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DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 45

[Docket No. OCC–2015–0023]

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FEDERAL RESERVE SYSTEM

12 CFR Part 237

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12 CFR Part 349

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FARM CREDIT ADMINISTRATION

12 CFR Part 624

RIN 3052–AC69

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1221

RIN 2590–AA45

Margin and Capital Requirements for Covered Swap Entities

AGENCY: Office of the Comptroller of the Currency, Treasury (''OCC''); Board of Governors of the Federal Reserve System (''Board''); Federal Deposit Insurance Corporation (''FDIC''); Farm Credit Administration (''FCA''); and the Federal Housing Finance Agency (''FHFA'').

ACTION: Final rule.

SUMMARY: The OCC, Board, FDIC, FCA, and FHFA (each an ''Agency'' and, collectively, the ''Agencies'') are adopting exemptions from the initial and variation margin requirements published by the Agencies in November 2015 pursuant to sections 731 and 764 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the ''Dodd-Frank Act'' or the ''Act''). Pursuant to Title III of the Terrorism Risk Insurance Program Reauthorization Act of 2015 (''TRIPRA''), this final rule exempts certain non-cleared swaps and non-cleared security-based swaps with certain financial and non-financial end users that qualify for an exception or exemption from clearing.

DATES: This final rule is effective October 1, 2016.

FOR FURTHER INFORMATION CONTACT:

OCC: Ang Middleton, Risk Specialist, Financial Markets Group, (202) 649–7138, or Carl Kaminski, Special Counsel, Legislative and Regulatory Activities Division, (202) 649–5490, for persons who are deaf or hard of hearing, TTY (202) 649–5597, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

Board: Sean D. Campbell, Associate Director, (202) 452–3760, Anna M. Harrington, Senior Supervisory Financial Analyst, (202) 452–6406, or Lesley Chao, Senior Supervisory Financial Analyst, (202) 974–7063, Division of Banking Supervision and Regulation; Victoria M. Szybillo, Counsel, (202) 475–6325, or Adam Cohen, Counsel, (202) 912–4658, Legal Division, Board of Governors of the Federal Reserve System, 20th and C Streets NW., Washington, DC 20551.

FDIC: Karl R. Reitz, Corporate Expert, Capital Markets, *kreitz@fdic.gov;* Michael E. Spencer, Chief, Capital Markets Strategy Section, *michspencer@fdic.gov,* Division of Risk Management Supervision, (202) 898–6888; Thomas F. Hearn, Counsel, *thohearn@fdic.gov,* (202) 898–6967, or Catherine Topping, Counsel, *ctopping@fdic.gov,* (202) 898–3975, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.

FCA: J.C. Floyd, Associate Director, Finance & Capital Markets Team, Timothy T. Nerdahl, Senior Policy Analyst—Capital Markets, Jeremy R. Edelstein, Senior Policy Analyst, Office of Regulatory Policy, (703) 883–4414, TTY (703) 883–4056, or Richard A. Katz, Senior Counsel, Office of General Counsel, (703) 883–4020, TTY (703) 883–4056, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090.

FHFA: George Sacco, Senior Financial Analyst, Division of Housing Mission and Goals, (202) 649–3276, *George.Sacco@fhfa.gov,* or Peggy K. Balsawer, Associate General Counsel, Office of General Counsel, (202) 649–3060, *Peggy.Balsawer@fhfa.gov,* Federal Housing Finance Agency, Constitution Center, 400 7th St. SW., Washington, DC 20219. The telephone number for the Telecommunications Device for the Hearing Impaired is (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

The Dodd-Frank Act was enacted on July 21, 2010.[1] Title VII of the Dodd-Frank Act established a comprehensive new regulatory framework for derivatives, which the Act generally characterizes as ''swaps'' and ''security-based swaps.'' [2] As part of this new regulatory framework, sections 731 and 764 of the Dodd-Frank Act added, respectively, a new section 4s to the Commodity Exchange Act of 1936 (the ''Commodity Exchange Act''), and a new section 15F to the Securities Exchange Act of 1934 (the ''Securities Exchange Act''), which require registration with the U.S. Commodity Futures Trading Commission (the ''CFTC'') of swap dealers and major swap participants and with the U.S. Securities and Exchange Commission (the ''SEC'') of security-based swap dealers and major security-based swap participants.[3] These

[1] Public Law 111–203, 124 Stat. 1376 (2010).

