http://www.nmfs.noaa.gov/pr/permits/incidental/military.htm*).

TABLE 11—ONSET TTS AND PTS THRESHOLDS FOR NON-IMPULSE SOUND

Group	Species	Onset TTS	Onset PTS
Low-Frequency Cetaceans	All mysticetes	178 dB re 1μPa2-sec (LF_{II})	198 dB re 1μPa2-sec (LF_{II}).
Mid-Frequency Cetaceans	Most delphinids, beaked whales, medium and large toothed whales.	178 dB re 1μPa2-sec (MF_{II})	198 dB re 1μPa2-sec (MF_{II}).
High-Frequency Cetaceans	Porpoises, Kogia spp	152 dB re 1μPa2-sec (HF_{II})	172 dB re 1μPa2-secSEL (HF_{II}).
Phocidae In-water	Harbor, Hawaiian monk, elephant seals.	183 dB re 1μPa2-sec (P_{WI})	197 dB re 1μPa2-sec (P_{WI}).
Otariidae & Obodenidae In-water	Sea lions and fur seals	206 dB re 1μPa2-sec (O_{WI})	220 dB re 1μPa2-sec (O_{WI}).
Mustelidae In-water	Sea otters.		

LF_{II}, MF_{II}, HF_{II}: New compound Type II weighting functions; P_{WI}, O_{WI}: Original Type I (Southall *et al.,* 2007) for pinniped and mustelid in water.

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Table 12. Impulsive sound and explosive criteria and thresholds for predicting injury and mortality.

Group	Species	Onset TTS	Onset PTS	Onset Slight GI Tract Injury	Onset Slight Lung Injury	Onset Mortality
Low Frequency Cetaceans	All mysticetes	172 dB re 1 μPa^2-s SEL (Type II weighting) or 224 dB re 1 µPa Peak SPL (unweighted)	187 dB re 1 μPa^2-s SEL (Type II weighting) or 230 dB re 1 µPa Peak SPL (unweighted)	237 dB re 1 µPa (unweighted)	Note 1	Note 2
Mid-Frequency Cetaceans	Most delphinids, medium and large toothed whales	172 dB re 1 μPa^2-s SEL (Type II weighting) or 224 dB re 1 µPa Peak SPL (unweighted)	187 dB re 1 μPa^2-s SEL (Type II weighting) or 230 dB re 1 µPa Peak SPL (unweighted)			
High Frequency Cetaceans	Porpoises and *Kogia* spp.	146 dB re 1 μPa^2-s SEL (Type II weighting) or 195 dB re 1 µPa Peak SPL (unweighted)	161 dB re 1 μPa^2-s SEL (Type II weighting) or 201 dB re 1 µPa Peak SPL (unweighted)			
Phocidae	Northern elephant seal and harbor seal	177 dB re 1 μPa^2-s (Type I weighting) or 212 dB re 1 µPa Peak SPL (unweighted)	192 dB re 1 μPa^2-s (Type I weighting) or 218 dB re 1 µPa Peak SPL (unweighted)			
Otariidae	Steller and California Sea Lion, Guadalupe and Northern fur seal	200 dB re 1 μPa^2-s (Type I weighting) or 212 dB re 1 µPa Peak SPL (unweighted)	215 dB re 1 μPa^2-s (Type I weighting) or 218 dB re 1 µPa Peak SPL (unweighted)			
Mustelidae	Sea Otter					
Note 1 $= 39.1M^{1/3}\left(1+\frac{D_{Rm}}{10.081}\right)^{1/2} Pa-\text{sec}$			Note 2 $= 91.4M^{1/3}\left(1+\frac{D_{Rm}}{10.081}\right)^{1/2} Pa-\text{sec}$			

[1] Impulse calculated over a delivery time that is the lesser of the initial positive pressure duration or 20 percent of the natural period of the assumed-spherical lung adjusted for animal size and depth.

Notes: GI = gastrointestinal, M = mass of animals in kilograms, D_{Rm} = depth of receiver (animal) in meters, SEL = Sound Exposure Level, SPL = Sound Pressure Level (re 1 µPa), dB = decibels, re 1 µPa = referenced to one micropascal, dB re 1 μPa^2-s = decibels referenced to one micropascal squared second

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TABLE 13—BEHAVIORAL THRESHOLDS FOR IMPULSIVE SOUND

Hearing group	Impulsive behavioral threshold for >2 pulses/24 hours
Low-Frequency Cetaceans	167 dB SEL (LF_{II}).
Mid-Frequency Cetaceans	167 dB SEL (MF_{II}).
High-Frequency Cetaceans	141 dB SEL (HF_{II}).
Phocid Seals (in water)	172 dB SEL (P_{WI}).
Otariidae & Mustelidae (in water)	195 dB SEL (O_{WI}).

Notes: (1) $LF_{II,}$ $MF_{II,}$ HF_{II} are New compound Type II weighting functions; $P_{WI,}$ O_{WI} = Original Type I (Southall *et al.* 2007) for pinniped and mustelid in water (see Finneran and Jenkins 2012). (2) SEL = re 1 μPa^2-s; SEL = Sound Exposure Level, dB = decibel.

Take Request

The NWTT FEIS/OEIS considered all training and testing activities proposed to occur in the Study Area that have the potential to result in the MMPA defined take of marine mammals. The potential stressors associated with these activities included the following:

- Acoustic (sonar and other active non-impulse sources, explosives, swimmer defense airguns, weapons firing, launch and impact noise, vessel noise, aircraft noise);
- Energy (electromagnetic devices);
- Physical disturbance or strikes (vessels, in-water devices, military expended materials, seafloor devices);
- Entanglement (fiber optic cables, guidance wires, parachutes);
- Ingestion (munitions, military expended materials other than munitions); and
- Secondary stressors (sediments and water quality).

NMFS has determined that two stressors could potentially result in the incidental taking of marine mammals from training and testing activities within the Study Area: (1) Non-impulsive stressors (sonar and other active acoustic sources) and (2) impulsive stressors (explosives). Non-impulsive and impulsive stressors have the potential to result in incidental takes of marine mammals by harassment, injury, or mortality. NMFS also considered the potential for vessel strikes to impact marine mammals, and that assessment is presented below.

In order to account for the accidental nature of vessel strikes to large whales in general, and the potential risk from any vessel movement within the NWTT Study Area, lethal takes of large whales were originally conservatively requested in the Navy's original LOA application for NWTT training and testing activities over the 5-year period of NMFS' final authorization. However, after further consideration of the Navy's ship strike analysis, the unlikelihood of a ship strike to occur and the fact that there has never been a ship strike to marine mammals in the Study Area, the Navy removed their request for mortality takes from vessel strike in the final LOA application. Therefore, NMFS is not authorizing takes (by injury or mortality) from vessel strikes during the 5-year period of the NWTT regulations, as discussed below.

Training Activities

A detailed analysis of effects due to marine mammal exposures to impulsive and non-impulsive sources in the Study Area is presented in Chapter 6 of the LOA application. Based on the model and post-model analysis described in Chapter 6 of the LOA application, Table 14 summarizes the authorized takes for training activities for a year (a 12-month period) and the summation over a 5-year period (annual events occurring five times and the non-annual event occurring three times). The Civilian Port Defense exercise (Maritime Homeland Defense/Security Mine Countermeasure exercise) is a non-annual event and is analyzed as occurring every other year, or three times during the 5-year period considered in this analysis. Annual totals presented in the tables are the summation of all annual events plus all the proposed non-annual events occurring in a 12-month period as a maximum year.

TABLE 14—SUMMARY OF ANNUAL AND 5-YEAR TAKES FOR NWTT TRAINING ACTIVITIES

MMPA category	Source	Training activities	
		Annual authorization sought	5-Year authorization sought
Level A	Impulsive and Non-Impulsive.	11—Species specific data shown in Tables 15 and 67.	55—Species specific data shown in Tables 15 and 16.
Level B	Impulsive and Non-Impulsive.	107,459—Species specific data shown in Tables 15 and 16.	533,543—Species specific data shown in Tables 15 and 16.

Impulsive and Non-Impulsive Sources

Table 15 provides the Navy's take request for training activities by species from the acoustic effects modeling estimates. The numbers provided in the annual columns are the totals for a maximum year (*i.e.,* a year in which a Civilian Port Defense (Maritime Homeland Defense/Security Mine Countermeasure exercise) occurs). Table 16 provides the contribution to the maximum year total (1,876 Level B exposures) resulting from the biennial Civilian Port Defense exercise (Maritime Homeland Defense/Security Mine Countermeasure exercise). The 5-year totals presented assume the biennial event would occur three times over the 5-year period (in the first, third, and fifth years). Derivations of the numbers presented in Tables 15 and 16 are described in more detail within Chapter 6 of the LOA application. There are no mortalities predicted for any training activities resulting from the use of impulsive or non-impulsive sources. Values shown in Table 15 also include Level B values from non-annual Civilian Port Defense (Maritime Homeland Defense/Security Mine Countermeasure exercise) training events.

TABLE 15—SPECIES-SPECIFIC TAKES FROM MODELING AND POST-MODEL ESTIMATES OF IMPULSIVE AND NON-IMPULSIVE SOURCE EFFECTS FOR ALL TRAINING ACTIVITIES

Species	Stock	Annual		5-year	
		Level B	Level A	Level B	Level A
North Pacific right whale	Eastern North Pacific	0	0	0	0
Humpback whale	Central North Pacific	0	0	0	0
	California, Oregon, & Washington	12	0	60	0
Blue whale	Eastern North Pacific	5	0	25	0
Fin whale	Northeast Pacific	0	0	0	0
	California, Oregon, & Washington	25	0	125	0
Sei whale	Eastern North Pacific	0	0	0	0
Minke whale	Alaska	0	0	0	0
	California, Oregon, & Washington	18	0	90	0
Gray whale	Eastern North Pacific	6	0	30	0
	Western North Pacific	0	0	0	0
Sperm whale	North Pacific	0	0	0	0
	California, Oregon, & Washington	81	0	405	0
Kogia (spp.)	California, Oregon, & Washington	73	0	365	0
Killer whale	Alaska Resident	0	0	0	0
	Northern Resident	0	0	0	0
	West Coast Transient	9	0	39	0
	East N. Pacific Offshore	13	0	65	0
	East N. Pacific Southern Resident	2	0	6	0
Short-finned pilot whale	California, Oregon, & Washington	0	0	0	0
Short-beaked common dolphin.	California, Oregon, & Washington	734	0	3,670	0
Bottlenose dolphin	California, Oregon, & Washington	0	0	0	0
Striped dolphin	California, Oregon, & Washington	22	0	110	0
Pacific white-sided dolphin	North Pacific	0	0	0	0
	California, Oregon, & Washington	3,482	0	17,408	0
Northern right whale dolphin	California, Oregon, & Washington	1,332	0	6,660	0
Risso's dolphin	California, Oregon, & Washington	657	0	3,285	0
Harbor porpoise	Southeast Alaska	0	0	0	0
	Northern OR/WA Coast	35,006	0	175,030	0
	Northern CA/Southern OR	52,509	0	262,545	0
	WA Inland Waters	1,417	1	4,409	5
Dall's porpoise	Alaska	0	0	0	0
	California, Oregon, & Washington	3,730	4	18,178	20
Cuvier's beaked whale	Alaska	0	0	0	0
	California, Oregon, & Washington	353	0	1,765	0
Baird's beaked whale	Alaska	0	0	0	0
	California, Oregon, & Washington	591	0	2,955	0
Mesoplodon beaked whales	California, Oregon, & Washington	1,417	0	7,085	0
Steller sea lion	Eastern U.S.	404	0	1,986	0
Guadalupe fur seal	Mexico	7	0	35	0
California sea lion	U.S. Stock	814	0	4,038	0
Northern fur seal	Eastern Pacific	2,495	0	12,475	0
	California	37	0	185	0
Northern elephant seal	California Breeding	1,271	0	6,353	0
Harbor seal	Southeast Alaska (Clarence Strait)	0	0	0	0
	OR/WA Coast	0	0	0	0
	California	0	0	0	0
	WA Northern Inland Waters	427	4	1,855	20
	Southern Puget Sound	58	0	252	0
	Hood Canal	452	2	2,054	10

TABLE 16—TRAINING EXPOSURES SPECIFIC TO THE BIENNIAL CIVILIAN PORT DEFENSE EXERCISE (MARITIME HOMELAND DEFENSE/SECURITY MINE COUNTERMEASURE EXERCISE)

[Values provided for informational purposes and are included in Table 15 species-specific totals]

Species	Stock	Biennial	
		Level B	Level A
North Pacific right whale	Eastern North Pacific	0	0
Humpback whale	Central North Pacific	0	0
	California, Oregon, & Washington	0	0
Blue whale	Eastern North Pacific	0	0
Fin whale	Northeast Pacific	0	0
	California, Oregon, & Washington	0	0
Sei whale	Eastern North Pacific	0	0
Minke whale	Alaska	0	0

TABLE 16—TRAINING EXPOSURES SPECIFIC TO THE BIENNIAL CIVILIAN PORT DEFENSE EXERCISE (MARITIME HOMELAND DEFENSE/SECURITY MINE COUNTERMEASURE EXERCISE)—Continued

[Values provided for informational purposes and are included in Table 15 species-specific totals]

Species	Stock	Biennial	
		Level B	Level A
	California, Oregon, & Washington	0	0
Gray whale	Eastern North Pacific	0	0
	Western North Pacific	0	0
Sperm whale	North Pacific	0	0
	California, Oregon, & Washington	0	0
Kogia (spp.)	California, Oregon, & Washington	0	0
Killer whale	Alaska Resident	0	0
	Northern Resident	0	0
	West Coast Transient	3	0
	East N. Pacific Offshore	0	0
	East N. Pacific Southern Resident	2	0
Short-finned pilot whale	California, Oregon, & Washington	0	0
Short-beaked common dolphin	California, Oregon, & Washington	0	0
Bottlenose dolphin	California, Oregon, & Washington	0	0
Striped dolphin	California, Oregon, & Washington	0	0
Pacific white-sided dolphin	North Pacific	0	0
	California, Oregon, & Washington	1	0
Northern right whale dolphin	California, Oregon, & Washington	0	0
Risso's dolphin	California, Oregon, & Washington	0	0
Harbor porpoise	Southeast Alaska	0	0
	Northern OR/WA Coast	0	0
	Northern CA/Southern OR	0	0
	WA Inland Waters	1,338	0
Dall's porpoise	Alaska	0	0
	California, Oregon, & Washington	236	0
Cuvier's beaked whale	Alaska	0	0
	California, Oregon, & Washington	0	0
Baird's beaked whale	Alaska	0	0
	California, Oregon, & Washington	0	0
Mesoplodon beaked whales	California, Oregon, & Washington	0	0
Steller sea lion	Eastern U.S.	17	0
Guadalupe fur seal	Mexico	0	0
California sea lion	U.S. Stock	16	0
Northern fur seal	Eastern Pacific	0	0
	California	0	0
Northern elephant seal	California Breeding	1	0
Harbor seal	Southeast Alaska (Clarence Strait)	0	0
	OR/WA Coast	0	0
	California	0	0
	WA Northern Inland Waters	140	0
	Southern Puget Sound	19	0
	Hood Canal	103	0

Vessel Strike

There has never been a recorded vessel strike of marine mammals during any training activities in the Study Area. A detailed analysis of strike data is contained in Section 6.7 (Estimated Take of Large Whales by Navy Vessel Strike) of the LOA application. The Navy's proposed actions would not result in any appreciable changes in locations or frequency of vessel activity, and there have been no whale strikes during any previous training activities in the Study Area. The manner in which the Navy has trained would remain consistent with the range of variability observed over the last decade so the Navy does not anticipate vessel strikes would occur within the Study Area during training events. Neither the Navy nor NMFS anticipates vessel strikes of marine mammals within the Study Area, nor were takes by injury or mortality resulting from vessel strike predicted in the Navy's quantitative analysis. Therefore, takes by injury or mortality resulting from vessel strikes are not authorized by NMFS in this final rule. However, the Navy has proposed measures (see Mitigation) to mitigate potential impacts to marine mammals from vessel strikes during training activities in the Study Area.

Testing Activities

A detailed analysis of effects due to marine mammal exposures to impulsive and non-impulsive sources in the Study Area is presented in Chapter 6 of the LOA application. Based on the model and post-model analysis described in Chapter 6 of the LOA application, Table 17 summarizes the authorized takes for testing activities for an annual (12-month) period and the summation over a 5-year period. There are no non-annual testing events.

TABLE 17—SUMMARY OF ANNUAL AND 5-YEAR TAKES FOR NWTT TESTING ACTIVITIES

MMPA category	Source	Testing activities	
		Annual authorization sought	5-Year authorization sought
Level A	Impulsive and Non-Impulsive.	184—Species specific data shown in Tables 18	920—Species specific data shown in Tables 18.
Level B	Impulsive and Non-Impulsive.	140,377—Species specific data shown in Tables 18	701,885—Species specific data shown in Tables 18.

Impulsive and Non-Impulsive Sources

Table 18 summarizes the authorized takes for testing activities by species. There are no non-annual testing events. Derivation of these values is described in more detail within Chapter 6 of the LOA application. There are no mortalities predicted for any testing activities based on the analysis of impulsive and non-impulsive sources.

TABLE 18—SPECIES-SPECIFIC TAKES FROM MODELING AND POST-MODEL ESTIMATES OF IMPULSIVE AND NON-IMPULSIVE SOURCE EFFECTS FOR ALL TESTING ACTIVITIES

Species	Stock	Annual		5-Year	
		Level B	Level A	Level B	Level A
North Pacific right whale	Eastern North Pacific	0	0	0	0
Humpback whale	Central North Pacific	1	0	5	0
	California, Oregon, & Washington	44	0	220	0
Blue whale	Eastern North Pacific	6	0	30	0
Fin whale	Northeast Pacific	2	0	10	0
	California, Oregon, & Washington	34	0	170	0
Sei whale	Eastern North Pacific	2	0	10	0
Minke whale	Alaska	0	0	0	0
	California, Oregon, & Washington	18	0	90	0
Gray whale	Eastern North Pacific	*12	0	*60	0
	Western North Pacific	0	0	0	0
Sperm whale	North Pacific	0	0	0	0
	California, Oregon, & Washington	78	0	390	0
Kogia (spp.)	California, Oregon, & Washington	106	1	530	5
Killer whale	Alaska Resident	2	0	10	0
	Northern Resident	0	0	0	0
	West Coast Transient	207	0	1,035	0
	East N. Pacific Offshore	22	0	110	0
	East N. Pacific Southern Resident	0	0	0	0
Short-finned pilot whale	California, Oregon, & Washington	0	0	0	0
Short-beaked common dolphin.	California, Oregon, & Washington	1,628	0	8,140	0
Bottlenose dolphin	California, Oregon, & Washington	0	0	0	0
Striped dolphin	California, Oregon, & Washington	14	0	70	0
Pacific white-sided dolphin	North Pacific	3	0	15	0
	California, Oregon, & Washington	4,869	0	24,345	0
Northern right whale dolphin	California, Oregon, & Washington	2,038	0	10,190	0
Risso's dolphin	California, Oregon, & Washington	1,154	0	5,770	0
Harbor porpoise	Southeast Alaska	926	0	4,630	0
	Northern OR/WA Coast	17,212	15	86,060	75
	Northern CA/Southern OR	25,819	23	129,095	115
	WA Inland Waters	*5,409	6	*27,045	30
Dall's porpoise	Alaska	1,200	0	6,000	0
	California, Oregon, & Washington	*10,157	43	*50,785	215
Cuvier's beaked whale	Alaska	15	0	75	0
	California, Oregon, & Washington	91	0	455	0
Baird's beaked whale	Alaska	25	0	125	0
	California, Oregon, & Washington	149	0	745	0
Mesoplodon beaked whales	California, Oregon, & Washington	369	0	1,845	0
Steller sea lion	Eastern U.S.	*521	0	*2,605	0
Guadalupe fur seal	Mexico	3	0	15	0
California sea lion	U.S. Stock	*2,146	0	*10,730	0
Northern fur seal	Eastern Pacific	1,830	0	9,150	0
	California	27	0	135	0
Northern elephant seal	California Breeding	1,325	2	6625	10
Harbor seal	Southeast Alaska (Clarence Strait)	22	0	110	0
	OR/WA Coast	1,655	4	8,275	20
	California	0	0	0	0
	WA Northern Inland Waters	*1,823	*22	**9,115	*110
	Southern Puget Sound	196	1	980	5

TABLE 18—SPECIES-SPECIFIC TAKES FROM MODELING AND POST-MODEL ESTIMATES OF IMPULSIVE AND NON-IMPULSIVE SOURCE EFFECTS FOR ALL TESTING ACTIVITIES—Continued

Species	Stock	Annual		5-Year	
		Level B	Level A	Level B	Level A
	Hood Canal	59,217	67	296,085	335

*These numbers have been updated since the proposed rule to reflect Navy corrections to the number of hours and the location of sonar use attributed to life cycle pierside sonar testing events.

Vessel Strike

There has never been a recorded vessel strike to marine mammals during any testing activities in the Study Area. A detailed analysis of strike data is contained in Section 6.7 (Estimated Take of Large Whales by Navy Vessel Strike) of the LOA application. Testing activities involving vessel movement could mainly occur in the Inland Waters and in Western Behm Canal with some additional testing activities in the offshore region. The majority of vessels used in the Inland Waters and Western Behm Canal are smaller vessels, which are less likely to be involved in a whale strike. The Navy's proposed actions would not result in any appreciable changes in locations or frequency of vessel activity, and there have been no whale strikes during any previous testing activities in the Study Area. The manner in which the Navy has tested would remain consistent with the range of variability observed over the last decade, so neither the Navy nor NMFS anticipates vessel strikes would occur within the Study Area during testing events. Further, takes by injury or mortality resulting from vessel strike were not predicted in the Navy's quantitative analysis. As such, NMFS is not authorizing take by injury or mortality resulting from vessel strike for this final rule. However, the Navy has proposed measures (see Mitigation) to mitigate potential impacts to marine mammals from vessel strikes during testing activities in the Study Area.