[2] ''Swaps'' are defined in section 721 of the Dodd-Frank Act to include interest rate swaps, commodity-based swaps, equity swaps and credit default swaps. ''Security-based swaps'' are defined in section 761 of the Dodd-Frank Act to include a swap based on a single security or loan or on a narrow-based security index. *See* 7 U.S.C. 1a(47); 15 U.S.C. 78c(a)(68).

[3] *See* 7 U.S.C. 6s; 15 U.S.C. 78o–10. Section 731 of the Dodd-Frank Act requires swap dealers and major swap participants to register with the CFTC, which is vested with primary responsibility for the oversight of the swaps market under Title VII of the Dodd-Frank Act. Section 764 of the Dodd-Frank Act requires security-based swap dealers and major security-based swap participants to register with the SEC, which is vested with primary responsibility for the oversight of the security-based swaps market under Title VII of the Dodd-Frank Act. Section 712(d)(1) of the Dodd-Frank Act requires the CFTC and SEC to issue joint rules further defining the terms swap, security-based swap, swap dealer, major swap participant, security-based swap dealer, and major security-based swap participant. The CFTC and SEC issued final joint rulemakings with

Continued

registrants are collectively referred to in this preamble as ''swap entities.''

Sections 731 and 764 of the Dodd-Frank Act require the Agencies to adopt joint rules that apply to all swap entities for which any one of the Agencies is the prudential regulator,[4] imposing capital requirements and initial and variation margin requirements on all swaps and security-based swaps not cleared by a registered derivatives clearing organization or clearing agency.[5] After a rulemaking process that began in 2011, the Agencies published a joint final rule to implement these Dodd-Frank Act requirements on November 30, 2015 (the ''joint final rule'').[6]

The capital and margin requirements under sections 731 and 764 of the Dodd-Frank Act apply to non-cleared swaps and non-cleared security-based swaps and complement other provisions of the Dodd-Frank Act that require the CFTC and SEC to make determinations as to whether certain swaps or security-based swaps, or a group, category, or class of such transactions, should be required to be cleared.[7] If the CFTC or SEC has made such a determination, it is generally unlawful for any person to engage in such a swap or security-based swap unless the transaction is submitted to a derivatives clearing organization or clearing agency, as applicable, for clearing.

The clearing requirements, however, do not apply to an entity that is not a financial entity, is using a swap or security-based swap to hedge or mitigate commercial risk, and notifies the CFTC or the SEC, in a manner set forth by the appropriate Commission, how it generally meets its financial obligations.[8] Thus, a particular swap or security-based swap might not be cleared either because it is not subject to the mandatory clearing requirement or because one of the parties to the swap is eligible for, and elects to use, an exception or exemption from the mandatory clearing requirement. Such a swap or security-based swap is ''non-cleared'' for purposes of the capital and margin requirements established under sections 731 and 764 of the Dodd-Frank Act.

Sections 731 and 764 direct the Agencies to impose initial and variation margin requirements on all non-cleared swaps and non-cleared security-based swaps. The joint final rule takes into account the risk posed by a covered swap entity's counterparties in establishing the minimum amount of initial and variation margin that the covered swap entity must exchange with its counterparties.[9] In implementing this risk-based approach, the joint final rule distinguishes among four separate types of swap counterparties: (1) Counterparties that are themselves swap entities; (2) counterparties that are financial end users with a material swaps exposure; (3) counterparties that are financial end users without a material swaps exposure, and (4) other counterparties, including non-financial end users, sovereigns, and multilateral development banks.[10] The joint final rule makes a covered swap entity's collection of margin from these ''other counterparties,'' including commercial end users, subject to the judgment of the covered swap entity. In particular, a covered swap entity is not required to collect initial and variation margin from these ''other counterparties'' as a matter of course; a covered swap entity should collect initial or variation margin at such times and in such forms and amounts (if any) as the covered swap entity determines appropriate in its overall credit risk management of the covered swap entity's exposure to the customer.[11]