Marine Mammal Habitat

The Navy's proposed training and testing activities could potentially affect marine mammal habitat through the introduction of sound into the water column, impacts to the prey species of marine mammals, bottom disturbance, or changes in water quality. Each of these components was considered in Chapter 3 of the NWTT FEIS/OEIS. Based on the information in the Marine Mammal Habitat section of the proposed rule (80 FR 31737, June 3, 2015; pages 31769–31771) and the supporting information included in the NWTT FEIS/OEIS, NMFS has determined that training and testing activities would not have adverse or long-term impacts on marine mammal habitat. In summary, expected effects to marine mammal habitat will include transitory elevated levels of anthropogenic sound in the water column; short-term physical alteration of the water column or bottom topography; brief disturbances to marine invertebrates; localized and infrequent disturbance to fish; a limited number of fish mortalities; and temporary marine mammal avoidance.

Analysis and Negligible Impact Determination

Negligible impact is ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival'' (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes, alone, is not enough information on which to base an impact determination, as the severity of harassment may vary greatly depending on the context and duration of the behavioral response, many of which would not be expected to have deleterious impacts on the fitness of any individuals. In determining whether the expected takes will have a negligible impact, in addition to considering estimates of the number of marine mammals that might be ''taken,'' NMFS must consider other factors, such as the likely nature of any responses (their intensity, duration, etc.), the context of any responses (critical reproductive time or location, migration, etc.), as well as the number and nature (*e.g.,* severity) of estimated Level A harassment takes, the number of estimated mortalities, and the status of the species.

The Navy's specified activities have been described based on best estimates of the maximum amount of sonar and other acoustic source use or detonations that the Navy would conduct. There may be some flexibility in that the exact number of hours, items, or detonations may vary from year to year, but take totals are not authorized to exceed the 5-year totals indicated in Tables 14–18. We base our analysis and NID on the maximum number of takes authorized.

To avoid repetition, we provide some general analysis immediately below that applies to all the species listed in Tables 14–18, given that some of the anticipated effects (or lack thereof) of the Navy's training and testing activities on marine mammals are expected to be relatively similar in nature. However, below that, we break our analysis into species, or groups of species where relevant similarities exist, to provide more specific information related to the anticipated effects on individuals or where there is information about the status or structure of any species that would lead to a differing assessment of the effects on the population.

The Navy's take request is based on its model and post-model analysis. In the discussions below, the ''acoustic analysis'' refers to the Navy's modeling results and post-model analysis. The model calculates sound energy propagation from sonar, other active acoustic sources, and explosives during naval activities; the sound or impulse received by animat dosimeters representing marine mammals distributed in the area around the modeled activity; and whether the sound or impulse received by a marine mammal exceeds the thresholds for effects. The model estimates are then further analyzed to consider animal avoidance and implementation of highly effective mitigation measures to prevent Level A harassment, resulting in final estimates of effects due to Navy training and testing. NMFS provided input to the Navy on this process and the Navy's qualitative analysis is described in detail in Chapter 6 of its LOA application (*http://www.nmfs.noaa.gov/pr/permits/incidental/militry.htm*).

Generally speaking, and especially with other factors being equal, the Navy and NMFS anticipate more severe effects from takes resulting from exposure to higher received levels (though this is in no way a strictly linear relationship throughout species, individuals, or circumstances) and less severe effects from takes resulting from exposure to lower received levels. The

requested number of Level B takes does not equate to the number of individual animals the Navy expects to harass (which is lower), but rather to the instances of take (*i.e.,* exposures above the Level B harassment threshold) that would occur. Additionally, these instances may represent either a very brief exposure (seconds) or, in some cases, longer durations of exposure within a day. Depending on the location, duration, and frequency of activities, along with the distribution and movement of marine mammals, individual animals may be exposed to impulse or non-impulse sounds at or above the Level B harassment threshold on multiple days. However, the Navy is currently unable to estimate the number of individuals that may be taken during training and testing activities. The model results estimate the total number of takes that may occur to a smaller number of individuals. While the model shows that an increased number of exposures may take place due to an increase in events/activities and ordnance, the types and severity of individual responses to training and testing activities are not expected to change.

Behavioral Harassment

As discussed previously in this document, marine mammals can respond to LF/MFAS/HFAS in many different ways, a subset of which qualifies as behavioral harassment. As described in the proposed rule, the Navy uses the behavioral response function to quantify the number of behavioral responses that would qualify as Level B behavioral harassment under the MMPA. As the statutory definition is currently applied, a wide range of behavioral reactions may qualify as Level B harassment under the MMPA, including but not limited to avoidance of the sound source, temporary changes in vocalizations or dive patterns, temporary avoidance of an area, or temporary disruption of feeding, migrating, or reproductive behaviors. The estimates calculated using the behavioral response function do not differentiate between the different types of potential reactions. Nor do the estimates provide information regarding the potential fitness or other biological consequences of the reactions on the affected individuals. We therefore consider the available scientific evidence to determine the likely nature of the modeled behavioral responses and the potential fitness consequences for affected individuals.

For LF/MFAS/HFAS, the Navy provided information (Table 19) estimating the percentage of the total number of takes by behavioral harassment that would occur within the 6-dB bins (without considering mitigation or avoidance). As mentioned above, an animal's exposure to a higher received level is more likely to result in a behavioral response that is more likely to adversely affect the health of the animal. As illustrated below, the majority (about 80 percent, at least for hull-mounted sonar, which is responsible for a large portion of the sonar takes) of calculated takes from MFAS result from exposures between 150 dB and 162 dB. Less than 0.5 percent of the takes are expected to result from exposures above 174 dB. Specifically, given a range of behavioral responses that may be classified as Level B harassment, to the degree that higher received levels are expected to result in more severe behavioral responses, only a small percentage of the anticipated Level B harassment from Navy activities might necessarily be expected to potentially result in more severe responses, especially when the distance from the source at which the levels below are received is considered (see Table 19). Marine mammals are able to discern the distance of a given sound source, and given other equal factors (including received level), they have been reported to respond more to sounds that are closer (DeRuiter *et al.,* 2013). Further, the estimated number of responses do not reflect either the duration or context of those anticipated responses, some of which will be of very short duration, and other factors should be considered when predicting how the estimated takes may affect individual fitness. A recent study by Moore and Barlow (2013) emphasizes the importance of context (*e.g.,* behavioral state of the animals, distance from the sound source, etc.) in evaluating behavioral responses of marine mammals to acoustic sources.

TABLE 19—NON-IMPULSIVE RANGES IN 6-dB BINS AND PERCENTAGE OF BEHAVIORAL HARASSMENTS

Received level	Sonar bin MF1 (*e.g.,* SQS–53; ASW hull mounted sonar)		Sonar bin MF4 (*e.g.,* AQS–22; ASW dipping sonar)		Sonar bin MF5 (*e.g.,* SSQ–62; ASW sonobuoy)	
	Distance at which levels occur within radius of source (m)	Percentage of behavioral harassments occurring at given levels	Distance at which levels occur within radius of source (m)	Percentage of behavioral harassments occurring at given levels	Distance at which levels occur within radius of source (m)	Percentage of behavioral harassments occurring at given levels
Low Frequency Cetaceans						
120 ≤ SPL <126	178,750–156,450	0.00%	100,000–92,200	0.00%	22,800–15,650	0.00%
126 ≤ SPL <132	156,450–147,500	0.00	92,200–55,050	0.11	15,650–11,850	0.05
132 ≤ SPL <138	147,500–103,700	0.21	55,050–46,550	1.08	11,850–6,950	2.84
138 ≤ SPL <144	103,700–97,950	0.33	46,550–15,150	35.69	6,950–3,600	16.04
144 ≤ SPL <150	97,950–55,050	13.73	15,150–5,900	26.40	3,600–1,700	33.63
150 ≤ SPL <156	55,050–49,900	5.28	5,900–2,700	17.43	1,700–250	44.12
156 ≤ SPL <162	49,900–10,700	72.62	2,700–1,500	9.99	250–100	2.56
162 ≤ SPL <168	10,700–4,200	6.13	1,500–200	9.07	100–<50	0.76
168 ≤ SPL <174	4,200–1,850	1.32	200–100	0.18	<50	0.00
174 ≤ SPL <180	1,850–850	0.30	100–<50	0.05	<50	0.00
180 ≤ SPL <186	850–400	0.07	<50	0.00	<50	0.00
186 ≤ SPL <192	400–200	0.01	<50	0.00	<50	0.00
192 ≤ SPL <198	200–100	0.00	<50	0.00	<50	0.00
Mid Frequency Cetaceans						
120 ≤ SPL <126	179,400–156,450	0.00	100,000–92,200	0.00	23,413–16,125	0.00

TABLE 19—NON-IMPULSIVE RANGES IN 6-dB BINS AND PERCENTAGE OF BEHAVIORAL HARASSMENTS—Continued

Received level	Sonar bin MF1 (*e.g.,* SQS–53; ASW hull mounted sonar)		Sonar bin MF4 (*e.g.,* AQS–22; ASW dipping sonar)		Sonar bin MF5 (*e.g.,* SSQ–62; ASW sonobuoy)	
	Distance at which levels occur within radius of source (m)	Percentage of behavioral harassments occurring at given levels	Distance at which levels occur within radius of source (m)	Percentage of behavioral harassments occurring at given levels	Distance at which levels occur within radius of source (m)	Percentage of behavioral harassments occurring at given levels
126 ≤ SPL <132	156,450–147,500	0.00	92,200–55,050	0.11	16,125–11,500	0.06
132 ≤ SPL <138	147,500–103,750	0.21	55,050–46,550	1.08	11,500–6,738	2.56
138 ≤ SPL <144	103,750–97,950	0.33	46,550–15,150	35.69	6,738–3,825	13.35
144 ≤ SPL <150	97,950–55,900	13.36	15,150–5,900	26.40	3,825–1,713	37.37
150 ≤ SPL <156	55,900–49,900	6.12	5,900–2,700	17.43	1,713–250	42.85
156 ≤ SPL <162	49,900–11,450	71.18	2,700–1,500	9.99	250–150	1.87
162 ≤ SPL <168	11,450–4,350	7.01	1,500–200	9.07	150–<50	1.93
168 ≤ SPL <174	4,350–1,850	1.42	200–100	0.18	<50	0.00
174 ≤ SPL <180	1,850–850	0.29	100–<50	0.05	<50	0.00
180 ≤ SPL <186	850–400	0.07	<50	0.00	<50	0.00
186 ≤ SPL <192	400–200	0.01	<50	0.00	<50	0.00
192 ≤ SPL <198	200–100	0.00	<50	0.00	<50	0.00

Notes: (1) ASW = anti-submarine warfare, m = meters, SPL = sound pressure level; (2) Odontocete behavioral response function is also used for high-frequency cetaceans, phocid seals, otariid seals and sea lions, and sea otters.

Although the Navy has been monitoring the effects of LF/MFAS/HFAS on marine mammals since 2006, and research on the effects of MFAS is advancing, our understanding of exactly how marine mammals in the Study Area will respond to LF/MFAS/HFAS is still improving. The Navy has submitted more than 80 reports, including Major Exercise Reports, Annual Exercise Reports, and Monitoring Reports, documenting hundreds of thousands of marine mammals across Navy range complexes, and there are only two instances of overt behavioral disturbances that have been observed. One cannot conclude from these results that marine mammals were not harassed from MFAS/HFAS, as a portion of animals within the area of concern were not seen (especially those more cryptic, deep-diving species, such as beaked whales or *Kogia* spp.), the full series of behaviors that would more accurately show an important change is not typically seen (*i.e.,* only the surface behaviors are observed), and some of the non-biologist watchstanders might not be well-qualified to characterize behaviors. However, one can say that the animals that were observed did not respond in any of the obviously more severe ways, such as panic, aggression, or anti-predator response.

Diel Cycle

As noted previously, many animals perform vital functions, such as feeding, resting, traveling, and socializing on a diel cycle (24-hour cycle). Behavioral reactions to noise exposure (when taking place in a biologically important context, such as disruption of critical life functions, displacement, or avoidance of important habitat) are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). Consequently, a behavioral response lasting less than one day and not recurring on subsequent days is not considered severe unless it could directly affect reproduction or survival (Southall *et al.,* 2007). Note that there is a difference between multiple-day substantive behavioral reactions and multiple-day anthropogenic activities. For example, just because at-sea exercises last for multiple days does not necessarily mean that individual animals are either exposed to those exercises for multiple days or, further, exposed in a manner resulting in a sustained multiple day substantive behavioral response. Moreover, there are no MTE in the NWTT Study Area. Navy sonar exercises typically include assets that travel at high speeds (typically 10–15 knots, or higher) and likely cover large areas that are relatively far from shore, in addition to the fact that marine mammals are moving as well, which would make it unlikely that the same animal could remain in the immediate vicinity of the ship for the entire duration of the exercise. Additionally, the Navy does not necessarily operate active sonar the entire time during an exercise. While it is certainly possible that these sorts of exercises could overlap with individual marine mammals multiple days in a row at levels above those anticipated to result in a take, because of the factors mentioned above, it is considered not to be likely for the majority of takes, does not mean that a behavioral response is necessarily sustained for multiple days, and still necessitates the consideration of likely duration and context to assess any effects on the individual's fitness.

Durations for non-impulsive activities utilizing tactical sonar sources vary and are fully described in Appendix A of the NWTT FEIS/OEIS. ASW training and testing exercises using MFAS/HFAS generally last for 2–16 hours, and may have intervals of non-activity in between. Because of the need to train in a large variety of situations, the Navy does not typically conduct successive ASW exercises in the same locations. Given the average length of ASW exercises (times of continuous sonar use) and typical vessel speed, combined with the fact that the majority of the cetaceans in the Study Area would not likely remain in an area for successive days, it is unlikely that an animal would be exposed to MFAS/HFAS at levels likely to result in a substantive response that would then be carried on for more than one day or on successive days. Further, as stated above, there are no MTEs proposed in the NWTT Study Area.

Most planned explosive exercises are of a short duration (1–6 hours). Although explosive exercises may sometimes be conducted in the same general areas repeatedly, because of their short duration and the fact that they are in the open ocean and animals can easily move away, it is similarly unlikely that animals would be exposed for long, continuous amounts of time.

Furthermore, most explosive activities in NWTT are conducted at least 20 nm off shore and most over 50 nm offshore. Since densities for most marine mammals decrease further from the shelf break, and these activities are conducted in areas of generally lower marine mammal densities thus further reducing potential impacts.

TTS

As mentioned previously, TTS can last from a few minutes to days, be of varying degree, and occur across various frequency bandwidths, all of which determine the severity of the impacts on the affected individual, which can range from minor to more severe. The TTS sustained by an animal is primarily classified by three characteristics:

1. Frequency—Available data (of mid-frequency hearing specialists exposed to mid- or high-frequency sounds; Southall *et al.,* 2007) suggest that most TTS occurs in the frequency range of the source up to one octave higher than the source (with the maximum TTS at ½ octave above). The more powerful MF sources used have center frequencies between 3.5 and 8 kHz and the other unidentified MF sources are, by definition, less than 10 kHz, which suggests that TTS induced by any of these MF sources would be in a frequency band somewhere between approximately 2 and 20 kHz. There are fewer hours of HF source use and the sounds would attenuate more quickly, plus they have lower source levels, but if an animal were to incur TTS from these sources, it would cover a higher frequency range (sources are between 20 and 100 kHz, which means that TTS could range up to 200 kHz; however, HF systems are typically used less frequently and for shorter time periods than surface ship and aircraft MF systems, so TTS from these sources is even less likely). TTS from explosives would be broadband. Vocalization data for each species, which would inform how TTS might specifically interfere with communications with conspecifics, was provided in the LOA application.

2. Degree of the shift (*i.e.,* by how many dB the sensitivity of the hearing is reduced)—Generally, both the degree of TTS and the duration of TTS will be greater if the marine mammal is exposed to a higher level of energy (which would occur when the peak dB level is higher or the duration is longer). The threshold for the onset of TTS was discussed previously in this document. An animal would have to approach closer to the source or remain in the vicinity of the sound source appreciably longer to increase the received SEL, which would be difficult considering the Lookouts and the nominal speed of an active sonar vessel (10–15 knots). In the TTS studies (see *Threshold Shift* section in the proposed rule), some using exposures of almost an hour in duration or up to 217 SEL, most of the TTS induced was 15 dB or less, though Finneran *et al.* (2007) induced 43 dB of TTS with a 64-second exposure to a 20 kHz source. However, MFAS emits a nominal ping every 50 seconds, and incurring those levels of TTS is highly unlikely.

3. Duration of TTS (recovery time)—In the TTS laboratory studies (see *Threshold Shift*) section in the proposed rule), some using exposures of almost an hour in duration or up to 217 SEL, almost all individuals recovered within 1 day (or less, often in minutes), although in one study (Finneran *et al.,* 2007), recovery took 4 days.

Based on the range of degree and duration of TTS reportedly induced by exposures to non-pulse sounds of energy higher than that to which free-swimming marine mammals in the field are likely to be exposed during MFAS/HFAS training exercises in the Study Area, it is unlikely that marine mammals would ever sustain a TTS from MFAS that alters their sensitivity by more than 20 dB for more than a few days (and any incident of TTS would likely be far less severe due to the short duration of the majority of the exercises and the speed of a typical vessel). Also, for the same reasons discussed in the Diel Cycle section, and because of the short distance within which animals would need to approach the sound source, it is unlikely that animals would be exposed to the levels necessary to induce TTS in subsequent time periods such that their recovery is impeded. Additionally, though the frequency range of TTS that marine mammals might sustain would overlap with some of the frequency ranges of their vocalization types, the frequency range of TTS from MFAS (the source from which TTS would most likely be sustained because the higher source level and slower attenuation make it more likely that an animal would be exposed to a higher received level) would not usually span the entire frequency range of one vocalization type, much less span all types of vocalizations or other critical auditory cues. If impaired, marine mammals would typically be aware of their impairment and are sometimes able to implement behaviors to compensate (see Acoustic Masking or Communication Impairment section), though these compensations may incur energetic costs.

Acoustic Masking or Communication Impairment

Masking only occurs during the time of the signal (and potential secondary arrivals of indirect rays), versus TTS, which continues beyond the duration of the signal. Standard MFAS nominally pings every 50 seconds for hull-mounted sources. For the sources for which we know the pulse length, most are significantly shorter than hull-mounted active sonar, on the order of several microseconds to tens of microseconds. For hull-mounted active sonar, though some of the vocalizations that marine mammals make are less than one second long, there is only a 1 in 50 chance that they would occur exactly when the ping was received, and when vocalizations are longer than one second, only parts of them are masked. Alternately, when the pulses are only several microseconds long, the majority of most animals' vocalizations would not be masked. Masking effects from MFAS/HFAS are expected to be minimal. If masking or communication impairment were to occur briefly, it would be in the frequency range of MFAS, which overlaps with some marine mammal vocalizations; however, it would likely not mask the entirety of any particular vocalization, communication series, or other critical auditory cue, because the signal length, frequency, and duty cycle of the MFAS/HFAS signal does not perfectly mimic the characteristics of any marine mammal's vocalizations. The other sources used in Navy training and testing, many of either higher frequencies (meaning that the sounds generated attenuate even closer to the source) or lower amounts of operation, are similarly not expected to result in masking.

PTS, Injury, or Mortality

NMFS believes that many marine mammals would deliberately avoid exposing themselves to the received levels of active sonar necessary to induce injury by moving away from or at least modifying their path to avoid a close approach. Additionally, in the unlikely event that an animal approaches the sonar vessel at a close distance, NMFS believes that the mitigation measures (*i.e.,* shutdown/powerdown zones for MFAS/HFAS) would typically ensure that animals would not be exposed to injurious levels of sound. As discussed previously, the Navy utilizes both aerial (when available) and passive acoustic monitoring (during all ASW exercises) in addition to watchstanders on vessels

to detect marine mammals for mitigation implementation.

If a marine mammal is able to approach a surface vessel within the distance necessary to incur PTS, the likely speed of the vessel (nominal 10–15 knots) would make it very difficult for the animal to remain in range long enough to accumulate enough energy to result in more than a mild case of PTS. As mentioned previously and in relation to TTS, the likely consequences to the health of an individual that incurs PTS can range from mild to more serious, depending upon the degree of PTS and the frequency band it is in, and many animals are able to compensate for the shift, although it may include energetic costs. Only 11 Level A PTS takes per year are predicted from NWTT training activities and 176 Level A (PTS) takes per year from testing activities.

As discussed previously, marine mammals (especially beaked whales) could potentially respond to MFAS at a received level lower than the injury threshold in a manner that indirectly results in the animals stranding. The exact mechanism of this potential response, behavioral or physiological, is not known. When naval exercises have been associated with strandings in the past, it has typically been when three or more vessels are operating simultaneously, in the presence of a strong surface duct, and in areas of constricted channels, semi-enclosed areas, and/or steep bathymetry. A combination of these environmental and operational parameters is not present in the NWTT action. Further, as stated earlier, there are no MTEs proposed in the Study Area. When this is combined with consideration of the number of hours of active sonar training that will be conducted and the nature of the exercises—which do not typically include the use of multiple hull-mounted sonar sources—we believe that the probability is small that this will occur. Furthermore, given that there has never been a stranding in the Study Area associated with sonar use and based on the number of occurrences where strandings have been definitively associated with military sonar versus the number of hours of active sonar training that have been conducted, we believe that the probability is small that this will occur as a result of the Navy's proposed training and testing activities. Lastly, an active sonar shutdown protocol for strandings involving live animals milling in the water minimizes the chances that these types of events turn into mortalities.

As stated previously, there have been no recorded Navy vessel strikes of any marine mammals during training or testing in the NWTT Study Area to date, nor were takes by injury or mortality resulting from vessel strike predicted in the Navy's quantitative analysis.

Group and Species-Specific Analysis

Predicted harassment of marine mammals from sonar and other active acoustic sources and explosions during annual training and testing activities are shown in Tables 14–18. The vast majority of predicted exposures (greater than 99 percent) are expected to be Level B harassment (non-injurious TTS and behavioral reactions) from sonar and other active acoustic sources at relatively low received levels (less than 156 dB) (Table 19). As mentioned earlier in the Analysis and Negligible Impact Determination section, an animal's exposure to a higher received level is more likely to adversely affect the health of the animal. Only low numbers of harbor porpoise, Dall's porpoise, *Kogia* spp., Northern elephant seal, and harbor seal are expected to have injurious take(s), in the form of PTS, resulting from sonar and other active acoustic sources.

For explosive (impulsive) sources, the acoustic analysis predicts only ten annual exposures that would exceed thresholds associated with Level B (from training or testing activities) and only 2 annual exposures at levels that exceed the threshold for injury (only from training activities). Only harbor porpoise, Dall's porpoise, Northern elephant seal, and harbor seals are predicted to have Level B (TTS) exposures resulting from explosives. The two Level A exposures would be of Dall's porpoise and would be in the form of PTS (Table 12). There are no mortality takes predicted for any marine mammal species for the NWTT activities.

The analysis below may in some cases (*e.g.,* mysticetes, porpoises, pinnipeds) address species collectively if they occupy the same functional hearing group (*i.e.,* low, mid, and high-frequency cetaceans and pinnipeds in water), have similar hearing capabilities, and/or are known to generally behaviorally respond similarly to acoustic stressors. Where there are meaningful differences between species or stocks in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, they will either be described within the section or the species will be included as a separate sub-section.

Mysticetes—The Navy's acoustic analysis predicts that 185 instances of Level B harassment of mysticete whales may occur in the Study Area each year from sonar and other active acoustic stressors during training and testing activities. Species-specific Level B take estimates are as follows: 57 humpback whales (Central North Pacific and California/Oregon/Washington stocks); 11 blue whales (Eastern North Pacific stock); 61 fin whales (Northeast Pacific and California/Oregon/Washington stocks); 2 sei whales (Eastern North Pacific stock); 36 minke whales (Alaska and California/Oregon/Washington stocks); and 18 gray whales (Eastern North Pacific and Western North Pacific stocks). Based on the distribution information presented in the LOA application, it is highly unlikely that North Pacific right whales would be encountered in the Study Area during events involving use of sonar and other active acoustic sources. The acoustic analysis did not predict any takes of North Pacific right whales, and NMFS is not authorizing any takes of this species. Of these species, humpback, blue, fin, and sei whales are currently listed as endangered under the ESA and depleted under the MMPA. ESA-listed humpback whales in the Study Area were proposed as a threatened Central America Distinct Population Segment and unlisted Distinct Population Segments on April 21, 2015 (80 FR 22304).

These exposure estimates represent a limited number of takes relative to population estimates for all mysticete stocks in the Study Area. When the numbers of behavioral takes are compared to the estimated stock abundance and if one assumes that each take happens to a separate animal, less than 20 percent of each of these stocks would be behaviorally harassed during the course of a year. Because the estimates given above represent the total number of exposures and not necessarily the number of individuals exposed, it is more likely that fewer individuals would be taken, but a subset would be taken more than one time per year. In the ocean, the use of sonar and other active acoustic sources is transient and is unlikely to repeatedly expose the same population of animals over a short period. Around heavily trafficked Navy ports and on fixed ranges, the possibility is greater for animals that are resident during all or part of the year to be exposed multiple times to sonar and other active acoustic sources. However, as discussed in the proposed rule, because neither the vessels nor the animals are stationary, significant long-term effects from repeated exposure are not expected.

Level B harassment takes are anticipated to be in the form of TTS and behavioral reactions and no injurious

takes of humpback, blue, fin, minke, gray, or sei whales from sonar and other active acoustic stressors or explosives are expected. The majority of acoustic effects to mysticetes from sonar and other active sound sources during training activities would be primarily from anti-submarine warfare events involving surface ships and hull mounted sonar. Research and observations show that if mysticetes are exposed to sonar or other active acoustic sources they may react in a number of ways depending on the characteristics of the sound source, their experience with the sound source, and whether they are migrating or on seasonal grounds (*i.e.,* breeding or feeding). Reactions may include alerting, breaking off feeding dives and surfacing, diving or swimming away, or no response at all (Richardson, 1995; Nowacek, 2007; Southall *et al.,* 2007; Finneran and Jenkins, 2012). Richardson *et al.* (1995) noted that avoidance (temporary displacement of an individual from an area) reactions are the most obvious manifestations of disturbance in marine mammals. Avoidance is qualitatively different from the startle or flight response, but also differs in the magnitude of the response (*i.e.,* directed movement, rate of travel, etc.). Oftentimes avoidance is temporary, and animals return to the area once the noise has ceased. Additionally, migrating animals may ignore a sound source, or divert around the source if it is in their path.

Specific to U.S. Navy systems using low frequency sound, studies were undertaken in 1997–98 pursuant to the Navy's Low Frequency Sound Scientific Research Program. These studies found only short-term responses to low frequency sound by mysticetes (fin, blue, and humpback whales) including changes in vocal activity and avoidance of the source vessel (Clark, 2001; Miller *et al.,* 2000; Croll *et al.,* 2001; Fristrup *et al.,* 2003; Nowacek *et al.,* 2007). Baleen whales exposed to moderate low-frequency signals demonstrated no variation in foraging activity (Croll *et al.,* 2001). Low-frequency signals of the Acoustic Thermometry of Ocean Climate sound source were not found to affect dive times of humpback whales in Hawaiian waters (Frankel and Clark, 2000).

Specific to mid-frequency sound, studies by Melcón *et al.* (2012) in the Southern California Bight found that the likelihood of blue whale low-frequency calling (usually associated with feeding behavior) decreased with an increased level of MFAS, beginning at a SPL of approximately 110–120 dB re 1 µPa. However, it is not known whether the lower rates of calling actually indicated a reduction in feeding behavior or social contact since the study used data from remotely deployed, passive acoustic monitoring buoys. Preliminary results from the 2010–2011 field season of an ongoing behavioral response study in Southern California waters indicated that in some cases and at low received levels, tagged blue whales responded to MFAS but that those responses were mild and there was a quick return to their baseline activity (Southall *et al.,* 2012b). Blue whales responded to a mid-frequency sound source, with a source level between 160 and 210 dB re 1 µPa at 1 m and a received sound level up to 160 dB re 1 µPa, by exhibiting generalized avoidance responses and changes to dive behavior during the exposure experiments (CEE) (Goldbogen *et al.,* 2013). However, reactions were not consistent across individuals based on received sound levels alone, and likely were the result of a complex interaction between sound exposure factors such as proximity to sound source and sound type (MFAS simulation vs. pseudo-random noise), environmental conditions, and behavioral state. Surface feeding whales did not show a change in behavior during CEEs, but deep feeding and non-feeding whales showed temporary reactions that quickly abated after sound exposure. Distances of the sound source from the whales during CEEs were sometimes less than a mile. Blue whales have been documented exhibiting a range of foraging strategies for maximizing feeding dependent on the density of their prey at a given location (Goldbogen *et al.,* 2015), so it may be that a temporary behavioral reaction or avoidance of a location where feeding was occurring is not meaningful to the life history of an animal. The preliminary findings from Goldbogen *et al.* (2013) and Melcón *et al.* (2012) are generally consistent with the Navy's criteria and thresholds for predicting behavioral effects to mysticetes from sonar and other active acoustic sources used in the quantitative acoustic effects analysis for NWTT. The Navy's behavioral response function predicts the probability of a behavioral response that rises to a Level B take for individuals exposed to a received SPL of 120 dB re 1 µPa or greater, with an increasing probability of reaction with increased received level as demonstrated in Melcón *et al.* (2012).

High-frequency systems are notably outside of mysticetes' ideal hearing and vocalization range and it is unlikely that they would cause a significant behavioral reaction.

Most Level B harassments to mysticetes from sonar in the Study Area would result from received levels less than 156 dB SPL (Table 19). Therefore, the majority of Level B takes are expected to be in the form of milder responses (*i.e.,* lower-level exposures that still rise to the level of take, but would likely be less severe in the range of responses that qualify as take) of a generally short duration. As mentioned earlier in the Analysis and Negligible Impact Determination section, we anticipate more severe effects from takes when animals are exposed to higher received levels. Most low-frequency (mysticetes) cetaceans observed in studies usually avoided sound sources at levels of less than or equal to 160 dB re 1µPa. Occasional milder behavioral reactions are unlikely to cause long-term consequences for individual animals or populations. Even if sound exposure were to be concentrated in a relatively small geographic area over a long period of time (*e.g.,* days or weeks during major training exercises), we would expect that some individual whales would avoid areas where exposures to acoustic stressors are at higher levels. For example, Goldbogen *et al.* (2013) indicated some horizontal displacement of deep foraging blue whales in response to simulated MFA sonar. Given these animal's mobility and large ranges, we would expect these individuals to temporarily select alternative foraging sites nearby until the exposure levels in their initially selected foraging area have decreased. Therefore, even temporary displacement from initially selected foraging habitat is not expected to impact the fitness of any individual animals because we would expect equivalent foraging to be available in close proximity. Because we do not expect any fitness consequences from any individual animals, we do not expect any population level effects from these behavioral responses.

As explained above, recovery from a threshold shift (TTS) can take a few minutes to a few days, depending on the exposure duration, sound exposure level, and the magnitude of the initial shift, with larger threshold shifts and longer exposure durations requiring longer recovery times (Finneran *et al.,* 2005; Finneran and Schlundt, 2010; Mooney *et al.,* 2009a; Mooney *et al.,* 2009b). However, large threshold shifts are not anticipated for these activities because of the unlikelihood that animals will remain within the ensonified area (due to the short duration of the majority of exercises, the speed of the vessels, and the short distance within which the animal would need to

approach the sound source) at high levels for the duration necessary to induce larger threshold shifts. Threshold shifts do not necessarily affect all hearing frequencies equally, so some threshold shifts may not interfere with an animal's hearing of biologically relevant sounds. Furthermore, the implementation of mitigation and the sightability of mysticetes (due to their large size) reduces the potential for a significant behavioral reaction or a threshold shift to occur.

There is no designated critical habitat for mysticetes in the NWTT Study Area. There are also no known specific breeding or calving areas for mysticete species within the Study Area. Some biologically-important seasonal feeding and migration areas for mysticetes (Northern Puget Sound Feeding Area for gray whales; Northwest Feeding Area for gray whales; Northbound Migration Phase A for gray whales; Northbound Migration Phase B for gray whales; Northern Washington Feeding Area for humpback whales; Stonewall and Heceta Bank Feeding Area for humpback whales; and Point St. George Feeding Area for humpback whales (Calambokidis *et al.,* 2015) overlap slightly with portions of the Study Area (see Figures 3.4–3–3.4–5 of the NWTT FEIS/OEIS). However, the Navy and NMFS conducted an assessment of these known biologically important areas (compiled and designated as BIAs in Van Parijs *et al.,* 2015) for humpback whales and gray whales against areas where most Navy acoustic activities (including those that involve ASW hull-mounted sonar, sonobuoys, and use of explosive munitions) have historically occurred or are proposed in the Study Area for 2015–2020 and identified that there is generally limited to no spatial overlap. Refer to the *Consideration of Time/Area Limitations* section within this final rule for a detailed assessment of the potential spatial and activity overlap with these gray and humpback whale feeding areas. NMFS and the Navy (see Chapter 3.4.3 of the NWTT FEIS/OEIS) have fully considered any potential impacts from Navy training and testing activities on a given BIA and have determined that the overall risk to species in these areas is extremely low or biologically insignificant, in part due to the generally infrequent, temporally and spatially variable, and extreme offshore nature of sonar-related activities and sound propagation relative to the more coastally distributed biologically important areas; the probability that propagated receive levels within these areas would be relatively low in terms of behavioral criteria (Debich *et al.,* 2014; U.S. Department of the Navy, 2013d); the likelihood of TTS or PTS sound levels being extremely low; and the overall application of Navy mitigation procedures for marine mammals sighted within prescribed mitigation zones if such activities were to occur near these areas. Thus, Navy training and testing activities using sonar and other active acoustic sources and explosives are unlikely to have an adverse effect on the ability of gray and humpback whales to engage in those activities for which the BIAs have been identified (feeding or migration).

The potential for the most overlap between Navy activities and the gray and humpback feeding areas will be in the following three feeding areas—the Humpback Whale Northern Washington feeding area, Stonewall Heceta Bank feeding area, and the Gray Whale Northern Puget Sound feeding area. As described in the Navy's and NMFS' analysis discussed in the *Consideration of Time/Area Limitations* section of this rule, though, very few takes are expected to result from activities within these feeding areas, and the nature of these activities along with the proposed mitigation measures would result in the least practicable adverse impacts on the species and their habitat. However, the Navy has agreed to monitor, and provide NMFS with reports of, hull-mounted mid-frequency and high frequency active sonar use during training and testing in the months specified in the following three feeding areas to the extent that active sonar training or testing does occur in these feeding areas: Humpback Whale Northern Washington feeding area (May through November); Stonewall and Heceta Bank feeding area (May through November) and Gray Whale Northern Puget Sound Feeding Area (March through May). The Navy will provide this information annually in the classified exercise report to the extent sonar use in those areas can be distinguished from data retrieved in Navy's system. The intent would be to inform future adaptive management discussions about future mitigation adjustments should sonar use increase above the existing low use/low overlap description provided by the Navy or if new science provides a biological basis for increased protective measures. If additional biologically important areas are identified by NMFS after finalization of this rule and the Navy's NWTT EIS/OEIS, the Navy and NMFS will use the Adaptive Management process to assess whether any additional mitigation should be considered in those areas.

Finally, the Navy has previously affirmed that it is not conducting nor is it proposing to conduct training with mid-frequency active hull-mounted sonar on vessels while underway in Puget Sound and the Strait of Juan de Fuca. The Navy's process since 2003 requires approval prior to operating mid-frequency active hull-mounted sonar in Puget Sound and the Strait of Juan de Fuca. The Navy will continue the permission and approval process, in place since 2003, through U.S. Pacific Fleet's designated authority for all mid-frequency active hull-mounted sonar on vessels while training underway in Puget Sound and Strait of Juan de Fuca. Pierside maintenance/testing of sonar systems within Puget Sound and the Strait of Juan de Fuca will also require approval by U.S. Pacific Fleet's designated authority or Systems Command designated authority as applicable, and must be conducted in accordance with PMAP for ship and submarine active sonar use, to include the use of Lookouts. The use of active sonar for anti-terrorism/force protection or for safe navigation within the Puget Sound or Strait of Juan de Fuca is always permitted for safety of ship/national security reasons. These mitigation measures are incorporated within this final rule and continue to minimize sonar use within these areas.

There has never been a recorded vessel strike of a mysticete whale during any active training or testing activities in the Study Area. A detailed analysis of strike data is contained in Chapter 6 (Section 6.7, Estimated Take of Large Whales by Navy Vessel Strike) of the LOA application. The Navy and NMFS do not anticipate vessel strikes to any marine mammals during training or testing activities within the Study Area, nor were takes by injury or mortality resulting from vessel strike predicted in the Navy's analysis. Therefore, NMFS is not authorizing mysticete takes (by injury or mortality) from vessel strikes during the 5-year period of the NWTT regulations.

Sperm Whales—The Navy's acoustic analysis predicts that 159 instances of Level B harassment of sperm whales (California/Oregon/Washington stock) may occur in the Study Area each year from sonar or other active acoustic stressors during training and testing activities. These Level B takes are anticipated to be in the form of TTS and behavioral reactions and no injurious takes of sperm whales from sonar and other active acoustic stressors or explosives are requested or proposed for authorization. Sperm whales have shown resilience to acoustic and human disturbance, although they may react to

sound sources and activities within a few kilometers. Sperm whales that are exposed to activities that involve the use of sonar and other active acoustic sources may alert, ignore the stimulus, avoid the area by swimming away or diving, or display aggressive behavior (Richardson, 1995; Nowacek, 2007; Southall *et al.,* 2007; Finneran and Jenkins, 2012). Some (but not all) sperm whale vocalizations might overlap with the MFAS/HFAS TTS frequency range, which could temporarily decrease an animal's sensitivity to the calls of conspecifics or returning echolocation signals. However, as noted previously, NMFS does not anticipate TTS of a long duration or severe degree to occur as a result of exposure to MFAS/HFAS. Recovery from a threshold shift (TTS) can take a few minutes to a few days, depending on the exposure duration, sound exposure level, and the magnitude of the initial shift, with larger threshold shifts and longer exposure durations requiring longer recovery times (Finneran *et al.,* 2005; Mooney *et al.,* 2009a; Mooney *et al.,* 2009b; Finneran and Schlundt, 2010). Large threshold shifts are not anticipated for these activities because of the unlikelihood that animals will remain within the ensonified area (due to the short duration of the majority of exercises, the speed of the vessels, and the short distance within which the animal would need to approach the sound source) at high levels for the duration necessary to induce larger threshold shifts. Threshold shifts do not necessarily affect all hearing frequencies equally, so some threshold shifts may not interfere with an animal's hearing of biologically relevant sounds. No sperm whales are predicted to be exposed to MFAS/HFAS sound levels associated with PTS or injury.

The majority of Level B takes are expected to be in the form of mild responses (low-level exposures) and of a generally short duration. Relative to the population size, this activity is anticipated to result only in a limited number of Level B harassment takes. When the number of behavioral takes is compared to the estimated stock abundance and if one assumes that each take happens to a separate animal, less than 8 percent of the California/Oregon/Washington stock would be behaviorally harassed during the course of a year. Because the estimates given above represent the total number of exposures and not necessarily the number of individuals exposed, it is more likely that fewer individuals would be taken, but a subset would be taken more than one time per year. In the ocean, the use of sonar and other active acoustic sources is transient and is unlikely to repeatedly expose the same population of animals over a short period. Around heavily trafficked Navy ports and on fixed ranges, the possibility is greater for animals that are resident during all or part of the year to be exposed multiple times to sonar and other active acoustic sources. However, as discussed in the proposed rule, because neither the vessels nor the animals are stationary, significant long-term effects from repeated exposure are not expected. Overall, the number of predicted behavioral reactions are unlikely to cause long-term consequences for individual animals or populations. The NWTT activities are not expected to occur in an area/time of specific importance for reproductive, feeding, or other known critical behaviors for sperm whales. Consequently, the activities are not expected to adversely impact annual rates of recruitment or survival of sperm whales. Sperm whales are listed as depleted under the MMPA and endangered under the ESA; however, there is no designated critical habitat in the Study Area.

There has never been a recorded vessel strike of a sperm whale during any active training or testing activities in the Study Area. A detailed analysis of strike data is contained in Chapter 6 (Section 6.7, Estimated Take of Large Whales by Navy Vessel Strike) of the LOA application. The Navy and NMFS do not anticipate vessel strikes to any marine mammals during training or testing activities within the Study Area, nor were takes by injury or mortality resulting from vessel strikes predicted in the Navy's analysis. Therefore, NMFS is not authorizing sperm whale takes (by injury or mortality) from vessel strikes during the 5-year period of the NWTT regulations.

Porpoises—The Navy's acoustic analysis predicts that 15,087 instances of Level B harassment of Dall's porpoises (Alaska and California/Oregon/Washington stocks) and 138,298 instances of Level B harassment of harbor porpoises (Southeast Alaska, Northern Oregon/Washington Coast, Northern California/Southern Oregon, and Washington Inland Waters stocks) (mainly non-TTS behavioral harassment) may occur each year from sonar and other active acoustic stressors and explosives associated with training and testing activities in the Study Area. These estimates represent the total number of exposures and not necessarily the number of individuals exposed, as a single individual may be exposed multiple times over the course of a year. Behavioral responses can range from a mild orienting response, or a shifting of attention, to flight and panic (Richardson, 1995; Nowacek, 2007; Southall *et al.,* 2007).

Acoustic analysis (factoring in the post-model correction for avoidance and mitigation) also predicted that 47 Dall's porpoises and 45 harbor porpoises might be exposed to sound levels likely to result in PTS or injury (Level A harassment) from mainly sonar and other active acoustic stressors; only 2 level A takes are predicted to Dall's porpoise from explosives. In the case of all explosive exercises, it is worth noting that the amount of explosive and acoustic energy entering the water, and therefore the effects on marine mammals, may be overestimated, as many explosions actually occur upon impact with above-water targets—nonetheless, here we analyze the effects of the takes authorized. However, sources such as these were modeled as exploding at 1-meter depth. Furthermore, in the case of all explosive exercises, the exclusion zones are considerably larger than the estimated distance at which an animal would be exposed to injurious sounds or pressure waves. Furthermore, in the case of all explosive exercises, the exclusion zones are considerably larger than the estimated distance at which an animal would be exposed to injurious sounds or pressure waves. When the numbers of takes for Dall's porpoise are compared to the estimated stock abundances and if one assumes that each take happens to a separate animal, approximately 33 percent of the Alaska stock and less than 2 percent of the California/Oregon/Washington stock would be harassed (behaviorally) during the course of a year. Because the estimates given above represent the total number of exposures and not necessarily the number of individuals exposed, it is more likely that fewer individuals would be taken, but a subset would be taken more than one time per year.