On January 12, 2015, President Obama signed TRIPRA into law.[12] Title III of TRIPRA, the ''Business Risk Mitigation and Price Stabilization Act of 2015,'' amends the statutory provisions added by the Dodd-Frank Act relating to margin requirements for non-cleared swaps and non-cleared security-based swaps. Specifically, section 302 of TRIPRA amends sections 731 and 764 of the Dodd-Frank Act to provide that the initial and variation margin requirements do not apply to certain transactions of specified counterparties that would qualify for an exception or exemption from clearing, as explained more fully below. Qualifying non-cleared swaps and non-cleared security-based swaps of entities covered by section 302 of TRIPRA are not subject to the Agencies' joint final rule.

Section 303 of TRIPRA requires the Agencies to implement the provisions of section 302 by promulgating an interim final rule pursuant to which public comment is sought before a final rule is issued. On November 30, 2015, the Agencies published and sought comment on an interim final rule, which added § __.1(d) to the joint final rule.[13] The Agencies are adopting as a final rule without change the interim final rule that went into effect on April 1, 2016.

II. Summary of Public Comments on Matters Raised in the Interim Final Rule

Three banking organizations, two individuals, two trade associations, and one nonprofit finance cooperative submitted comments in response to the interim final rule.[14] Four of the commenters expressed strong support for the approach taken in the interim final rule.

Comments were received from two public sector entities organized under foreign laws whose obligations are guaranteed by foreign governments (''foreign public sector entities''). These

respect to these definitions in May 2012 and August 2012, respectively. *See* 77 FR 30596 (May 23, 2012); 77 FR 39626 (July 5, 2012) (correction of footnote in the Supplementary Information accompanying the rule); and 77 FR 48207 (August 13, 2012). 17 CFR part 1; 17 CFR parts 230, 240 and 241.

[4] Section 1a(39) of the Commodity Exchange Act defines the term ''prudential regulator'' for purposes of the capital and margin requirements applicable to swap dealers, major swap participants, security-based swap dealers and major security-based swap participants. 7 U.S.C. 1a(39).

[5] *See* 7 U.S.C. 6s(e)(2)(A); 15 U.S.C. 78o–10(e)(2)(A).

[6] 80 FR 74840 (November 30, 2015).

[7] 7 U.S.C. 2(h); 15 U.S.C. 78c–3. The Commodity Exchange Act and the Securities Exchange Act set out standards that the CFTC and the SEC, respectively, are required to apply when making determinations about clearing, which generally address whether a swap or security-based swap is sufficiently standardized to be cleared. 7 U.S.C. 2(h)(2)(D); 15 U.S.C. 78c–3(b)(4).

[8] *See* 7 U.S.C. 2(h)(7); 15 U.S.C. 78c–3(g). Further, the CFTC has authority to exempt swaps from the clearing requirement. 7 U.S.C. 6(c)(1). Pursuant to this authority, the CFTC has provided an exemption from clearing to certain cooperatives that are financial entities. *See* 17 CFR 50.51. The SEC has similar exemptive authority under section 36(c) of the Securities Exchange Act. 15 U.S.C. 78mm(c).

[9] Each Agency has codified its rule within its respective title of the Code of Federal Regulations. Specifically, the Agencies codified the rules as follows: 12 CFR part 45 (OCC); 12 CFR part 237 (the Board); 12 CFR part 349 (FDIC); 12 CFR part 624 (FCA); and 12 CFR part 1221 (FHFA).