The number of harbor porpoises—in particular, Northern Oregon/Washington Coast and Northern California/Southern Oregon stocks—behaviorally harassed by exposure to MFAS/HFAS in the Study Area is higher than the other species (and, in fact, suggests that every member of the stock could potentially be taken by Level B harassment multiple times, although it is more likely that fewer individuals are harassed but a subset are harassed more than one time during the course of the year). This is due to the low Level B harassment threshold (we assume for the purpose of estimating take that all harbor porpoises exposed to

120 dB or higher MFAS/HFAS will be taken by Level B behavioral harassment), which essentially makes the ensonified area of effects significantly larger than for the other species. However, the fact that the threshold is a step function and not a curve (and assuming uniform density) means that the vast majority of the takes occur in the very lowest levels that exceed the threshold (it is estimated that approximately 80 percent of the takes are from exposures to 120 dB–126 dB), which means that anticipated behavioral effects are not expected to be severe (*e.g.,* temporary avoidance). As mentioned above, an animal's exposure to a higher received level is more likely to result in a behavioral response that is more likely to adversely affect the health of an animal.

Animals that do experience hearing loss (TTS or PTS) may have reduced ability to detect relevant sounds such as predators, prey, or social vocalizations. Some porpoise vocalizations might overlap with the MFAS/HFAS TTS frequency range (2–20 kHz). Recovery from a threshold shift (TTS; partial hearing loss) can take a few minutes to a few days, depending on the exposure duration, sound exposure level, and the magnitude of the initial shift, with larger threshold shifts and longer exposure durations requiring longer recovery times (Finneran *et al.,* 2005; Mooney *et al.,* 2009a; Mooney *et al.,* 2009b; Finneran and Schlundt, 2010). More severe shifts may not fully recover and thus would be considered PTS. However, large degrees of PTS are not anticipated for these activities because of the unlikelihood that animals will remain within the ensonified area (due to the short duration of the majority of exercises, the speed of the vessels, and the short distance within which the animal would need to approach the sound source) at high levels for the duration necessary to induce larger threshold shifts. Threshold shifts do not necessarily affect all hearing frequencies equally, so some threshold shifts may not interfere with an animal hearing biologically relevant sounds. The likely consequences to the health of an individual that incurs PTS can range from mild to more serious, depending upon the degree of PTS and the frequency band it is in, and many animals are able to compensate for the shift, although it may include energetic costs. Furthermore, likely avoidance of intense activity and sound coupled with mitigation measures would further reduce the potential for severe PTS exposures to occur. If a marine mammal is able to approach a surface vessel within the distance necessary to incur PTS, the likely speed of the vessel (nominal 10–15 knots) would make it very difficult for the animal to remain in range long enough to accumulate enough energy to result in more than a mild case of PTS.

Harbor porpoises have been observed to be especially sensitive to human activity (Tyack *et al.,* 2011; Pirotta *et al.,* 2012). The information currently available regarding harbor porpoises suggests a very low threshold level of response for both captive (Kastelein *et al.,* 2000; Kastelein *et al.,* 2005) and wild (Johnston, 2002) animals. Southall *et al.* (2007) concluded that harbor porpoises are likely sensitive to a wide range of anthropogenic sounds at low received levels (~ 90 to 120 dB). Research and observations of harbor porpoises for other locations show that this small species is wary of human activity and will display profound avoidance behavior for anthropogenic sound sources in many situations at levels down to 120 dB re 1 µPa (Southall, 2007). Harbor porpoises routinely avoid and swim away from large motorized vessels (Barlow *et al.,* 1988; Evans *et al.,* 1994; Palka and Hammond, 2001; Polacheck and Thorpe, 1990). The vaquita, which is closely related to the harbor porpoise in the Study Area, appears to avoid large vessels at about 2,995 ft. (913 m) (Jaramillo-Legorreta *et al.,* 1999). The assumption is that the harbor porpoise would respond similarly to large Navy vessels, possibly prior to commencement of sonar or explosive activity (*i.e.,* pre-activity avoidance). Harbor porpoises may startle and temporarily leave the immediate area of the training or testing until after the event ends. Since a large proportion of training and testing activities occur within harbor porpoise habitat in the Study Area and given their very low behavioral threshold, predicted effects are more likely than with most other odontocetes, especially at closer ranges (within a few kilometers). Since this species is typically found in nearshore and inshore habitats, resident animals that are present throughout the Study Area could receive multiple exposures over a short period of time year round. As mentioned earlier in the Analysis and Negligible Impact Determination section, we anticipate more severe effects from takes when animals are exposed to higher received levels. Animals that do not exhibit a significant behavioral reaction would likely recover from any incurred costs, which reduces the likelihood of long-term consequences, such as reduced fitness, for the individual or population.

ASW training and testing exercises using MFAS/HFAS generally last for 2–16 hours, and may have intervals of non-activity in between. In addition, the Navy does not typically conduct ASW exercises in the same locations. Given the average length of ASW exercises (times of continuous sonar use) and typical vessel speed, combined with the fact that the majority of the harbor porpoises in the Study Area would not likely remain in an area for successive days, it is unlikely that an animal would be exposed to MFAS/HFAS at levels likely to result in a substantive response (*e.g.,* interruption of feeding) that would then be carried on for more than one day or on successive days. Thompson *et al.* (2013) showed that seismic surveys conducted over a 10-day period in the North Sea did not result in the broad-scale displacement of harbor porpoises away from preferred habitat. The harbor porpoises were observed to leave the area at the onset of survey, but returned within a few hours, and the overall response of the porpoises decreased over the 10-day period.

The harbor porpoise is a common species in the nearshore coastal waters of the Study Area year-round (Barlow, 1988; Green *et al.,* 1992; Osmek *et al.,* 1996, 1998; Forney and Barlow, 1998; Carretta *et al.,* 2009). Since 1999, Puget Sound Ambient Monitoring Program data and stranding data documented increasing numbers of harbor porpoise in Puget Sound, indicating that the species may be returning to the area (Nysewander, 2008; Washington Department of Fish and Wildlife, 2008; Jeffries, 2013a). Sightings in northern Hood Canal (north of the Hood Canal Bridge) have increased in recent years (Calambokidis, 2010). Harbor porpoise continue to inhabit the waters of Hood Canal (including Dabob Bay), which has for decades served as the location for training and testing events using sonar and other active acoustic sources.

Considering the information above, the predicted effects to Dall's and harbor porpoises are unlikely to cause long-term consequences for individual animals or the population. The NWTT activities are not expected to occur in an area/time of specific importance for reproductive, feeding, or other known critical behaviors for Dall's and harbor porpoises. Pacific stocks of Dall's and harbor porpoises are not listed as depleted under the MMPA. Consequently, the activities are not expected to adversely impact annual rates of recruitment or survival of porpoises.

Pygmy and Dwarf Sperm Whales (Kogia spp.)—Due to the difficulty in differentiating these two species at sea, an estimate of the effects on the two species have been combined. The Navy's acoustic analysis predicts that 179 instances of Level B harassment (TTS and behavioral reaction) of the California/Oregon/Washington stock of *Kogia* spp. may occur each year from sonar and other active acoustic stressors associated with training and testing activities in the Study Area. The Navy's acoustics analysis (factoring in the post-model correction for avoidance and mitigation) also indicates that 1 exposure of *Kogia* to sound levels from non-impulsive acoustic sources likely to result in level A harassment (PTS) may occur during testing activities in the Study Area. Relative to population size these likely represent only a limited number of takes if one assumes that each take happens to a separate animal. Because the estimates given above represent the total number of exposures and not necessarily the number of individuals exposed, it is more likely that fewer individuals would be taken, but a subset would be taken more than one time per year.

Recovery from a threshold shift (TTS; partial hearing loss) can take a few minutes to a few days, depending on the exposure duration, sound exposure level, and the magnitude of the initial shift, with larger threshold shifts and longer exposure durations requiring longer recovery times (Finneran *et al.,* 2005; Mooney *et al.,* 2009a; Mooney *et al.,* 2009b; Finneran and Schlundt, 2010). An animal incurring PTS would not fully recover. However, large degrees of threshold shifts (PTS or TTS) are not anticipated for these activities because of the unlikelihood that animals will remain within the ensonified area (due to the short duration of the majority of exercises, the speed of the vessels, and the short distance within which the animal would need to approach the sound source) at high levels for the duration necessary to induce larger threshold shifts. Threshold shifts do not necessarily affect all hearing frequencies equally, so some threshold shifts may not interfere with an animal hearing biologically relevant sounds. The likely consequences to the health of an individual that incurs PTS can range from mild to more serious, depending upon the degree of PTS and the frequency band it is in, and many animals are able to compensate for the shift, although it may include energetic costs. Furthermore, likely avoidance of intense activity and sound coupled with mitigation measures would further reduce the potential for more-severe PTS exposures to occur. If a pygmy or dwarf sperm whale is able to approach a surface vessel within the distance necessary to incur PTS, the likely speed of the vessel (nominal 10–15 knots) would make it very difficult for the animal to remain in range long enough to accumulate enough energy to result in more than a mild case of PTS.

Some *Kogia* spp. vocalizations might overlap with the MFAS/HFAS TTS frequency range (2–20 kHz), but the limited information for *Kogia* spp. indicates that their clicks are at a much higher frequency and that their maximum hearing sensitivity is between 90 and 150 kHz.

Research and observations on *Kogia* spp. are limited. These species tend to avoid human activity and presumably anthropogenic sounds. Pygmy and dwarf sperm whales may startle and leave the immediate area of activity, reducing potential impacts. Pygmy and dwarf sperm whales have been observed to react negatively to survey vessels or low altitude aircraft by quick diving and other avoidance maneuvers, and none were observed to approach vessels (Wursig *et al.,* 1998). Based on their tendency to avoid acoustic stressors (*e.g.,* quick diving and other vertical avoidance maneuvers) coupled with the short duration and intermittent nature (*e.g.,* sonar pings during ASW activities occur about every 50 seconds) of the majority of training and testing exercises and the speed of the Navy vessels involved, it is unlikely that animals would receive multiple exposures over a short period of time, allowing animals to recover lost resources (*e.g.,* food) or opportunities (*e.g.,* mating).

The predicted effects to *Kogia* spp. are predominantly temporary, and effects are unlikely to cause long-term consequences for individual animals or populations. The NWTT activities are not expected to occur in an area/time of specific importance for reproductive, feeding, or other known critical behaviors. Pacific stocks of *Kogia* are not depleted under the MMPA. Consequently, the activities are not expected to adversely impact annual rates of recruitment or survival of pygmy and dwarf sperm whales.

Beaked Whales—The Navy's acoustic analysis predicts that the following numbers of Level B harassment of beaked whales may occur annually from sonar and other active acoustic stressors associated with training and testing activities in the Study Area: 765 Baird's beaked whales (California/Oregon/Washington and Alaska stocks), 459 Cuvier's beaked whales (California/Oregon/Washington and Alaska stocks), and 1,786 *Mesoplodon* beaked whales (California/Oregon/Washington stock). These estimates represent the total number of exposures and not necessarily the number of individuals exposed, as a single individual may be exposed multiple times over the course of a year. These takes are anticipated to be in the form of behavioral harassment (TTS and behavioral reaction) and no injurious takes of beaked whales from active acoustic stressors or explosives are requested or proposed. When the numbers of behavioral takes are compared to the estimated stock abundances and if one assumes that each take happens to a separate animal, less than 6 percent of the California/Oregon/Washington stock of Cuvier's beaked whale would be behaviorally harassed during the course of a year (stock abundance for the Alaska stock is unknown). Because the estimates given above represent the total number of exposures and not necessarily the number of individuals exposed, it is more likely that fewer individuals would be taken, but a subset would be taken more than one time per year.

Virtually all of the Baird's and *Mesoplodon* beaked whale stocks (California/Oregon/Washington) would potentially be behaviorally harassed each year, although it is more likely that fewer individuals would be harassed but a subset would be harassed more than one time during the course of the year. As is the case with harbor porpoises, beaked whales have been shown to be particularly sensitive to sound and therefore have been assigned a lower harassment threshold based on observations of wild animals by McCarthy *et al.* (2011) and Tyack *et al.* (2011). The fact that the Level B harassment threshold is a step function (The Navy has adopted an unweighted 140 dB re 1 μPa SPL threshold for significant behavioral effects for all beaked whales) and not a curve (and assuming uniform density) means that the vast majority of the takes occur in the very lowest levels that exceed the threshold (it is estimated that approximately 80 percent of the takes are from exposures to 140 dB to 146 dB), which means that the anticipated effects for the majority of exposures are not expected to be severe (As mentioned above, an animal's exposure to a higher received level is more likely to result in a behavioral response that is more likely to adversely affect the health of an animal). Further, Moretti *et al.* (2014) recently derived an empirical risk function for Blainville's beaked whale that predicts there is a 0.5 probability of

disturbance at a received level of 150 dB (CI: 144–155), suggesting that in some cases the current Navy step function may over-estimate the effects of an activity using sonar on beaked whales. Irrespective of the Moretti *et al.* (2014) risk function, NMFS' analysis assumes that all of the beaked whale Level B takes that are proposed for authorization will occur, and we base our negligible impact determination, in part, on the fact that these exposures would mainly occur at the very lowest end of the 140-dB behavioral harassment threshold where behavioral effects are expected to be much less severe and generally temporary in nature.

Behavioral responses can range from a mild orienting response, or a shifting of attention, to flight and panic (Richardson, 1995; Nowacek, 2007; Southall *et al.,* 2007; Finneran and Jenkins, 2012). Research has also shown that beaked whales are especially sensitive to the presence of human activity (Tyack *et al.,* 2011; Pirotta *et al.,* 2012). Beaked whales have been documented to exhibit avoidance of human activity or respond to vessel presence (Pirotta *et al.,* 2012). Beaked whales were observed to react negatively to survey vessels or low altitude aircraft by quick diving and other avoidance maneuvers, and none were observed to approach vessels (Wursig *et al.,* 1998). Some beaked whale vocalizations may overlap with the MFAS/HFAS TTS frequency range (2–20 kHz); however, as noted above, NMFS does not anticipate TTS of a serious degree or extended duration to occur as a result of exposure to MFA/HFAS. Recovery from a threshold shift (TTS) can take a few minutes to a few days, depending on the exposure duration, sound exposure level, and the magnitude of the initial shift, with larger threshold shifts and longer exposure durations requiring longer recovery times (Finneran *et al.,* 2005; Mooney *et al.,* 2009a; Mooney *et al.,* 2009b; Finneran and Schlundt, 2010). Large threshold shifts are not anticipated for these activities because of the unlikelihood that animals will remain within the ensonified area (due to the short duration of the majority of exercises, the speed of the vessels, and the short distance within which the animal would need to approach the sound source) at high levels for the duration necessary to induce larger threshold shifts. Threshold shifts do not necessarily affect all hearing frequencies equally, so some threshold shifts may not interfere with an animal's hearing of biologically relevant sounds.

It has been speculated for some time that beaked whales might have unusual sensitivities to sonar sound due to their likelihood of stranding in conjunction with MFAS use. Research and observations show that if beaked whales are exposed to sonar or other active acoustic sources they may startle, break off feeding dives, and avoid the area of the sound source to levels of 157 dB re 1 µPa, or below (McCarthy *et al.,* 2011). Acoustic monitoring during actual sonar exercises revealed some beaked whales continuing to forage at levels up to 157 dB re 1 µPa (Tyack *et al.* 2011). Stimpert *et al.* (2014) tagged a Baird's beaked whale, which was subsequently exposed to simulated MFAS. Changes in the animal's dive behavior and locomotion were observed when received level reached 127 dB re 1µPa. However, Manzano-Roth *et al.* (2013) found that for beaked whale dives that continued to occur during MFAS activity, differences from normal dive profiles and click rates were not detected with estimated received levels up to 137 dB re 1 µPa while the animals were at depth during their dives. And in research done at the Navy's fixed tracking range in the Bahamas, animals were observed to leave the immediate area of the anti-submarine warfare training exercise (avoiding the sonar acoustic footprint at a distance where the received level was ''around 140 dB'' SPL, according to Tyack *et al.* [2011]) but return within a few days after the event ended (Claridge and Durban, 2009; Moretti *et al.,* 2009, 2010; Tyack *et al.,* 2010, 2011; McCarthy *et al.,* 2011). Tyack *et al.* (2011) report that, in reaction to sonar playbacks, most beaked whales stopped echolocating, made long slow ascent to the surface, and moved away from the sound. A similar behavioral response study conducted in Southern California waters during the 2010–2011 field season found that Cuvier's beaked whales exposed to MFAS displayed behavior ranging from initial orientation changes to avoidance responses characterized by energetic fluking and swimming away from the source (DeRuiter *et al.,* 2013b). However, the authors did not detect similar responses to incidental exposure to distant naval sonar exercises at comparable received levels, indicating that context of the exposures (*e.g.,* source proximity, controlled source ramp-up) may have been a significant factor. The study itself found the results inconclusive and meriting further investigation. Cuvier's beaked whale responses suggested particular sensitivity to sound exposure as consistent with results for Blainville's beaked whale.

Populations of beaked whales and other odontocetes on the Bahamas and other Navy fixed ranges that have been operating for decades, appear to be stable. Behavioral reactions (avoidance of the area of Navy activity) seem likely in most cases if beaked whales are exposed to anti-submarine sonar within a few tens of kilometers, especially for prolonged periods (a few hours or more) since this is one of the most sensitive marine mammal groups to anthropogenic sound of any species or group studied to date and research indicates beaked whales will leave an area where anthropogenic sound is present (Tyack *et al.,* 2011; De Ruiter *et al.,* 2013; Manzano-Roth *et al.,* 2013; Moretti *et al.,* 2014). Research involving tagged Cuvier's beaked whales in the SOCAL Range Complex reported on by Falcone and Schorr (2012, 2014) indicates year-round prolonged use of the Navy's training and testing area by these beaked whales and has documented movements in excess of hundreds of kilometers by some of those animals. Given that some of these animals may routinely move hundreds of kilometers as part of their normal pattern, leaving an area where sonar or other anthropogenic sound is present may have little, if any, cost to such an animal. Photo identification studies in the SOCAL Range Complex, a Navy range that is utilized for training and testing more frequently than the NWTT Study Area, have identified approximately 100 individual Cuvier's beaked whale individuals with 40 percent having been seen in one or more prior years, with re-sightings up to 7 years apart (Falcone and Schorr, 2014). These results indicate long-term residency by individuals in an intensively used Navy training and testing area, which may also suggest a lack of long-term consequences as a result of exposure to Navy training and testing activities. Finally, results from passive acoustic monitoring estimated regional Cuvier's beaked whale densities were higher than indicated by the NMFS's broad scale visual surveys for the U.S. west coast (Hildebrand and McDonald, 2009).

Based on the findings above, it is clear that the Navy's long-term ongoing use of sonar and other active acoustic sources has not precluded beaked whales from also continuing to inhabit those areas. In summary, based on the best available science, the Navy and NMFS believe that beaked whales that exhibit a significant TTS or behavioral reaction due to sonar and other active acoustic testing activities would generally not have long-term consequences for

individuals or populations. Claridge (2013) speculated that sonar use in a Bahamas range could have ''a possible population-level effect'' on beaked whales based on lower abundance in comparison to control sites. In summary, Claridge suggested that lower reproductive rates observed at the Navy's Atlantic Undersea Test and Evaluation Center (AUTEC), when compared to a control site, were due to stressors associated with frequent and repeated use of Navy sonar. It is also important to note that there were some relevant shortcomings of this study. For example, all of the re-sighted whales during the 5-year study at both sites were female, which Claridge acknowledged can lead to a negative bias in the abundance estimation. There was also a reduced effort and shorter overall study period at the AUTEC site that failed to capture some of the emigration/immigration trends identified at the control site. Furthermore, Claridge assumed that the two sites were identical and therefore should have equal potential abundances; when in reality, there were notable physical differences. The author also acknowledged that ''information currently available cannot provide a quantitative answer to whether frequent sonar use at [the Bahamas range] is causing stress to resident beaked whales,'' and cautioned that the outcome of ongoing studies ''is a critical component to understanding if there are population-level effects.'' Moore and Barlow (2013) have noted a decline in beaked whale populations in a broad area of the Pacific Ocean area out to 300 nm from the coast and extending from the Canadian-U.S. border to the tip of Baja Mexico. There are scientific caveats and limitations to the data used for that analysis, as well as oceanographic and species assemblage changes on the U.S. Pacific coast not thoroughly addressed. Although Moore and Barlow (2013) have noted a decline in the overall beaked whale population along the Pacific coast, in the small fraction of that area where the Navy has been training and testing with sonar and other systems for decades (the Navy's SOCAL Range Complex), higher densities and long-term residency by individual Cuvier's beaked whales suggest that the decline noted elsewhere is not apparent where Navy sonar use is most intense. Navy sonar training and testing is not conducted along a large part of the U.S. west coast from which Moore and Barlow (2013) drew their survey data. In Southern California, based on a series of surveys from 2006 to 2008 and a high number encounter rate, Falcone *et al.* (2009) suggested the ocean basin west of San Clemente Island may be an important region for Cuvier's beaked whales given the number of animals encountered there. Follow-up research (Falcone and Schorr, 2012, 2014) in this same location suggests that Cuvier's beaked whales may have population sub-units with higher than expected residency, particularly in the Navy's instrumented Southern California Anti-Submarine Warfare Range. Encounters with multiple groups of Cuvier's and Baird's beaked whales indicated not only that they were prevalent on the range where Navy routinely trains and tests, but also that they were potentially present in much higher densities than had been reported for anywhere along the U.S. west coast (Falcone *et al.,* 2009, Falcone and Schorr, 2012). This finding is also consistent with concurrent results from passive acoustic monitoring that estimated regional Cuvier's beaked whale densities were higher where Navy trains in the SOCAL training and testing area than indicated by NMFS's broad scale visual surveys for the U.S. west coast (Hildebrand and McDonald, 2009).