[10] *See* § __.2 of the joint final rule for the various definitions that identify these four types of swaps counterparties. The terms ''non-financial end user'' and ''commercial end user'' are used interchangeably throughout this preamble. Although the term ''commercial end user'' is not defined in the Dodd-Frank Act, it is used in this preamble to mean a company that is eligible for the exception to the mandatory clearing requirement for swaps under section 2(h)(7)(A) of the Commodity Exchange Act and section 3C(g)(1) of the Securities Exchange Act, respectively. This exception is generally available to a person that (1) is not a financial entity, (2) is using the swap to hedge or mitigate commercial risk, and (3) has notified the CFTC or SEC how it generally meets its financial obligations with respect to non-cleared swaps or security-based swaps, respectively. *See* 7 U.S.C. 2(h)(7)(A) and 15 U.S.C. 78c–3(g)(1); *see also* 80 FR 74848 note 70.

[11] *See* §§ __.3(d) and __.4(c) of the joint final rule.

[12] Public Law 114–1, 129 Stat. 3 (2015).

[13] 80 FR 74916 (November 30, 2015) (the ''interim final rule'').

[14] The Agencies carefully considered all comments received on the interim final rule. In addition, representatives of the FDIC and FCA had a telephone call with one commenter after the comment period closed. Comments received on the interim final rule, as well as a summary of the call with this commenter, are available on the applicable Agencies' respective public Web sites.

commenters argued that, even though they are not included among the type of entities expressly covered by section 302 of TRIPRA, foreign public sector entities should still not be subject to the joint final rule because the CFTC has determined that these types of entities are not subject to the mandate to clear swaps that are otherwise required to be cleared.

The Agencies are not providing the relief requested by these commenters since the purpose of this final rule is to incorporate the terms of section 302 of TRIPRA, and the treatment of foreign public sector entities is not specified by section 302. Even though the CFTC has interpreted the Commodity Exchange Act to exclude certain foreign public sector entities from the clearing mandate that the Dodd-Frank Act added to the Commodity Exchange Act, such entities are not addressed in section 302 of TRIPRA.[15]

One commenter asked for clarification that swap transaction documentation that contains ''flip clauses'' or ''rating agency condition'' (''RAC'') provisions cannot qualify for an exemption from the Agencies' joint final rule or this final rule.[16] Specifically, the commenter stated that Title III of TRIPRA does not exempt a swap with a flip clause or RAC provision from the margin requirements of the joint final rule. The commenter further requested that an entity covered by section 302 of TRIPRA be required to file with the CFTC a signed affidavit stating that all swaps that are exempt from the joint final rule's margin requirements because of section 302 of TRIPRA do not have a flip clause or any other clause that can be reasonably classified as a walk-away provision or RAC provision. Finally, the commenter recommended that the prudential regulators should obligate a covered swap entity to post initial margin and variation margin to its guarantor or hedging affiliate against a swap that contains a ''flip clause'' or any other clause that can be reasonably classified as a walk-away provision. The Agencies are declining to make the requested changes, since the purpose of the final rule is to incorporate the terms of section 302 of TRIPRA, and the treatment of flip clauses or RAC provisions is not specified by section 302.

The Agencies received one request for clarification with respect to paragraph (1)(xi) of the definition of ''financial end user'' set forth in the joint final rule. Specifically, the commenter asked the Agencies to clarify and consider the use of certain terms and phrases (*i.e.,* ''investing or trading,'' ''other assets,'' and ''primarily'') in this prong of the financial end user definition. While § __.1(d), as adopted in this final rule, works in conjunction with the joint final rule, the Agencies find this comment does not relate to § __.1(d) and thus is outside of the scope of the interim final rule, which implements section 302 of TRIPRA.

The Agencies also received four comments in support of the treatment of certain cooperative entities under the interim final rule. One comment was received from an individual expressing his support for the approach taken in the interim final rule.

III. Description of the Final Rule

The interim final rule adopted § __.1(d) to implement section 302 of TRIPRA. The final rule makes no changes to § __.1(d).

TRIPRA provides that the initial and variation margin requirements in sections 731 and 764 of the Dodd-Frank Act do not apply to qualifying non-cleared swaps and non-cleared security-based swaps of certain categories of counterparties. In particular, section 302(a) of TRIPRA amends section 731 of the Dodd-Frank Act so that initial and variation margin requirements will not apply to a swap in which a counterparty (to a covered swap entity) is:

(1) A non-financial entity (including a small financial institution and a captive finance company) that qualifies for the clearing exception under section 2(h)(7)(A) of the Commodity Exchange Act;

(2) A cooperative entity that qualifies for an exemption from the clearing requirements issued under section 4(c)(1) of the Commodity Exchange Act; or

(3) A treasury affiliate that satisfies the criteria for an exception from clearing in section 2(h)(7)(D) of the Commodity Exchange Act.

Similarly, section 302(b) of TRIPRA amends section 764 of the Dodd-Frank Act so that initial and variation margin requirements will not apply to a security-based swap in which a counterparty (to a covered swap entity) is:

(1) A non-financial entity (including a small financial institution) that qualifies for the clearing exception under section 3C(g)(1) of the Securities Exchange Act; or

(2) A treasury affiliate that satisfies the criteria for an exception from clearing in section 3C(g)(4) of the Securities Exchange Act.

Below is a discussion of each type of entity covered by section 302 of TRIPRA as well as a discussion of how related reporting requirements can be satisfied.

A. Non-Financial Entities

TRIPRA provides that the initial and variation margin requirements of the joint final rule shall not apply to a non-cleared swap in which a counterparty qualifies for an exception under section 2(h)(7)(A) of the Commodity Exchange Act or a non-cleared security-based swap in which a counterparty qualifies for an exception under section 3C(g)(1) of the Securities Exchange Act.[17] Section 2(h)(7)(A) and section 3C(g)(1) except from clearing swaps or security-based swaps where one of the counterparties: (1) Is not a financial entity; (2) is using the swap to hedge or mitigate commercial risk; and (3) notifies the CFTC or SEC how it generally meets its financial obligations associated with entering into non-cleared swaps or non-cleared security-based swaps. A number of different types of counterparties may qualify for an exception from clearing under section 2(h)(7)(A) and section 3C(g)(1), including non-financial end users and small banks, savings associations, Farm Credit System institutions, and credit unions. In addition, captive finance companies qualify for an exception from clearing swaps under section 2(h)(7)(A).[18]

[15] Alternatively, each of these two foreign public sector entities sought clarification that it meets the definition of ''sovereign entity'' or ''multilateral development bank'' under the joint final rule. The joint final rule expressly excludes from the definition of ''financial end user'' an entity that meets the definition of ''sovereign entity'' or ''multilateral development bank.'' Whether an entity meets the definition of ''sovereign entity'' or ''multilateral development bank'' depends on facts and circumstances that may vary from entity to entity and is outside the scope of this rulemaking. The Agencies note that they considered similar comments received on the joint final rule and determined not to exclude entities guaranteed by a foreign sovereign from the definition of financial end user. *See* 80 FR 74,840, 74,856 (The Agencies explained: ''[a]n entity guaranteed by a sovereign entity is not explicitly excluded from the definition of financial end user in the final rule, unless that entity qualifies as a central government agency, department, or central bank. The existence of a government guarantee does not in and of itself exclude the entity from the definition of financial end user.'')

[16] The commenter has previously referred to a description of a ''flip clause'' as a contractual provision in a swap to which a special purpose vehicle (''SPV'') is a party and under which the payments owed by the SPV to a swap provider are at least *pari passu* with interest of the senior most class of debt issued by the structured finance vehicle. In the description that the commenter referred to, a ''flip clause'' was described as a provision that provides that should the swap provider be the defaulting party to a swap, such default causes the swap provider to ''flip'' to a more junior position in the priority of payments.

[17] *See* 7 U.S.C. 2(h)(7)(A); 15 U.S.C. 78c–3(g)(1).

[18] There is no corresponding exclusion from clearing security-based swaps under section

Continued

Non-financial end users. A counterparty that is not a financial entity [19] and that is using swaps to hedge or mitigate commercial risk generally would qualify for an exception from clearing under section 2(h)(7)(A) or section 3C(g)(1) and thus from the requirements of the joint final rule for non-cleared swaps and non-cleared security-based swaps pursuant to § __.1(d).