NMFS also considered New *et al.* (2013) and their mathematical model simulating a functional link between foraging energetics and requirements for survival and reproduction for 21 species of beaked whales. However, NMFS concluded that New *et al.* (2013) model lacks critical data and accurate inputs necessary to form valid conclusions specifically about impacts of anthropogenic sound from Navy activities on beaked whale populations. The study itself notes the need for ''future research,'' identifies ''key data needs'' relating to input parameters that ''particularly affected'' the model results, and states only that the use of the model ''in combination with more detailed research'' *could* help predict the effects of management actions on beaked whale species. In short, information is not currently available to specifically support the use of this model in a project-specific evaluation of the effects of navy activities on the impacted beaked whale species in NWTT.

No beaked whales are predicted in the acoustic analysis to be exposed to sound levels associated with PTS, other injury, or mortality. After decades of the Navy conducting similar activities in the NWTT Study Area without incident, NMFS does not expect strandings, injury, or mortality of beaked whales to occur as a result of training and testing activities. Stranding events coincident with Navy MFAS use in which exposure to sonar is believed to have been a contributing factor were detailed in the Stranding and Mortality section of the proposed rule. However, for some of these stranding events, a causal relationship between sonar exposure and the stranding could not be clearly established (Cox *et al.,* 2006). In other instances, sonar was considered only one of several factors that, in their aggregate, may have contributed to the stranding event (Freitas, 2004; Cox *et al.,* 2006). Because of the association between tactical MFAS use and a small number of marine mammal strandings, the Navy and NMFS have been considering and addressing the potential for strandings in association with Navy activities for years. In addition to a suite of mitigation measures intended to more broadly minimize impacts to marine mammals, the reporting requirements set forth in this rule ensure that NMFS is notified immediately (or as soon as clearance procedures allow) if a stranded marine mammal is found during or shortly after, and in the vicinity of, any Navy training exercise utilizing MFAS, HFAS, or underwater explosive detonations (see General Notification of Injured or Dead Marine Mammals in the regulatory text below). Additionally, through the MMPA process (which allows for adaptive management), NMFS and the Navy will determine the appropriate way to proceed in the event that a causal relationship were to be found between Navy activities and a future stranding.

The NWTT training and testing activities are not expected to occur in an area/time of specific importance for reproductive, feeding, or other known critical behaviors for beaked whales. None of the Pacific stocks for beaked whales species found in the Study Area are depleted under the MMPA. The degree of predicted Level B harassment is expected to be mild, and no beaked whales are predicted in the acoustic analysis to be exposed to sound levels associated with PTS, other injury, or mortality. Consequently, the activities are not expected to adversely impact annual rates of recruitment or survival of beaked whales.

Dolphins and Small Whales—The Navy's acoustic analysis predicts the following numbers of Level B harassment of the associated species of delphinids (dolphins and small whales, excluding killer whales) may occur each year from sonar and other active acoustic sources during training and testing activities in the Study Area: 2,362 short-beaked common dolphins (California/Oregon/Washington stock); 36 striped dolphins (California/Oregon/Washington stock); 8,354 Pacific white-

sided dolphins (California/Oregon/Washington and North Pacific stocks); 3,370 Northern right whale dolphins (California/Oregon/Washington stock); and 1,811 Risso's dolphins (California/Oregon/Washington stock). Based on the distribution information presented in the LOA application, it is highly unlikely that short-finned pilot whales or common bottlenose dolphins would be encountered in the Study Area. The acoustic analysis did not predict any takes of short-finned pilot whales or bottlenose dolphins and NMFS is not authorizing any takes of these species. Relative to delphinid population sizes, these activities are anticipated to generally result only in a limited number of level B harassment takes. When the numbers of behavioral takes are compared to the estimated stock abundance and if one assumes that each take happens to a separate animal, less than 30 percent of the California/Oregon/Washington stock of Risso's dolphin; less than 30 percent of the California/Oregon/Washington stock and less than 0.02 percent of the North Pacific stock of pacific white-sided dolphin; less than 28 percent of the California/Oregon/Washington stock of northern right whale dolphin; less than 0.6 percent of the California/Oregon/Washington stock of short-beaked common dolphin; and less than 0.4 percent of the California/Oregon/Washington stock of striped dolphin would be behaviorally harassed during the course of a year. More likely, slightly fewer individuals are harassed, but a subset are harassed more than one time during the course of the year. Because the estimates given above represent the total number of exposures and not necessarily the number of individuals exposed, it is more likely that fewer individuals would be taken, but a subset would be taken more than one time per year.

All of these takes are anticipated to be in the form of behavioral harassment (TTS and behavioral reaction) and no injurious takes of delphinids from sonar and other active acoustic stressors or explosives are requested or proposed for authorization. Further, the majority of takes are anticipated to be by behavioral harassment in the form of mild responses (low received levels and of a short duration). Behavioral responses can range from alerting, to changing their behavior or vocalizations, to avoiding the sound source by swimming away or diving (Richardson, 1995; Nowacek, 2007; Southall *et al.,* 2007; Finneran and Jenkins, 2012). Delphinid species generally travel in large pods and should be visible from a distance in order to implement mitigation measures and reduce potential impacts. Many of the recorded delphinid vocalizations overlap with the MFAS/HFAS TTS frequency range (2–20 kHz); however, as noted above, NMFS does not anticipate TTS of a serious degree or extended duration to occur as a result of exposure to MFAS/HFAS. Recovery from a threshold shift (TTS) can take a few minutes to a few days, depending on the exposure duration, sound exposure level, and the magnitude of the initial shift, with larger threshold shifts and longer exposure durations requiring longer recovery times (Finneran *et al.,* 2005; Mooney *et al.,* 2009a; Mooney *et al.,* 2009b; Finneran and Schlundt, 2010). Large threshold shifts are not anticipated for these activities because of the unlikelihood that animals will remain within the ensonified area (due to the short duration of the majority of exercises, the speed of the vessels, and the short distance within which the animal would need to approach the sound source) at high levels for the duration necessary to induce larger threshold shifts. Threshold shifts do not necessarily affect all hearing frequencies equally, so some threshold shifts may not interfere with an animal's hearing of biologically relevant sounds.

The predicted effects to delphinids are unlikely to cause long-term consequences for individual animals or populations. The NWTT activities are not expected to occur in an area/time of specific importance for reproductive, feeding, or other known critical behaviors for delphinids. Pacific stocks of delphinid species found in the Study Area are not depleted under the MMPA. Consequently, the activities are not expected to adversely impact annual rates of recruitment or survival of delphinid species.

Killer Whales—The Navy's acoustic analysis predicts 255 instances of Level B harassment of killer whales (Alaska Resident, Northern Resident, West Coast Transient, Eastern North Pacific Offshore, and Eastern North Pacific Southern Resident stocks), including 2 Level B behavioral takes of southern resident killer whales (but no more than 6 over five years), from sonar and other active acoustic sources during annual training activities in the Study Area. Relative to population sizes, these activities are anticipated to generally result only in a limited number of level B harassment takes. When the numbers of behavioral takes are compared to the estimated stock abundance and if one assumes that each take happens to a separate animal, less than 10 percent of all killer whale stocks in the Study Area—and 2 percent of the Southern Resident stock of killer whale—would be behaviorally harassed during the course of a year. More likely, slightly fewer individuals would be harassed, but a subset would be harassed more than one time during the course of the year.

All of these takes are anticipated to be in the form of behavioral harassment (TTS and behavioral reaction) and no injurious takes of killer whales from sonar and other active acoustic stressors or explosives are requested or proposed for authorization. Further, the majority of takes are anticipated to be by behavioral harassment in the form of mild responses. The killer whale's size and detectability makes it unlikely that these animals would be exposed to the higher energy or pressure expected to result in more severe effects. Killer whales generally travel in pods and should be visible from a distance in order to implement mitigation measures and reduce potential impacts.

Research and observations show that if killer whales are exposed to sonar or other active acoustic sources they may react in a number of ways depending on their experience with the sound source and what activity they are engaged in at the time of the acoustic exposure. Killer whales may not react at all until the sound source is approaching within a few hundred meters to within a few kilometers depending on the environmental conditions and species. Killer whales that are exposed to activities that involve the use of sonar and other active acoustic sources may alert, ignore the stimulus, change their behaviors or vocalizations, avoid the sound source by swimming away or diving, or be attracted to the sound source. Research has demonstrated that killer whales may routinely move over long large distances (Andrews and Matkin, 2014; Fearnbach *et al.,* 2013). In a similar documented long-distance movement, an Eastern North Pacific Offshore stock killer whale tagged off San Clemente Island, California, moved (over a period of 147 days) to waters off northern Mexico, then north to Cook Inlet, Alaska, and finally (when the tag ceased transmitting) to coastal waters off Southeast Alaska (Falcone and Schorr, 2014). Given these findings, temporary displacement due to avoidance of training and testing activities are therefore unlikely to have biological significance to individual animals. Long-term consequences to individual killer whales or populations are not likely due to exposure to sonar or other active acoustic sources.

The vocalizations of killer whales fall directly into the frequency range in which TTS would be incurred from the

MFAS sources used during ASW exercises; however, the Navy is conducting ASW exercises mainly in the Offshore Area while killer whales are predominantly situated in the Inland Waters Area. Both behavioral and auditory brainstem response techniques indicate killer whales can hear a frequency range of 1 to 100 kHz and are most sensitive at 20 kHz. This is one the lowest maximum-sensitivity frequencies known among toothed whales (Szymanski *et al.,* 1999). Recovery from a threshold shift (TTS) can take a few minutes to a few days, depending on the exposure duration, sound exposure level, and the magnitude of the initial shift, with larger threshold shifts and longer exposure durations requiring longer recovery times (Finneran *et al.,* 2005; Mooney *et al.,* 2009a; Mooney *et al.,* 2009b; Finneran and Schlundt, 2010). Large threshold shifts are not anticipated for these activities because of the unlikelihood that animals will remain within the ensonified area (due to the short duration of the majority of exercises, the speed of the vessels, and the short distance within which the animal would need to approach the sound source) at high levels for the duration necessary to induce larger threshold shifts. Threshold shifts do not necessarily affect all hearing frequencies equally, so some threshold shifts may not interfere with an animal's hearing of biologically relevant sounds.

The southern resident killer whale is the only ESA-listed marine mammal species with designated critical habitat located in the NWTT Study Area (NMFS, 2006). The majority of the Navy's proposed training and testing activities would, however, not occur in the southern resident killer whale's designated critical habitat (NMFS, 2006). For all substressors that would occur within the critical habitat, those training and testing activities are not expected to impact the identified primary constituent elements of that habitat and therefore would have no effect on that critical habitat. Furthermore, the majority of testing events would occur in Hood Canal, where southern resident killer whales are not believed to be present (southern resident killer whales have not been reported in Hood Canal or Dabob Bay since 1995 [NMFS, 2008c]), while the majority of training activities would occur in the offshore portions of the Study Area where they are only present briefly during their annual migration period.

The predicted effects to southern resident killer whale would occur in the Inland Waters area of Puget Sound as a result of the Civilian Port Defense exercise (Maritime Homeland Defense/Security Mine Countermeasures Integrated Exercise) where they could be exposed to sonar and other active acoustic sources that may result in two behavioral reactions annually. NMFS issued a Biological Opinion concluding that training and testing activities are likely to adversely affect, but are not likely to jeopardize, the continued existence of southern resident killer whale and are not likely to result in the destruction or adverse modification of critical habitat in the NWTT Study Area. As described in the Biological Opinion, the available scientific information does not provide evidence that exposure to acoustic stressors from Navy training and testing activities will impact the fitness of any individuals of this species. Therefore exposure to acoustic stressors will not have population or species level impacts.

The NWTT training and testing activities are generally not expected to occur in an area/time of specific importance for reproductive, feeding, or other known critical behaviors for killer whales. Consequently, the activities are not expected to adversely impact annual rates of recruitment or survival of killer whale species and will therefore not result in population-level impacts. As discussed in the *Area-Specific Mitigation* section of this rule, for Civilian Port Defense exercises (Maritime Homeland Defense/Security Mine Countermeasures Integrated Exercise) the Navy shall conduct pre-event planning and training to ensure environmental awareness of all exercise participants. When this event is proposed to be conducted in Puget Sound, Navy event planners shall consult with Navy biologists who shall contact NMFS during the planning process in order to determine likelihood of southern resident killer whale presence in the proposed exercise area as planners consider specifics of the event.

Pinnipeds—The Navy's acoustic analysis predicts that the following numbers of Level B harassment (TTS and behavioral reaction) may occur annually from sonar and other active acoustic stressors and sound or energy from explosions associated with training and testing activities in the Study Area: 925 Steller sea lions (Eastern U.S. stock); 10 Guadalupe fur seals (Mexico stock); 2,960 California sea lions (U.S. stock); 4,389 northern fur seals (Eastern Pacific and California stocks); 2,596 northern elephant seals (California Breeding stock); and 63,850 harbor seals (Southeast Alaska [Clarence Strait], Oregon/Washington Coast, Washington Northern Inland Waters, Southern Puget Sound, and Hood Canal stocks). These estimates represents the total number of exposures and not necessarily the number of individuals exposed, as a single individual may be exposed multiple times over the course of a year. Northern elephant seals are the only pinnipeds predicted to incur takes (one Level B take) from exposure to explosives. The acoustic analysis (factoring in the post-model correction for avoidance and mitigation) also indicates that 2 Northern elephant seals and 100 harbor seals would be exposed to sound levels likely to result in Level A harassment (PTS) from sonar or other active acoustic sources.

Generally speaking, pinniped stocks in the Study Area are thought to be stable or increasing. Relative to population size, training and testing activities are anticipated to result only in a limited number of takes for the majority of pinniped species. When the numbers of takes are compared to the estimated stock abundances and if one assumes that each take happens to a separate animal, less than 2 percent of each Steller sea lion, California sea lion, northern fur seal, harbor seal (Southeast Alaska [Clarence Strait] only; all other harbor seal stock abundances are unknown), and northern elephant seal stock would be harassed (behaviorally) during the course of a year. Because the estimates given above represent the total number of exposures and not necessarily the number of individuals exposed, it is more likely that fewer individuals would be taken, but a subset would be taken more than one time per year. Takes of depleted (as defined under the MMPA) stocks of northern fur seals (Eastern Pacific) and Guadalupe fur seals (Mexico) represent only 0.7 percent and 0.07 percent of their respective stock.

Research has demonstrated that for pinnipeds, as for other mammals, recovery from a hearing threshold shift (*i.e.,* TTS; temporary partial hearing loss) can take a few minutes to a few days depending on the severity of the initial shift. More severe shifts may not fully recover and thus would be considered PTS. However, large degrees of PTS are not anticipated for these activities because of the unlikelihood that animals will remain within the ensonified area (due to the short duration of the majority of exercises, the speed of the vessels, and the short distance within which the animal would need to approach the sound source) at high levels for the duration necessary to induce larger threshold shifts. Threshold shifts do not necessarily affect all hearing frequencies equally, so threshold shifts may not

necessarily interfere with an animal's ability to hear biologically relevant sounds. The likely consequences to the health of an individual that incurs PTS can range from mild to more serious, depending upon the degree of PTS and the frequency band it is in, and many animals are able to compensate for the shift, although it may include energetic costs. Likely avoidance of intense activity and sound coupled with mitigation measures would further reduce the potential for severe PTS exposures to occur. If a marine mammal is able to approach a surface vessel within the distance necessary to incur PTS, the likely speed of the vessel (nominal 10–15 knots) would make it very difficult for the animal to remain in range long enough to accumulate enough energy to result in more than a mild case of PTS.

Research and observations show that pinnipeds in the water may be tolerant of anthropogenic noise and activity (a review of behavioral reactions by pinnipeds to impulsive and non-impulsive noise can be found in Richardson *et al.,* 1995 and Southall *et al.,* 2007). Available data, though limited, suggest that exposures between approximately 90 and 140 dB SPL do not appear to induce strong behavioral responses in pinnipeds exposed to nonpulse sounds in water (Jacobs and Terhune, 2002; Costa *et al.,* 2003; Kastelein *et al.,* 2006c). Based on the limited data on pinnipeds in the water exposed to multiple pulses (small explosives, impact pile driving, and seismic sources), exposures in the approximately 150 to 180 dB SPL range generally have limited potential to induce avoidance behavior in pinnipeds (Harris *et al.,* 2001; Blackwell *et al.,* 2004; Miller *et al.,* 2004). If pinnipeds are exposed to sonar or other active acoustic sources they may react in a number of ways depending on their experience with the sound source and what activity they are engaged in at the time of the acoustic exposure. Pinnipeds may not react at all until the sound source is approaching within a few hundred meters and then may alert, ignore the stimulus, change their behaviors, or avoid the immediate area by swimming away or diving. Houser *et al.* (2013) performed a controlled exposure study involving California sea lions exposed to a simulated MFAS signal. The purpose of this Navy-sponsored study was to determine the probability and magnitude of behavioral responses by California sea lions exposed to differing intensities of simulated MFAS signals. Behavioral reactions included increased respiration rates, prolonged submergence, and refusal to participate, among others. Younger animals were more likely to respond than older animals, while some sea lions did not respond consistently at any level. Houser *et al.*'s findings are consistent with current scientific studies and criteria development concerning marine mammal reactions to MFAS. Effects on pinnipeds in the Study Area that are taken by Level B harassment, on the basis of reports in the literature as well as Navy monitoring from past activities, will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring). Most likely, individuals will simply move away from the sound source and be temporarily displaced from those areas, or not respond at all. In areas of repeated and frequent acoustic disturbance, some animals may habituate or learn to tolerate the new baseline or fluctuations in noise level. Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.,* 2003). While some animals may not return to an area, or may begin using an area differently due to training and testing activities, most animals are expected to return to their usual locations and behavior. Given their documented tolerance of anthropogenic sound (Richardson *et al.,* 1995 and Southall *et al.,* 2007), repeated exposures of individuals (*e.g.,* harbor seals) to levels of sound that may cause Level B harassment are unlikely to result in hearing impairment or to significantly disrupt foraging behavior. As stated above, pinnipeds may habituate to or become tolerant of repeated exposures over time, learning to ignore a stimulus that in the past has not accompanied any overt threat.

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 to those individuals, and would not result in any adverse impact to the stock as a whole. Evidence from areas where the Navy extensively trains and tests provides some indication of the possible consequences resulting from those proposed activities. In the confined waters of Washington State's Hood Canal where the Navy has been training and intensively testing for decades and harbor seals are present year-round, the population level has remained stable suggesting the area's carrying capacity likely has been reached (Jeffries *et al.,* 2003; Gaydos *et al.,* 2013). Within Puget Sound there are several locations where pinnipeds use Navy structures (*e.g.,* submarines, security barriers) for haulouts. Given that animals continue to choose these areas for their resting behavior, it would appear there are no long-term effects or consequences to those animals as a result of ongoing and routine Navy activities.

NMFS has determined that the Level A and Level B harassment exposures to the Hood Canal stock of harbor seals are not biologically significant to the population because (1) the vast majority of the exposures are within the non-injurious TTS or behavioral effects zones and none of the estimated exposures result in mortality; (2) the majority of predicted harbor seal exposures result from testing activities which are generally of an intermittent or short duration and should prevent animals from being exposed to stressors on a continuous basis; (3) there are no indications that the historically occurring activities resulting in these behavioral harassment exposures are having any effect on this population's survival by altering behavior patterns such as breeding, nursing, feeding, or sheltering; (4) the population has been stable and likely at carrying capacity (Jeffries *et al.,* 2003; Gaydos *et al.,* 2013); (5) the population continues to use known large haulouts in Hood Canal and Dabob Bay that are adjacent to Navy testing and training activities (London *et al.,* 2012); (6) the population continues to use known haulouts for pupping; and (7) the population continues to use the waters in and around Dabob Bay and Hood Canal.

The Guadalupe fur seal is the only ESA-listed pinniped species found within the NWTT Study Area. Guadalupe fur seals are considered ''seasonally migrant'' and are present within the offshore portion of the Study Area during the warm season (summer and early autumn) and during that portion of the year may be exposed to sonar and other active acoustic sources associated with training and testing activities. Predicted Level B takes of Guadalupe fur seals in the Study Area represent a negligible percentage of the Mexico stock. Furthermore, critical habitat has not been designated for Guadalupe fur seals.

We believe that factors described above, as well as the available body of evidence from past Navy activities in the Study Area, demonstrate that the potential effects of the specified activity will have only short-term effects on individuals. The NWTT training and testing activities are not expected to occur in an area/time of specific importance for reproductive, feeding, or

other known critical behaviors for pinnipeds. Consequently, the activities are not expected to adversely impact annual rates of recruitment or survival of pinniped species and will therefore not result in population-level impacts.

Revised Analysis Based on Corrections to Sonar Testing Activities

As discussed earlier in this final rule, the Navy revised the number of hours and the location of sonar use attributed to life cycle pierside sonar testing events already described as occurring at each of the Navy's installations in the Pacific Northwest. The resulting revised predicted exposures (take) calculations for several species as a result of these corrections are depicted in Table 18.

None of the species/stocks that could be affected by life cycle pierside testing events are listed under the ESA. Gray whale and harbor seal densities are somewhat higher in the vicinity of Naval Station Everett (Possession Sound) than they are near NBK—Bremerton (Sinclair Inlet). While gray whales seasonally occur in the vicinity of Naval Station Everett, they are rarely sighted as far inside Puget Sound as NBK—Bremerton. The net change in annual testing effects reflects these environmental differences. However, the net change represents a less than 5 percent increase in predicted annual Level A harassments and a less than 1 percent increase in predicted annual Level B harassments across all sonar and explosive testing activities proposed to occur within the NWTT Study Area.

The species with the most potential for harassment by this correction—Dall's porpoise, Steller sea lions, California sea lions, harbor seals, and harbor porpoise—are all species/stocks with robust, stable populations. All these species/stocks are also predicted to be affected by pierside surface ship sonar maintenance events at Naval Station Everett, and by life cycle pierside sonar testing events at NBK—Bremerton already accounted for in Navy and NMFS analyses. The longer duration of the testing events is predicted to result in 8 Level A harassment exposures of harbor seals; Level A harassment would not be incurred from the shorter duration training events. In addition, the analysis shows that the longer MF1 testing events could result in 1 Level B harassment (by temporary threshold shift [TTS]) of a gray whale. The shorter duration pierside surface ship sonar maintenance training events at Naval Station Everett would not affect this species, and effects to this species were not predicted for life cycle pierside sonar testing at NBK—Bremerton.

As a result of the correction, the gray whale is the only species with predicted effects at Naval Station Everett that was not predicted to have effects at NBK—Bremerton. If a gray whale were to experience a TTS, its hearing sensitivity would only be affected for a short duration of time (a few minutes to a few days), and any effect on its hearing would be in a very narrow bandwidth equivalent to the exposure. Because marine mammals hear over a large range of frequencies, they are likely to be able to compensate for any temporary reduction in sensitivity over a small frequency band. Therefore, TTS is unlikely to affect their ability to carry out necessary life functions (*i.e.,* feeding, breeding, communication), and no long-term effects on their fitness would be expected.

The species with the greatest increase in predicted exposures and for which the only instances of Level A takes are predicted are harbor seals from the Washington Northern Inland Waters stock. The net change in annual testing exposures would not alter the conclusions of the analysis presented above for harbor seals in this section or in the NWTT FEIS/OEIS.

In summary, correcting the number of life cycle pierside sonar testing event hours will result in an insignificant increase in overall Level B and Level A takes of a few species within the NWTT Study Area. All populations are healthy and exposures to sound from these events would be short term (no more than 4 hours) and infrequent (a maximum of 8 times per year). These testing events are qualitatively described in documents released to the public as potentially occurring at both NBK—Bremerton and Naval Station Everett. Furthermore, the testing events are similar to pierside surface ship sonar system maintenance training events using MF1 sonar systems also proposed to occur at Naval Station Everett that were quantitatively analyzed in public documents and pose similar potential effects on marine mammals. Therefore, the addition of life cycle pierside sonar testing events to Naval Station Everett and their associated predicted exposures does not reflect a significant departure from or a substantial change in the nature of activities or environmental effects already analyzed as potentially occurring there, and NMFS concludes that no long-term consequences to or significant impacts on marine mammal species/stocks would be expected.

Long-Term Consequences

The best assessment of long-term consequences from training and testing activities will be to monitor the populations over time within a given Navy range complex. A U.S. workshop on Marine Mammals and Sound (Fitch *et al.,* 2011) indicated a critical need for baseline biological data on marine mammal abundance, distribution, habitat, and behavior over sufficient time and space to evaluate impacts from human-generated activities on long-term population survival. The Navy has developed monitoring plans for protected marine mammals occurring on Navy ranges with the goal of assessing the impacts of training and testing activities on marine species and the effectiveness of the Navy's current mitigation practices. Continued monitoring efforts over time will be necessary to completely evaluate the long-term consequences of exposure to noise sources.

Since 2006 across all Navy Range Complexes (in the Atlantic, Gulf of Mexico, and the Pacific), there have been more than 80 reports; including Major Exercise Reports, Annual Exercise Reports, and Monitoring Reports. For the Pacific since 2011, there have been 29 monitoring and exercise reports (as shown in Table 6–1 of the LOA application) submitted to NMFS to further research goals aimed at understanding the Navy's impact on the environment as it carries out its mission to train and test.

In addition to this multi-year record of reports from across the Navy, there have also been ongoing Behavioral Response Study research efforts (in Southern California and the Bahamas) specifically focused on determining the potential effects from Navy MFAS (Southall *et al.,* 2011, 2012; Tyack *et al.,* 2011; DeRuiter *et al.,* 2013b; Goldbogen *et al.,* 2013; Moretti *et al.,* 2014). This multi-year compendium of monitoring, observation, study, and broad scientific research is informative with regard to assessing the effects of Navy training and testing in general. Given that this record involves many of the same Navy training and testing activities being considered for the Study Area, and because it includes all the marine mammal taxonomic families and many of the same species, this compendium of Navy reporting is directly applicable to the Study Area. Other research findings related to the general topic of long-term impacts are discussed above in the Species/Group Specific Analysis.

Based on the findings from surveys in Puget Sound and research efforts and monitoring before, during, and after

training and testing events across the Navy since 2006, NMFS' assessment is that it is unlikely there would be impacts to populations of marine mammals having any long-term consequences as a result of the proposed continuation of training and testing in the ocean areas historically used by the Navy, including the Study Area. This assessment of likelihood is based on four indicators from areas in the Pacific where Navy training and testing has been ongoing for decades: (1) Evidence suggesting or documenting increases in the numbers of marine mammals present (Calambokidis and Barlow, 2004; Calambokidis *et al.,* 2009a; Falcone *et al.,* 2009; Hildebrand and McDonald, 2009; Berman-Kowalewski *et al.,* 2010; Moore and Barlow, 2011; Barlow *et al.* 2011; Falcone and Shorr, 2012; Kerosky *et al,.* 2012; Širović *et al.,* 2015; Smultea *et al.,* 2013), (2) examples of documented presence and site fidelity of species and long-term residence by individual animals of some species (Hooker *et al.,* 2002; McSweeney *et al.,* 2007; McSweeney *et al.,* 2009; McSweeney *et al.,* 2010; Martin and Kok, 2011; Baumann-Pickering *et al.,* 2012; Falcone and Schorr, 2014), (3) use of training and testing areas for breeding and nursing activities (Littnan, 2010), and (4) 6 years of comprehensive monitoring data indicating a lack of any observable effects to marine mammal populations as a result of Navy training and testing activities.

To summarize, while the evidence covers most marine mammal taxonomic suborders, it is limited to a few species and only suggestive of the general viability of those species in intensively used Navy training and testing areas (Barlow *et al.,* 2011; Calambokidis *et al.,* 2009b; Falcone *et al.,* 2009; Littnan, 2011; Martin and Kok, 2011; McCarthy *et al.,* 2011; McSweeney *et al.,* 2007; McSweeney *et al.,* 2009; Moore and Barlow, 2011; Tyack *et al.,* 2011; Southall *et al.,* 2012a; Melcon, 2012; Goldbogen, 2013; Baird *et al.,* 2013). However, there is no direct evidence that routine Navy training and testing spanning decades has negatively impacted marine mammal populations at any Navy Range Complex. Although there have been a few strandings associated with use of sonar in other locations (see U.S. Department of the Navy, 2013b), Ketten (2012) has recently summarized, ''to date, there has been no demonstrable evidence of acute, traumatic, disruptive, or profound auditory damage in any marine mammal as the result of anthropogenic noise exposures, including sonar.'' Therefore, based on the best available science (Barlow *et al.,* 2011; Falcone *et al.,* 2009; Falcone and Schorr, 2012, 2014; Littnan, 2011; Martin and Kok, 2011; McCarthy *et al.,* 2011; McSweeney *et al.,* 2007; McSweeney *et al.,* 2009; Moore and Barlow, 2011; Tyack *et al.,* 2011; Southall *et al.,* 2012; Manzano-Roth *et al.,* 2013; DeRuiter *et al.,* 2013b; Goldbogen *et al.,* 2013; Moretti *et al.,* 2014; Smultea and Jefferson, 2014), including data developed in the series of reports submitted to NMFS, we believe that long-term consequences for individuals or populations are unlikely to result from Navy training and testing activities in the Study Area.

Final Determination

Training and testing activities proposed in the NWTT Study Area would result in Level B and Level A takes, as summarized in Tables 14–18. Based on best available science, as summarized in this rule and in the NWTT FEIS/OEIS (Section 3.4.4.1), NMFS concludes that exposures to marine mammal species and stocks due to NWTT activities would result in primarily short-term (temporary and short in duration) and relatively infrequent effects to most individuals exposed, and not of the type or severity that would be expected to be additive for the generally small portion of the stocks and species likely to be exposed.

Chapter 4 of the NWTT FEIS/OEIS contains a comprehensive assessment of potential cumulative impacts, including analyzing the potential for cumulatively significant impacts to the marine environment and marine mammals. In addition, the Biological Opinion concludes that the proposed regulations and any take associated with activities authorized by those regulations are not likely to jeopardize the continued existence of threatened or endangered species (or species proposed for listing) in the action area during any single year or as a result of the cumulative impacts of a 5-year authorization. The Biological Opinion includes an explanation of how the results of NMFS' baseline and effects analyses in Biological Opinions relate to those contained in the cumulative impact section of the NWTT FEIS/OEIS.

Marine mammal takes from Navy activities are not expected to impact annual rates of recruitment or survival and will therefore not result in population-level impacts for the following reasons:

- Most acoustic exposures (greater than 99 percent) are within the non-injurious TTS or behavioral effects zones (Level B harassment consisting of generally temporary modifications in behavior) and none of the estimated exposures result in mortality.
- As mentioned earlier, an animal's exposure to a higher received level is more likely to result in a behavioral response that is more likely to adversely affect the health of the animal. For low frequency cetaceans (mysticetes) in the Study Area, most Level B exposures will occur at received levels less than 156 dB. The majority of estimated odontocete takes from MFAS/HFAS (at least for hull-mounted sonar, which is responsible for most of the sonar-related takes) also result from exposures to received levels less than 156 dB. Therefore, the majority of Level B takes are expected to be in the form of milder responses (*i.e.,* lower-level exposures that still rise to the level of a take, but would likely be less severe in the range of responses that qualify as a take) and are not expected to have deleterious impacts on the fitness of any individuals.
- Acoustic disturbances caused by Navy sonar and explosives are short-term, intermittent, and (in the case of sonar) transitory. Moreover, there are no MTEs in the NWTT Study Area. Navy activities are generally unit level. Unit level events occur over a small spatial scale (one to a few 10s of square miles) and with few participants (usually one or two). Single-unit unit level training would typically involve a few hours of sonar use, with a typical nominal ping of every 50 seconds (duty cycle). Even though an animal's exposure to active sonar may be more than one time, the intermittent nature of the sonar signal, its low duty cycle, and the fact that both the vessel and animal are moving provide a very small chance that exposure to active sonar for individual animals and stocks would be repeated over extended periods of time. Consequently, we would not expect the Navy's activities to create conditions of long-term, continuous underwater noise leading to habitat abandonment or long-term hormonal or physiological stress responses in marine mammals.
- Range complexes where intensive training and testing have been occurring for decades have populations of multiple species with strong site fidelity (including highly sensitive resident beaked whales at some locations) and increases in the number of some species. Populations of beaked whales and other odontocetes in the Bahamas, and other Navy fixed ranges that have been operating for tens of years, appear to be stable.
- Years of monitoring of Navy-wide activities (since 2006) have documented hundreds of thousands of marine mammals on the range complexes and

there are only two instances of overt behavioral change that have been observed.

• Years of monitoring of Navy-wide activities on the range complexes have documented no demonstrable instances of injury to marine mammals as a direct result of non-impulsive acoustic sources.

• In at least three decades of the same type of activities, only one instance of injury to marine mammals (March 4, 2011; three long-beaked common dolphin off Southern California) has occurred as a known result of training or testing using an impulsive source (underwater explosion). Of note, the time-delay firing underwater explosive training activity implicated in the March 4 incident is not proposed for the training activities in the NWTT Study Area.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, which includes consideration of the materials provided in the Navy's LOA application and NWTT FEIS/OEIS, and dependent upon the implementation of the mitigation and monitoring measures, NMFS finds that the total marine mammal take from the Navy's training and testing activities in the NWTT Study Area will have a negligible impact on the affected marine mammal species or stocks. NMFS has issued regulations for these activities that prescribe the means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat and set forth requirements pertaining to the monitoring and reporting of that taking.

Subsistence Harvest of Marine Mammals

There are no relevant subsistence uses of marine mammals implicated by this action. Therefore, NMFS has 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.

ESA

There are nine marine mammal species under NMFS jurisdiction that are listed as endangered or threatened under the ESA with confirmed or possible occurrence in the NWTT Study Area: North Pacific right whale, blue whale, humpback whale, fin whale, sei whale, gray whale (Western North Pacific stock), sperm whale, killer whale (Eastern North Pacific Southern Resident stock), and Guadalupe fur seal. The Navy consulted with NMFS pursuant to section 7 of the ESA, and NMFS also consulted internally on the issuance of a rule and LOAs under section 101(a)(5)(A) of the MMPA for NWTT activities. NMFS issued a Biological Opinion concluding that the issuance of the rule and subsequent LOAs are likely to adversely affect, but are not likely to jeopardize, the continued existence of the threatened and endangered species (and species proposed for listing) under NMFS' jurisdiction and are not likely to result in the destruction or adverse modification of critical habitat in the NWTT Study Area. The Biological Opinion for this action is available on NMFS' Web site (*http://www.nmfs.noaa.gov/pr/permits/incidental/military.htm*).

NEPA

NMFS participated as a cooperating agency on the NWTT FEIS/OEIS, which was published on October 2, 2015 and is available on the Navy's Web site: *http://www.nwtteis.com.* NMFS determined that the NWTT FEIS/OEIS is adequate and appropriate to meet our responsibilities under NEPA for the issuance of regulations and LOAs and adopted the Navy's NWTT FEIS/OEIS.

NMSA

Some Navy NWTT activities will occur within the Olympic Coast National Marine Sanctuary (OCNMS). Federal agency actions that are likely to injure sanctuary resources are subject to consultation with the NOAA Office of National Marine Sanctuaries (ONMS) under section 304(d) of the National Marine Sanctuaries Act (NMSA) to determine if there are reasonable and prudent alternatives to the proposed action that will protect sanctuary resources. The Navy and NMFS initiated joint consultation with ONMS through the submittal of a Sanctuary Resource Statement (SRS) on August 31, 2015, with follow-up information provided to ONMS on October 1, 2015. The SRS provided by the Navy and NMFS estimated the numbers of marine mammals within the OCNMS that could be exposed, annually, to acoustic transmissions associated with NWTT activities. The impacts of these exposures were predicted as numbers of marine mammals that could experience temporary and permanent threshold shifts and behavioral responses, all of which constitute ''injury'' as defined by the NMSA. ONMS provided recommended alternatives to the Navy and NMFS to further protect sanctuary resources on October 23, 2015. On November 9, 2015, the Navy and NMFS jointly responded in writing to each of the ONMS recommendations.

Classification

The Office of Management and Budget has determined that this final rule is not significant for purposes of Executive Order 12866.

Pursuant to the Regulatory Flexibility Act (RFA), the Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration at the proposed rule stage that this rule would not have a significant economic impact on a substantial number of small entities. The Navy is the sole entity that would be affected by this rulemaking, and the Navy is not a small governmental jurisdiction, small organization, or small business, as defined by the RFA. Any requirements imposed by an LOA issued pursuant to these regulations, and any monitoring or reporting requirements imposed by these regulations, would be applicable only to the Navy. NMFS does not expect the issuance of these regulations or the associated LOAs to result in any impacts to small entities pursuant to the RFA. Because this action, if adopted, would directly affect the Navy and not a small entity, NMFS concludes the action would not result in a significant economic impact on a substantial number of small entities.

The Assistant Administrator for Fisheries has determined that there is good cause under the Administrative Procedure Act (5 U.S.C. 553(d)(3)) to waive the 30-day delay in the effective date of the measures contained in the final rule. NMFS is unable to accommodate the 30-day delay of effectiveness due to delays in the release of this rule which resulted from an initial delay in the publication of the proposed rule. That delay occurred when updated species density information became available immediately prior to the release of the proposed rule. As those new data represented the best available science at the time, NMFS determined that it was necessary to incorporate those data, and the resulting analyses, into the proposed rule, which was subsequently delayed due to the added time needed to perform the additional analyses and provide the necessary revisions to the notice of the proposed rule. The Navy is the only entity subject to the regulations, and it has informed NMFS that it requests that this final rule take effect by November 9, 2015, when the regulations issued by NMFS to govern the unintentional taking of marine mammals incidental to the Navy's activities in the Northwest Training Range Complex and the Keyport Range

Complex from 2010 to 2015 expire. A waiver of the 30-day delay of the effective date of the final rule will allow the Navy to finalize operational procedures to ensure compliance with required mitigation, monitoring, and reporting requirements, and have MMPA authorization in place prior to expiration of the existing regulations to support unit level training and testing activities events scheduled for November 2015. Any delay of enacting the final rule would result in either: (1) A suspension of planned naval training, which would disrupt vital training essential to national security; or (2) the Navy's procedural non-compliance with the MMPA (should the Navy conduct training without an LOA), thereby resulting in the potential for unauthorized takes of marine mammals. Moreover, the Navy is ready to implement the rule immediately. For these reasons, the Assistant Administrator finds good cause to waive the 30-day delay in the effective date.

List of Subjects in 50 CFR Part 218

Exports, Fish, Imports, Incidental take, Indians, Labeling, Marine mammals, Navy, Penalties, Reporting and recordkeeping requirements, Seafood, Sonar, Transportation.

Dated: November 9, 2015.

Samuel D. Rauch III,

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

For reasons set forth in the preamble, 50 CFR part 218 is amended as follows:

PART 218—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 218 continues to read as follow:

Authority: 16 U.S.C. 1361 *et seq.*

■ 2. In § 218.75, revise the introductory text of paragraph (f)(1)(ii)(F) to read as follows:

§ 218.75 Requirements for monitoring and reporting.

* * * * *

(f) * * *

(1) * * *

(ii) * * *

(F) Individual marine mammal sighting information for each sighting when mitigation occurred during each MTE:

* * * * *

■ 3. In § 218.85, revise the introductory text of paragraph (f)(1)(ii)(F) to read as follows:

§ 218.85 Requirements for monitoring and reporting.

* * * * *

(f) * * *

(1) * * *

(ii) * * *

(F) Individual marine mammal sighting information for each sighting when mitigation occurred during each MTE:

* * * * *

■ 4. In § 218.95, revise the introductory text of paragraph (g)(1)(ii)(F) to read as follows:

§ 218.95 Requirements for monitoring and reporting.

* * * * *

(g) * * *

(1) * * *

(ii) * * *

(F) Individual marine mammal sighting information for each sighting when mitigation occurred during each MTE:

* * * * *

■ 5. In § 218.125, revise the introductory text of paragraph (f)(1)(ii) to read as follows:

§ 218.125 Requirements for monitoring and reporting.

* * * * *

(f) * * *

(1) * * *

(ii) Individual marine mammal sighting information for each sighting in each exercise when mitigation occurred:

* * * * *

Subpart R—[Removed and Reserved]

■ 6. Remove and reserve subpart R, consisting of §§ 218.170 through 218.178.

■ 7. Subpart O is added to part 218 to read as follows:

Subpart O—Taking and Importing Marine Mammals; U.S. Navy's Northwest Training and Testing (NWTT) Study Area

Sec.

Subpart O—Taking and Importing Marine Mammals; U.S. Navy's Northwest Training and Testing (NWTT) Study Area

§ 218.140 Specified activity and specified geographical region.

(a) Regulations in this subpart apply only to the U.S. Navy for the taking of marine mammals that occurs in the area outlined in paragraph (b) of this section and that occurs incidental to the activities described in paragraph (c) of this section.

(b) The taking of marine mammals by the Navy is only authorized if it occurs within the NWTT Study Area, which is composed of established maritime operating and warning areas in the eastern North Pacific Ocean region, including areas of the Strait of Juan de Fuca, Puget Sound, and Western Behm Canal in southeastern Alaska. The Study Area includes air and water space within and outside Washington state waters, and outside state waters of Oregon and Northern California. The Study Area includes four existing range complexes and facilities: The Northwest Training Range Complex (NWTRC), the Keyport Range Complex, Carr Inlet Operations Area, and SEAFAC. In addition to these range complexes, the Study Area also includes Navy pierside locations where sonar maintenance and testing occurs as part of overhaul, modernization, maintenance and repair activities at NAVBASE Kitsap, Bremerton; NAVBASE Kitsap, Bangor; and Naval Station Everett.

(c) The taking of marine mammals by the Navy is only authorized if it occurs incidental to the following activities within the designated amounts of use:

(1) Sonar and other Active Sources Used During Training:

(i) Mid-frequency (MF) Source Classes:

(A) MF1—an average of 166 hours per year.

(B) MF3—an average of 70 hours per year.

(C) MF4—an average of 4 hours per year.

(D) MF5—an average of 896 items per year.

(E) MF11—an average of 16 hours per year.

(ii) High-frequency (HF) Source Classes:

(A) HF1—an average of 48 hours per year.

(B) HF4—an average of 384 hours per year.

(C) HF6—an average of 192 hours per year

(iii) Anti-Submarine Warfare (ASW) Source Classes:

(A) ASW2—an average of 720 items per year per year.

(B) ASW3—an average of 78 hours per year.

(2) Sonar and other Active Sources Used During Testing:

(i) Low-frequency (LF) Source Classes:

(A) LF4—an average of 110 hours per year.

(B) LF5—an average of 71 hours per year.

(ii) Mid-frequency (MF):

(A) MF1—an average of 32 hours per year

(B) MF3—an average of 145 hours per year.

(C) MF4—an average of 10 hours per year.

(D) MF5—an average of 273 items per year.

(E) MF6—an average of 12 items per year.

(F) MF8—an average of 40 hours per year.

(G) MF9—an average of 1,183 hours per year.

(H) MF10—an average of 1,156 hours per year.

(I) MF11—an average of 34 hours per year.

(J) MF12—an average of 24 hours per year.

(iii) High-frequency (HF) and Very High-frequency (VHF):

(A) HF1—an average of 161 hours per year.

(B) HF3—an average of 145 hours per year.

(C) HF5—an average of 360 hours per year.

(D) HF6—an average of 2,099 hours per year.

(iv) VHF:

(A) VHF2—an average of 35 hours per year.

(B) [Reserved]

(v) ASW:

(A) ASW1—an average of 16 hours per year.

(B) ASW2—an average of 64 hours per year.

(C) ASW2—an average of 170 items per year.

(D) ASW3—an average of 444 hours per year.

(E) ASW4—an average of 1,182 items per year.

(vi) Acoustic Modems (M):

(A) M3—an average of 1,519 hours per year.

(B) [Reserved]

(vii) Torpedoes (TORP):

(A) TORP1—an average of 315 items per year.

(B) TORP2—an average of 299 items per year.

(viii) Swimmer Detection Sonar (SD):

(A) SD1—an average of 757 hours per year.

(B) [Reserved]

(ix) Synthetic Aperture Sonar (SAS):

(A) SAS2—an average of 798 hours per year.

(B) [Reserved]

(3) Impulsive Source Detonations During Training:

(i) Explosive Classes:

(A) E1 (0.1 to 0.25 pound [lb] NEW)—an average of 48 detonations per year.

(B) E3 (>0.5 to 2.5 lb NEW)—an average of 6 detonations per year.

(C) E5 (>5 to 10 lb NEW)—an average of 80 detonations per year.

(D) E10 (>250 to 500 lb NEW)—an average of 4 detonations per year.

(E) E12 (>650 to 1,000 lb NEW)—an average of 10 detonations per year.

(ii) [Reserved]

(4) Impulsive Source Detonations During Testing:

(i) Explosive Classes:

(A) E3 (>0.5 to 2.5 lb NEW)—an average of 72 detonations per year.

(B) E4 (>2.5 to 5 lb NEW)—an average of 140 detonations (70 sonobuoys) per year.

(C) E8 (>60 to 100 lb NEW)—an average of 3 detonations per year.

(D) E11 (>500 to 650 lb NEW)—an average of 3 detonations per year.

(ii) [Reserved]

§ 218.141 Applicability dates.

Regulations in this subpart are applicable November 9, 2015, through November 8, 2020.

§ 218.142 Permissible methods of taking.

(a) Under Letters of Authorization (LOAs) issued pursuant to § 218.147, the Holder of, and those operating under, the LOA may incidentally, but not intentionally, take marine mammals within the area described in § 218.140, provided the activity is in compliance with all terms, conditions, and requirements of these regulations and the appropriate LOA.

(b) The activities identified in § 218.140(c) must be conducted in a manner that minimizes, to the greatest extent practicable, any adverse impacts on marine mammals and their habitat.

(c) The incidental take of marine mammals under the activities identified in § 218.140(c) is limited to the following species, by the identified method of take and the indicated number of times:

(1) Level B Harassment for all Training Activities:

(i) Mysticetes:

(A) Blue whale (*Balaenoptera musculus*), Eastern North Pacific—25 (an average of 5 per year).

(B) Fin whale (*Balaenoptera physalus*), California, Oregon, and Washington (CA/OR/WA)—125 (an average of 25 per year).

(C) Gray whale (*Eschrichtius robustus*), Eastern North Pacific—30 (an average of 6 per year).

(D) Humpback whale (*Megaptera novaeangliae*), CA/OR/WA—60 (an average of 12 per year).

(E) Minke whale (*Balaenoptera acutorostrata*), CA/OR/WA—90 (an average of 18 per year).

(ii) Odontocetes:

(A) Baird's beaked whale (*Berardius bairdii*), CA/OR/WA—2,955 (an average of 591 per year).

(B) Mesoplodont beaked whale (*Mesoplodon* spp.), CA/OR/WA—7,085 (an average of 1,417 per year).

(C) Cuvier's beaked whale (*Ziphius cavirostris*), CA/OR/WA—1,765 (an average of 353 per year).

(D) Dall's porpoise (*Phocoenoidea dalli*), CA/OR/WA—18,178 (an average of 3,730 per year).

(E) Harbor porpoise (*Phocoena phocoena*), Northern OR/WA Coast—175,030 (an average of 35,006 per year).

(F) Harbor porpoise (*Phocoena phocoena*), Northern CA/Southern OR—262,545 (an average of 52,509 per year).

(G) Harbor porpoise (*Phocoena phocoena*), WA Inland Waters—4,409 (an average of 1,417 per year).

(H) Killer whale (*Orcinus orca*), West Coast Transient—39 (an average of 9 per year).

(I) Killer whale (*Orcinus orca*), Eastern North Pacific Offshore—65 (an average of 13 per year).

(J) Killer whale (*Orcinus orca*), Eastern North Pacific Southern Resident—6 (an average of 2 per year).

(K) *Kogia* spp., CA/OR/WA—365 (an average of 73 per year).

(L) Northern right whale dolphin (*Lissodelphis borealis*), CA/OR/WA—6,660 (an average of 1,332 per year).

(M) Pacific white-sided dolphin (*Lagenorhynchus obliquidens*), CA/OR/WA—17,408 (an average of 3,482 per year).

(N) Risso's dolphin (*Grampus griseus*), CA/OR/WA—3,285 (an average of 657 per year).

(O) Short-beaked common dolphin (*Delphinus delphis*), CA/OR/WA—3,670 (an average of 734 per year).

(P) Sperm whale (*Physeter macrocephalus*), CA/OR/WA—405 (an average of 81 per year).

(Q) Striped dolphin (*Stenella coerulealba*), CA/OR/WA—110 (an average of 22 per year).

(iii) Pinnipeds:

(A) California sea lion (*Zalophus californianus*), U.S.—4,038 (an average of 814 per year).

(B) Steller sea lion (*Eumetopias jubatus*), Eastern U.S.—1,986 (an average of 404 per year).

(C) Guadalupe fur seal (*Arctocephalus townsendi*), Mexico—35 (an average of 7 per year).

(D) Harbor seal (*Phoca vitulina*), WA Northern Inland Waters—1,855 (an average of 427 per year).

(E) Harbor seal (*Phoca vitulina*), Southern Puget Sound—252 (an average of 58 per year).

(F) Harbor seal (*Phoca vitulina*), Hood Canal—2,054 (an average of 452 per year).

(G) Northern elephant seal (*Mirounga angustirostris*), CA Breeding—6,353 (an average of 1,271 per year).

(H) Northern fur seal (*Callorhinus ursinus*), Eastern Pacific—12,475 (an average of 2,495 per year).

(I) Northern fur seal (*Callorhinus ursinus*), California—185 (an average of 37 per year).

(2) Level A Harassment for all Training Activities:

(i) Mysticetes:

(A)–(B) [Reserved]

(ii) Odontocetes:

(A) Dall's porpoise (*Phocoenoidea dalli*), CA/OR/WA—20 (an average of 4 per year).

(B) Harbor porpoise (*Phocoena phocoena*), WA Inland Waters—5 (an average of 1 per year).

(iii) Pinnipeds:

(A) Harbor seal (*Phoca vitulina*), WA Northern Inland Waters—20 (an average of 4 per year).

(B) Harbor seal (*Phoca vitulina*), Hood Canal—10 (an average of 2 per year).

(C) [Reserved]

(3) Level B Harassment for all Testing Activities:

(i) Mysticetes:

(A) Blue whale (*Balaenoptera musculus*), Eastern North Pacific—30 (an average of 6 per year).

(B) Fin whale (*Balaenoptera physalus*), CA/OR/WA—170 (an average of 34 per year).

(C) Fin whale (*Balaenoptera physalus*), Northeast Pacific—10 (an average of 2 per year).

(D) Gray whale (*Eschrichtius robustus*), Eastern North Pacific—60 (an average of 12 per year).

(E) Humpback whale (*Megaptera novaeangliae*), Central North Pacific—5 (an average of 1 per year).

(F) Humpback whale (*Megaptera novaeangliae*), CA/OR/WA—220 (an average of 44 per year).

(G) Minke whale (*Balaenoptera acutorostrata*), CA/OR/WA—90 (an average of 18 per year).

(H) Sei whale (*Balaenoptera borealis*), Eastern North Pacific—10 (an average of 2 per year).

(ii) Odontocetes:

(A) Baird's beaked whale (*Berardius bairdii*), Alaska—125 (an average of 25 per year).

(B) Baird's beaked whale (*Berardius bairdii*), CA/OR/WA—745 (an average of 149 per year).

(C) Mesoplodont beaked whale (*Mesoplodon* spp.), CA/OR/WA—1,845 (an average of 369 per year).

(D) Cuvier's beaked whale (*Ziphius cavirostris*), Alaska—75 (an average of 15 per year).

(E) Cuvier's beaked whale (*Ziphius cavirostris*), CA/OR/WA—455 (an average of 91 per year).

(F) Dall's porpoise (*Phocoenoidea dalli*), Alaska—6,000 (an average of 1,200 per year).

(G) Dall's porpoise (*Phocoenoidea dalli*), CA/OR/WA—50,785 (an average of 10,157 per year).

(H) Harbor porpoise (*Phocoena phocoena*), Southeast Alaska—4,630 (an average of 926 per year).

(I) Harbor porpoise (*Phocoena phocoena*), Northern OR/WA Coast—86,060 (an average of 17,212 per year).

(J) Harbor porpoise (*Phocoena phocoena*), Northern CA/Southern OR—129,095 (an average of 25,819 per year).

(K) Harbor porpoise (*Phocoena phocoena*), WA Inland Waters—27,045 (an average of 5,409 per year).

(L) Killer whale (*Orcinus orca*), Alaska Resident—10 (an average of 2 per year).

(M) Killer whale (*Orcinus orca*), West Coast Transient—1,035 (an average of 207 per year).

(N) Killer whale (*Orcinus orca*), Eastern North Pacific Offshore—110 (an average of 22 per year).

(O) *Kogia* spp., CA/OR/WA—530 (an average of 106 per year).

(P) Northern right whale dolphin (*Lissodelphis borealis*), CA/OR/WA—10,190 (an average of 2,038 per year).

(Q) Pacific white-sided dolphin (*Lagenorhynchus obliquidens*), North Pacific—15 (an average of 3 per year).

(R) Pacific white-sided dolphin (*Lagenorhynchus obliquidens*), CA/OR/WA—24,345 (an average of 4,869 per year).

(S) Risso's dolphin (*Grampus griseus*), CA/OR/WA—5,770 (an average of 1,154 per year).

(T) Short-beaked common dolphin (*Delphinus delphis*), CA/OR/WA—8,140 (an average of 1,628 per year).

(U) Sperm whale (*Physeter macrocephalus*), CA/OR/WA—390 (an average of 78 per year).

(V) Striped dolphin (*Stenella coerulealba*), CA/OR/WA—70 (an average of 14 per year).

(iii) Pinnipeds:

(A) California sea lion (*Zalophus californianus*), U.S.—10,730 (an average of 2,146 per year).

(B) Steller sea lion (*Eumetopias jubatus*), Eastern U.S.—2,605 (an average of 521 per year).

(C) Guadalupe fur seal (*Arctocephalus townsendi*), Mexico—15 (an average of 3 per year).

(D) Harbor seal (*Phoca vitulina*), Southeast Alaska (Clarence Sound)—110 (an average of 22 per year).

(E) Harbor seal (*Phoca vitulina*), OR/WA Coast—8,275 (an average of 1,655 per year).

(F) Harbor seal (*Phoca vitulina*), WA Northern Inland Waters—9,115 (an average of 1,823 per year).

(G) Harbor seal (*Phoca vitulina*), Southern Puget Sound—980 (an average of 196 per year).

(H) Harbor seal (*Phoca vitulina*), Hood Canal—296,085 (an average of 59,217 per year).

(I) Northern elephant seal (*Mirounga angustirostris*), CA Breeding—6,625 (an average of 1,325 per year).

(J) Northern fur seal (*Callorhinus ursinus*), Eastern Pacific—9,150 (an average of 1,830 per year).

(K) Northern fur seal (*Callorhinus ursinus*), California—135 (an average of 27 per year).

(4) Level A Harassment for all Testing Activities:

(i) Mysticetes:

(A) Gray whale (*Eschrichtius robustus*), Eastern North Pacific—5 (an average of 1 per year).

(B) [Reserved]

(ii) Odontocetes:

(A) *Kogia* spp., CA/OR/WA—5 (an average of 1 per year).

(B) Dall' porpoise (*Phocoenoidea dalli*), CA/OR/WA—215 (an average of 43 per year).

(C) Harbor porpoise (*Phocoena phocoena*), Northern OR/WA Coast—75 (an average of 15 per year).

(D) Harbor porpoise (*Phocoena phocoena*), Northern CA/Southern OR—115 (an average of 23 per year).

(E) Harbor porpoise (*Phocoena phocoena*), WA Inland Waters—30 (an average of 6 per year).

(iii) Pinnipeds:

(A) Harbor seal (*Phoca vitulina*), OR/WA Coast—20 (an average of 4 per year).

(B) Harbor seal (*Phoca vitulina*), WA Northern Inland Waters—110 (an average of 22 per year).

(C) Harbor seal (*Phoca vitulina*), Southern Puget Sound—5 (an average of 1 per year).

(D) Harbor seal (*Phoca vitulina*), Hood Canal—335 (an average of 67 per year).

(E) Northern elephant seal (*Mirounga angustirostris*), CA Breeding—10 (an average of 2 per year).

(F) [Reserved]

§ 218.143 Prohibitions.

Notwithstanding takings contemplated in § 218.142 and authorized by an LOA issued under §§ 216.106 and 218.147 of this chapter, no person in connection with the activities described in § 218.140 may:

(a) Take any marine mammal not specified in § 218.142(c);

(b) Take any marine mammal specified in § 218.142(c) other than by incidental take as specified in § 218.142(c);

(c) Take a marine mammal specified in § 218.142(c) if such taking results in more than a negligible impact on the species or stocks of such marine mammal; or

(d) Violate, or fail to comply with, the terms, conditions, and requirements of these regulations or an LOA issued under §§ 216.106 and 218.147.

§ 218.144 Mitigation.

(a) When conducting training and testing activities, as identified in § 218.140, the mitigation measures contained in the LOA issued under §§ 216.106 and 218.147 of this chapter must be implemented. These mitigation measures include, but are not limited to:

(1) *Lookouts*—The following are protective measures concerning the use of Lookouts.

(i) Lookouts positioned on surface ships will be dedicated solely to diligent observation of the air and surface of the water. Their observation objectives will include, but are not limited to, detecting the presence of biological resources and recreational or fishing boats, observing mitigation zones, and monitoring for vessel and personnel safety concerns.

(ii) Lookouts positioned ashore, in aircraft or on boats will, to the maximum extent practicable and consistent with aircraft and boat safety and training and testing requirements, comply with the observation objectives described in paragraph (a)(1)(i) of this section.

(iii) Lookout Measures for Non-Impulsive Sound:

(A) With the exception of vessels less than 65 ft (20 m) in length or minimally manned vessels, ships using low-frequency or hull-mounted mid-frequency active sonar sources associated with anti-submarine warfare and mine warfare activities at sea will have two Lookouts at the forward position of the vessel. For the purposes of this rule, low-frequency active sonar does not include surface towed array surveillance system low-frequency active sonar.

(B) While using low-frequency or hull-mounted mid-frequency active sonar sources associated with anti-submarine warfare and mine warfare activities at sea, vessels less than 65 ft (20 m) in length or minimally manned vessels will have one Lookout at the forward position of the vessel due to space and manning restrictions.

(C) Ships conducting active sonar activities while moored or at anchor (including pierside or shore-based testing or maintenance) will maintain one Lookout.

(D) Minimally manned vessels conducting hull-mounted mid-frequency testing will employ one Lookout.

(E) Ships, small boats, range craft, or aircraft conducting non-hull-mounted mid-frequency active sonar, such as helicopter dipping sonar systems, will maintain one Lookout.

(F) Surface ships or aircraft conducting high-frequency or non-hull-mounted mid-frequency active sonar activities associated with anti-submarine warfare and mine warfare activities at sea will have one Lookout.

(iv) Lookout measures for impulsive sound (*e.g.,* explosives):

(A) Aircraft conducting improved extended echo ranging sonobuoy activities will have one Lookout.

(B) Aircraft conducting explosive sonobuoy activities using >0.5 to 2.5-lb net explosive weight (NEW) will have one Lookout.

(C) General mine countermeasure and neutralization activities involving positive control diver placed charges using >0.5 to 2.5 lb NEW will have a total of two Lookouts (one Lookout positioned in each of the two support vessels). All divers placing the charges on mines will support the Lookouts while performing their regular duties. The divers and Lookouts will report all marine mammal sightings to their dive support vessel.

(D) Surface vessels or aircraft conducting small-, medium-, and large-caliber gunnery exercises will have one Lookout. Towing vessels, if applicable, will also maintain one Lookout.

(E) Aircraft conducting missile exercises against a surface target will have one Lookout.

(F) Aircraft conducting explosive bombing exercises will have one Lookout and any surface vessels involved will have trained Lookouts.

(G) During explosive torpedo testing from aircraft one Lookout will be used and positioned in an aircraft. During explosive torpedo testing from a surface ship the Lookout procedures implemented for hull-mounted mid-frequency active sonar activities will be used.

(H) To mitigate effects from weapon firing noise, ships conducting explosive and non-explosive large-caliber gunnery exercises will have one Lookout. This may be the same Lookout used for small, medium, and large-caliber gunnery exercises using a surface target when that activity is conducted from a ship against a surface target.

(v) Lookout measures for physical strike and disturbance:

(A) While underway, surface ships and range craft will have at least one Lookout.

(B) During activities using towed in-water devices towed from a manned platform, one Lookout will be used. During activities in which in-water devices are towed by unmanned platforms, a manned escort vessel will be included and one Lookout will be employed.

(C) Activities involving non-explosive practice munitions (*e.g.,* small-, medium-, and large-caliber gunnery exercises) using a surface target will have one Lookout.

(D) During non-explosive bombing exercises one Lookout will be positioned in an aircraft and trained Lookouts will be positioned in any surface vessels involved.

(2) *Mitigation zones*—The following are protective measures concerning the implementation of mitigation zones.

(i) Mitigation zones will be measured as the radius from a source and represent a distance to be monitored.

(ii) Visual detections of marine mammals (or sea turtles) within a mitigation zone will be communicated immediately to a watch station for information dissemination and appropriate action.

(iii) Mitigation Zones for Non-Impulsive Sound:

(A) The Navy shall ensure that hull-mounted mid-frequency active sonar transmission levels are limited to at least 6 dB below normal operating levels if any detected marine mammals (or sea turtles) are within 1,000 yd. (914 m) of the sonar dome (the bow).

(B) The Navy shall ensure that hull-mounted mid-frequency active sonar transmissions are limited to at least 10 dB below the equipment's normal operating level if any detected marine mammals (or sea turtles) are within 500 yd. (457 m) of the sonar dome.

(C) The Navy shall ensure that hull-mounted mid-frequency active sonar transmissions are ceased if any detected cetaceans (or sea turtles) are within 200 yd. (183 m) and pinnipeds are within 100 yd. (91 m) of the sonar dome. Transmissions will not resume until the marine mammal has been observed exiting the mitigation zone, is thought to have exited the mitigation zone based on its course and speed, has not been detected for 30 minutes, the vessel has transited more than 2,000 yd. beyond the location of the last detection, or the Lookout concludes that dolphins are deliberately closing in on the ship to

ride the ship's bow wave (and there are no other marine mammal sightings within the mitigation zone). Active transmission may resume when dolphins are bow riding because they are out of the main transmission axis of the active sonar while in the shallow-wave area of the ship bow. The pinniped mitigation zone does not apply to pierside sonar in the vicinity of pinnipeds hauled out on or in the water near man-made structures and vessels.

(D) The Navy shall ensure that low-frequency active sonar transmission levels are ceased if any detected cetaceans (or sea turtles) are within 200 yd. (183 m) and pinnipeds are within 100 yd. (91 m) of the source. Transmissions will not resume until the marine mammal has been observed exiting the mitigation zone, is thought to have exited the mitigation zone based on its course and speed, has not been detected for 30 minutes, or the vessel has transited more than 2,000 yd. beyond the location of the last detection. The pinniped mitigation zone does not apply for pierside sonar in the vicinity of pinnipeds hauled out on or in the water near man-made structures and vessels.

(E) For training, the Navy shall ensure that high-frequency and non-hull-mounted mid-frequency active sonar transmission levels are ceased if any detected marine mammals are within 200 yd. (183 m) of the source. For testing, the Navy shall ensure that high-frequency and non-hull-mounted mid-frequency active sonar transmission levels are ceased if any detected cetaceans are within 200 yd. (183 m) and pinnipeds are within 100 yd. (91 m) of the source. Transmissions will not resume until the marine mammal has been observed exiting the mitigation zone, is thought to have exited the mitigation zone based on its course and speed, the mitigation zone has been clear from any additional sightings for a period of 10 minutes for an aircraft-deployed source, the mitigation zone has been clear from any additional sightings for a period of 30 minutes for a vessel-deployed source, the vessel or aircraft has repositioned itself more than 400 yd. (370 m) away from the location of the last sighting, or the vessel concludes that dolphins are deliberately closing in to ride the vessel's bow wave (and there are no other marine mammal sightings within the mitigation zone). The pinniped mitigation zone does not apply for pierside or shore-based testing in the vicinity of pinnipeds hauled out on or in the water near man-made structures and vessels.

(iv) Mitigation Zones and Procedures for Explosive and Impulsive Sound:

(A) For activities using IEER sonobuoys, mitigation will include pre-exercise aerial observation and passive acoustic monitoring, which will begin 30 minutes before the first source/receiver pair detonation and continue throughout the duration of the exercise. IEER sonobuoys will not be deployed if concentrations of floating vegetation (kelp paddies) are observed in the mitigation zone around the intended deployment location. Explosive detonations will cease if a marine mammal, sea turtle, or concentrations of floating vegetation are sighted within a 600-yd. (549 m) mitigation zone. Detonations will recommence if the animal is observed exiting the mitigation zone, the animal is thought to have exited the mitigation zone based on its course and speed, or the mitigation zone has been clear from any additional sightings for a period of 30 minutes.

(B) A mitigation zone with a radius of 350 yd. (320 m) shall be established for explosive signal underwater sonobuoys using >0.5 to 2.5 lb net explosive weight. Mitigation will include pre-exercise aerial monitoring of the mitigation zone during deployment. Explosive SUS buoys will not be deployed if concentrations of floating vegetation (kelp paddies) are observed within the mitigation zone around the intended deployment location. A SUS detonation will cease if a marine mammal or sea turtle is sighted within the mitigation zone. Detonations will recommence if the animal is observed exiting the mitigation zone, the animal is thought to have exited the mitigation zone based on its course and speed, or the mitigation zone has been clear from any additional sightings for a period of 10 minutes.

(C) A mitigation zone with a radius of 400 yd. (366 m) shall be established for mine countermeasures and neutralization activities using positive control firing devices. For Demolition and Mine Countermeasures Operations, pre-exercise surveys shall be conducted within 30 minutes prior to the commencement of the scheduled explosive event. The survey may be conducted from the surface, by divers, or from the air, and personnel shall be alert to the presence of any marine mammal or sea turtle. Should a marine mammal or sea turtle be present within the survey area, the explosive event shall not be started until the animal voluntarily leaves the area. The Navy will ensure the area is clear of marine mammals for a full 30 minutes prior to initiating the explosive event. Explosive detonations will cease if a marine mammal is sighted in the water portion of the mitigation zone (*i.e.,* not on shore). Detonations will recommence if the animal is observed exiting the mitigation zone, the animal is thought to have exited the mitigation zone based on its course and speed, or the mitigation zone has been clear from any additional sightings for a period of 30 minutes.

(D) A mitigation zone with a radius of 200 yd. (183 m) shall be established for small- and medium-caliber gunnery exercises with a surface target. Vessels will observe the mitigation zone from the firing position. When aircraft are firing, the aircrew will maintain visual watch of the mitigation zone during the activity. The exercise will not commence if concentrations of floating vegetation (kelp paddies) are observed within the mitigation zone. Firing will cease if a marine mammal or sea turtle is sighted within the mitigation zone. Firing will recommence if the animal is observed exiting the mitigation zone, the animal is thought to have exited the mitigation zone based on its course and speed, the mitigation zone has been clear from any additional sightings for a period of 10 minutes for a firing aircraft, the mitigation zone has been clear from any additional sightings for a period of 30 minutes for a firing ship, or the intended target location has been repositioned more than 400 yd. (370 m) away from the location of the last sighting.

(E) A mitigation zone with a radius of 600 yd. (549 m) shall be established for large-caliber gunnery exercises with a surface target. Ships will observe the mitigation zone from the firing position. The exercise will not commence if concentrations of floating vegetation (kelp paddies) are observed in the mitigation zone. Firing will cease if a marine mammal or sea turtle is sighted within the mitigation zone. Firing will recommence if the animal is observed exiting the mitigation zone, the animal is thought to have exited the mitigation zone based on its course and speed, or the mitigation zone has been clear from any additional sightings for a period of 30 minutes.

(F) A mitigation zone with a radius of 2,000 yd. (1.8 km) shall be established for missile exercises up to 500 lb NEW using a surface target. When aircraft are involved in the missile firing, mitigation will include visual observation by the aircrew prior to commencement of the activity within a mitigation zone of 2,000 yd. (1.8 km) around the intended impact location. The exercise will not commence if concentrations of floating vegetation (kelp paddies) are observed in the mitigation zone. Firing will not commence or will cease if a marine

mammal or sea turtle is sighted within the mitigation zone. Firing will recommence if the animal is observed exiting the mitigation zone, the animal is thought to have exited the mitigation zone based on its course and speed, or the mitigation zone has been clear from any additional sightings for a period of 10 minutes or 30 minutes (depending on aircraft type).

(G) A mitigation zone with a radius of 2,500 yd. (2.3 km) for explosive bombs and a mitigation zone of 1,000 yd (914 m) for non-explosive bombs around the intended impact location shall be established for bombing exercises. Aircraft shall visually survey the target and buffer zone for marine mammals prior to and during the exercise. The exercise will not commence if concentrations of floating vegetation (kelp paddies) are observed in the mitigation zone. Bombing will not commence or will cease if a marine mammal or sea turtle is sighted within the mitigation zone. Bombing will recommence if the animal is observed exiting the mitigation zone, the animal is thought to have exited the mitigation zone based on its course and speed, or the mitigation zone has been clear from any additional sightings for a period of 10 minutes.

(H) A mitigation zone with a radius of 2,100 yd. (1.9 km) shall be established for torpedo (explosive) testing. Mitigation will include visual observation by aircraft immediately before, during, and after the event of the mitigation zone. The exercise will not commence if concentrations of floating vegetation (kelp paddies) are sighted within the mitigation zone. Firing will not commence or will cease if a marine mammal, sea turtle, or aggregation of jellyfish is sighted within the mitigation zone. Firing will recommence if the animal is observed exiting the mitigation zone, the animal is thought to have exited the mitigation zone based on its course and speed, or the mitigation zone has been clear from any additional sightings for a period of 10 minutes or 30 minutes (depending on aircraft type). In addition to visual observation, passive acoustic monitoring shall be conducted by Navy assets, such as passive ship sonar systems or sonobuoys already participating in the activity. These assets would only detect vocalizing marine mammals within the frequency band monitored by Navy personnel. Passive acoustic detections would not provide range or bearing to detected animals, and therefore cannot provide locations of these animals. Passive acoustic detections shall be reported to the Lookout posted in the aircraft in order to increase vigilance of the visual surveillance, and to the person in control of the activity for their consideration in determining when the mitigation zone is determined free of visible marine mammals.

(I) A mitigation zone with a radius of 70 yd. (46 m) within 30 degrees on either side of the gun target line on the firing side shall be established for weapons firing noise during large-caliber gunnery exercises. Mitigation shall include visual observation immediately before and during the exercise. The exercise will not commence if concentrations of floating vegetation (kelp paddies) are observed in the mitigation zone. Firing will cease if a marine mammal or sea turtle is sighted within the mitigation zone. Firing will recommence if the animal is observed exiting the mitigation zone, the animal is thought to have exited the mitigation zone based on its course and speed, the mitigation zone has been clear from any additional sightings for a period of 30 minutes, or the vessel has repositioned itself more than 140 yd. (128 m) away from the location of the last sighting.

(v) Mitigation Zones for Vessels and In-Water Devices:

(A) For all training activities and for testing activities involving surface ships, vessels shall avoid approaching marine mammals head on and shall maneuver to keep at least 500 yd. (457 m) away from observed whales and 200 yd (183 m) away from all other marine mammals (except bow riding dolphins, and pinnipeds hauled out on man-made navigational and port structures and vessels) during vessel movements. These requirements shall not apply if a vessel's safety is threatened and to the extent that vessels are restricted in their ability to maneuver. Restricted maneuverability includes, but is not limited to, situations when vessels are engaged in dredging, submerged activities, launching and recovering aircraft or landing craft, minesweeping activities, replenishment while underway and towing activities that severely restrict a vessel's ability to deviate course.

(B) For testing activities not involving surface ships (*e.g.* range craft) vessels shall maneuver to keep at least 100 yd. (91 m) away from marine mammals (except bow-riding dolphins, pinnipeds hauled out on man-made navigational and port structures and vessels, and pinnipeds during test body retrieval) during vessel movements. This requirement shall not apply if a vessel's safety is threatened and to the extent that vessels are restricted in their ability to maneuver. Restricted maneuverability includes, but is not limited to, situations when vessels are engaged in dredging, submerged activities, launching and recovering aircraft or landing craft, minesweeping activities, replenishment while underway and towing activities that severely restrict a vessel's ability to deviate course.

(C) The Navy shall ensure that towed in-water devices being towed from manned platforms avoid coming within a mitigation zone of 250 yd. (230 m) for all training events and testing activities involving surface ships, and a mitigation zone of 100 yd (91 m) for testing activities not involving surface ships (*e.g.* range craft) around any observed marine mammal, providing it is safe to do so.

(vi) Mitigation zones for non-explosive practice munitions:

(A) A mitigation zone of 200 yd. (183 m) shall be established for small-, medium, and large-caliber gunnery exercises using a surface target. Mitigation will include visual observation from a vessel or aircraft immediately before and during the exercise within the mitigation zone of the intended impact location. The exercise will not commence if concentrations of floating vegetation (kelp paddies) are observed in the mitigation zone. Firing will cease if a marine mammal is sighted within the mitigation zone. Firing will recommence if the animal is observed exiting the mitigation zone, the animal is thought to have exited the mitigation zone based on its course and speed, the mitigation zone has been clear from any additional sightings for a period of 10 minutes for a firing aircraft, the mitigation zone has been clear from any additional sightings for a period of 30 minutes for a firing ship, or the intended target location has been repositioned more than 400 yd. (370 m) away from the location of the last sighting.

(B) A mitigation zone of 1,000 yd. (914 m) shall be established for non-explosive bombing exercises. Mitigation shall include visual observation from the aircraft immediately before the exercise and during target approach within the mitigation zone around the intended impact location. The exercise will not commence if concentrations of floating vegetation (kelp paddies) are observed within the mitigation zone. Bombing will not commence or will cease if a marine mammal is sighted within the mitigation zone. Bombing will recommence if the animal is observed exiting the mitigation zone, the animal is thought to have exited the mitigation zone based on its course and speed, or the mitigation zone has been

clear from any additional sightings for a period of 10 minutes.

(3) *NWTT-Specific Mitigation*—The following are additional measures the Navy shall comply with when conducting training or testing activities in the NWTT Study Area:

(i) Maritime Homeland Defense/Security Mine Countermeasure Integrated Exercises—The Navy shall conduct pre-event planning and training to ensure environmental awareness of all exercise participants. When this event is proposed to be conducted in Puget Sound, Navy event planners shall consult with Navy biologists who shall contact NMFS during the planning process in order to determine likelihood of gray whale or southern resident killer whale presence in the proposed exercise area as planners consider specifics of the event.

(ii) Small Boat Attack Gunnery Exercises—The Navy shall conduct pre-event planning and training to ensure environmental awareness of all exercise participants. When this event is proposed to be conducted in and around Naval Station Everett, Naval Base Kitsap Bangor, or Naval Base Kitsap Bremerton in Puget Sound, Navy event planners shall consult with Navy biologists who shall contact NMFS early in the planning process in order to determine the extent marine mammals may be present in the immediate vicinity of the proposed exercise area as planners consider the specifics of the event.

(iii) Missile Exercise—The Navy shall conduct Missile Exercises using high explosives at least 50 nm from shore in the NWTT Offshore Area.

(iv) BOMBEX—The Navy shall conduct BOMBEX (high explosive munitions) greater than 50 nm from shore.

(v) BOMBEX (non-explosive practice munitions)—The Navy shall conduct BOMBEX (non-explosive practice munitions) events at least 20 nm from shore and shall not conduct BOMBEX events within the Olympic Coast National Marine Sanctuary.

(vi) Mine Countermeasure and Neutralization Underwater Detonations—The Navy shall require approval from U.S. Third Fleet prior to conducting mine countermeasure and neutralization underwater detonations at Hood Canal or Crescent Harbor.

(vii) Hull Mounted Mid-Frequency Active Sonar Training—The Navy shall require approval from U.S. Pacific Fleet's designated authority prior to conducting hull-mounted mid-frequency active sonar on vessels while training underway in Puget Sound and the Strait of Juan de Fuca.

(viii) Pierside Maintenance or Testing of Sonar Systems—The Navy shall require approval from U.S. Pacific Fleet's designated authority or Systems Command designated authority (as applicable to ship and submarine active sonar use) prior to conducting pierside maintenance or testing in Puget Sound or the Strait of Juan de Fuca.

(b) [Reserved]

§ 218.145 Requirements for monitoring and reporting.

(a) The Navy is required to cooperate with the NMFS, and any other Federal, state or local agency monitoring the impacts of the activity on marine mammals.

(b) General Notification of Injured or Dead Marine Mammals—Navy personnel shall ensure that NMFS is notified immediately (or as soon as clearance procedures allow) if an injured, stranded, or dead marine mammal is found during or shortly after, and in the vicinity of, any Navy training exercise utilizing MFAS, HFAS, or underwater explosive detonations. The Navy will provide NMFS with species or description of the animal(s), the condition of the animal(s) (including carcass condition if the animal is dead), location, time of first discovery, observed behaviors (if alive), and photo or video (if available). In the event that an injured, stranded, or dead marine mammal is found by the Navy that is not in the vicinity of, or during or shortly after, MFAS, HFAS, or underwater explosive detonations, the Navy will report the same information as listed above as soon as operationally feasible and clearance procedures allow.

(c) General Notification of Ship Strike—In the event of a ship strike by any Navy vessel, at any time or place, the Navy shall do the following:

(1) Immediately report to NMFS the species identification (if known), location (lat/long) of the animal (or the strike if the animal has disappeared), and whether the animal is alive or dead (or unknown), and the time of the strike.

(2) Report to NMFS as soon as operationally feasible the size and length of animal, an estimate of the injury status (ex., dead, injured but alive, injured and moving, unknown, etc.), vessel class/type and operational status.

(3) Report to NMFS the vessel length, speed, and heading as soon as feasible.

(4) Provide NMFS a photo or video, if equipment is available.

(5) Within 2 weeks of the strike, provide NMFS with a detailed description of the specific actions of the vessel in the 30-minute timeframe immediately preceding the strike, during the event, and immediately after the strike (*e.g.,* the speed and changes in speed, the direction and changes in direction, other maneuvers, sonar use, etc., if not classified); a narrative description of marine mammal sightings during the event and immediately after, and any information as to sightings prior to the strike, if available; and use established Navy shipboard procedures to make a camera available to attempt to capture photographs following a ship strike.

(d) Event Communication Plan—The Navy shall develop a communication plan that will include all of the communication protocols (phone trees, etc.) and associated contact information required for NMFS and the Navy to carry out the necessary expeditious communication required in the event of a stranding or ship strike, including as described in the proposed notification measures above.

(e) The Navy must conduct all monitoring and/or research required under the Letter of Authorization including abiding by the NWTT monitoring plan. (*http://www.nmfs.noaa.gov/pr/permits/incidental/military.htm*).

(f) Annual NWTT Monitoring Report—The Navy shall submit an annual report of the NWTT monitoring describing the implementation and results of the NWTT monitoring efforts from the previous calendar year. Data collection methods will be standardized across range complexes and study areas to allow for comparison in different geographic locations. Although additional information will be gathered, the protected species observers collecting marine mammal data pursuant to the NWTT monitoring plan shall, at a minimum, provide the same marine mammal observation data required in this section. The report shall be submitted either 90 days after the calendar year, or 90 days after the conclusion of the monitoring year to be determined by the Adaptive Management process. The NWTT Monitoring Report may be provided to NMFS within a larger report that includes the required Monitoring Plan reports from multiple range complexes and study areas (the multi-Range Complex Annual Monitoring Report). Such a report would describe progress of knowledge made with respect to monitoring plan study questions across all Navy ranges associated with the Integrated Comprehensive Monitoring Program. Similar study questions shall be treated together so that progress on each topic shall be summarized across all Navy ranges. The report need not include analyses and content that does

not provide direct assessment of cumulative progress on the monitoring plan study questions.

(g) Annual NWTT Exercise and Testing Reports—The Navy shall submit preliminary reports detailing the status of authorized sound sources within 21 days after the anniversary of the date of issuance of the LOA. The Navy shall submit detailed reports 3 months after the annual anniversary of the date of issuance of the LOA. The detailed annual reports shall describe the level of training and testing conducted during the reporting period, and a summary of sound sources used (total annual hours or quantity [per the LOA] of each bin of sonar or other non-impulsive source; total annual number of each type of explosive exercises; total annual expended/detonated rounds [missiles, bombs, etc.] for each explosive bin; and improved Extended Echo-Ranging System (IEER)/sonobuoy summary, including total number of IEER events conducted in the Study Area, total expended/detonated rounds (buoys), and total number of self-scuttled IEER rounds. The analysis in the detailed reports will be based on the accumulation of data from the current year's report and data collected from previous reports. The annual classified exercise reports will also include the amount of hull-mounted mid-frequency and high frequency active sonar use during training and testing activities in the Olympic Coast National Marine Sanctuary and in the months specified for the following three feeding areas (to the extent that active sonar training or testing does occur in these areas): The Humpback Whale Northern Washington feeding area (May through November); the Stonewall and Heceta Bank feeding area (May through November) and the Gray Whale Northern Puget Sound Feeding Area (March through May).

(h) 5-year Close-out Exercise and Testing Report—This report will be included as part of the 2020 annual exercise or testing report. This report will provide the annual totals for each sound source bin with a comparison to the annual allowance and the 5-year total for each sound source bin with a comparison to the 5-year allowance. Additionally, if there were any changes to the sound source allowance, this report will include a discussion of why the change was made and include the analysis to support how the change did or did not result in a change in the EIS and final rule determinations. The report will be submitted 3 months after the expiration of the rule. NMFS will submit comments on the draft close-out report, if any, within 3 months of receipt. The report will be considered final after the Navy has addressed NMFS' comments, or 3 months after the submittal of the draft if NMFS does not provide comments.

§ 218.146 Applications for Letters of Authorization.

To incidentally take marine mammals pursuant to the regulations in this subpart, the U.S. citizen (as defined by § 216.106) conducting the activity identified in § 218.140(c) (the U.S. Navy) must apply for and obtain either an initial LOA in accordance with § 218.147 or a renewal under § 218.148.

§ 218.147 Letters of Authorization.

(a) An LOA, unless suspended or revoked, will be valid for a period of time not to exceed the period of validity of this subpart.

(b) Each LOA will set forth:

(1) Permissible methods of incidental taking;

(2) Means of effecting the least practicable adverse impact on the species, its habitat, and on the availability of the species for subsistence uses (*i.e.,* mitigation); and

(3) Requirements for mitigation, monitoring and reporting.

(c) Issuance, modification, or renewals of LOAs will be based on a determination that the total number of marine mammals taken by the activity as a whole will have no more than a negligible impact on the affected species or stock of marine mammal(s).

§ 218.148 Renewals and Modifications of Letters of Authorization and Adaptive Management.

(a) A Letter of Authorization issued under §§ 216.106 and 218.147 of this chapter for the activity identified in § 218.140(c) will be renewed or modified upon request of the applicant, provided that:

(1) The proposed specified activity and mitigation, monitoring, and reporting measures, as well as the anticipated impacts, are the same as those described and analyzed for these regulations (excluding changes made pursuant to the adaptive management provision of this chapter), and;

(2) NMFS determines that the mitigation, monitoring, and reporting measures required by the previous LOA under these regulations were adequately implemented.

(b) For LOA modification or renewal requests by the applicant that include changes to the activity or the mitigation, monitoring, or reporting (excluding changes made pursuant to the adaptive management provision of this chapter) that do not change the findings made for the regulations or result in no more than a minor change in the total estimated number of takes (or distribution by species or years), NMFS may publish a notice of proposed LOA in the **Federal Register**, including the associated analysis illustrating the change, and solicit public comment before issuing the LOA.

(c) An LOA issued under §§ 216.106 and 218.147 of this chapter for the activity identified in § 218.144 of this chapter may be modified by NMFS under the following circumstances:

(1) Adaptive Management—NMFS may modify (including add to, change, or remove) the existing mitigation, monitoring, or reporting measures (after consulting with the Navy regarding the practicability of the modifications) if doing so creates a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring set forth in the preamble for these regulations.

(i) Possible sources of data that could contribute to the decision to modify the mitigation, monitoring, and reporting measures in an LOA include (but are not limited to):

(A) Results from Navy's monitoring from the previous year(s);

(B) Results from other marine mammal and/or sound research or studies; or

(C) Any information that reveals marine mammals may have been taken in a manner, extent, or number not authorized by these regulations or subsequent LOAs.

(ii) If, through adaptive management, the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS would publish a notice of proposed LOA in the **Federal Register** and solicit public comment.

(2) Emergencies—If NMFS determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in § 218.142(c), an LOA may be modified without prior notification and an opportunity for public comment. Notification would be published in the **Federal Register** within 30 days of the action.

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