Small banks, savings associations, Farm Credit System institutions, and credit unions. Section 2(h)(7)(C)(ii) provides that the CFTC shall consider whether to exempt small banks, savings associations, Farm Credit System institutions, and credit unions with total assets of $10 billion or less from the definition of financial entity. Pursuant to this authority, the CFTC has exempted small banks, savings associations, Farm Credit System institutions, and credit unions with total assets of $10 billion or less from the definition of ''financial entity,'' thereby permitting these institutions to avail themselves of the clearing exception when they are using swaps to hedge or mitigate risk.[20] As a result, non-cleared swaps used by these small financial institutions to hedge or mitigate commercial risk would also qualify for an exemption from the initial and variation margin requirements of the joint final rule pursuant to § __.1(d).

Similarly, section 3C(g) provides that the SEC shall consider whether to exempt small banks, savings associations, Farm Credit System institutions, and credit unions with total assets of $10 billion or less from the definition of ''financial entity.'' [21] If the SEC were to implement an exemption for such entities from clearing, non-cleared security-based swaps with those entities would be eligible for the exemption in the joint final rule pursuant to § __.1(d) as required under TRIPRA, provided they met the other requirements for the clearing exemption.[22]

Captive finance companies. Section 2(h)(7)(C) also provides that the definition of ''financial entity'' does not include an entity whose primary business is providing financing and uses derivatives for the purposes of hedging underlying commercial risks relating to interest rate and foreign exchange exposures, 90 percent or more of which arise from financing that facilitates the purchase or lease of products, 90 percent or more of which are manufactured by the parent company or another subsidiary of the parent company (''captive finance company'').[23] These entities can qualify for a clearing exception when they are using swaps to hedge or mitigate commercial risk and thus non-cleared swaps of these entities would be eligible for the exemption in the joint final rule pursuant to § __.1(d).

B. Treasury Affiliates

Section 302 of TRIPRA provides that the initial and variation margin requirements shall not apply to a non-cleared swap or non-cleared security-based swap in which a counterparty satisfies the criteria in section 2(h)(7)(D) of the Commodity Exchange Act or section 3C(g)(4) of the Securities Exchange Act. At the time the interim final rule was published, these sections provided that, where a person qualifies for an exception from the clearing requirements, an affiliate of that person (including an affiliate predominantly engaged in providing financing for the purchase of the merchandise or manufactured goods of the person) would have qualified for the exception as well, but only if the affiliate is acting on behalf of the person and as an agent and uses the swap to hedge or mitigate the commercial risk of the person or other affiliate of the person that is not a financial entity (''treasury affiliate acting as agent'').[24] Under the interim final rule, non-cleared swaps and non-cleared security-based swaps of a treasury affiliate acting as agent that met the requirements for a clearing exception would also be eligible for an exemption pursuant to § __.1(d) from the joint final rule.

The Consolidated Appropriations Act, 2016 (''Appropriations Act of 2016''), which was enacted on December 18, 2015, amended section 2(h)(7)(D) of the Commodity Exchange Act and section 3C(g)(4) of the Securities Exchange Act.[25] Specifically, section 705 of the Appropriations Act of 2016 removed the requirement that treasury affiliates must act on behalf of a person and as an agent in order to avail themselves of the clearing exception. The Appropriations Act of 2016 also included certain conditions on the application of the treasury affiliate exception [26] and imposed certain limitations on the types of entities that can qualify for the exception.[27]

3C(g)(1) of the Securities Exchange Act for captive finance companies. Similarly, with respect to financial cooperatives, TRIPRA exempts such entities from exchanging initial and variation margin under the joint final rule on all swaps that are subject to the exemption from clearing provided by the CFTC. *See* 7 U.S.C. 6(c)(1). There is no corresponding exclusion under the Securities Exchange Act.

[19] *See* 7 U.S.C. 2(h)(7)(A); 15 U.S.C. 78c–3(g)(1); 17 CFR 50.50. A ''financial entity'' is defined to mean (i) a swap dealer; (ii) a security-based swap dealer; (iii) a major swap participant; (iv) a major security-based swap participant; (v) a commodity pool; (vi) a private fund as defined in section 202(a) of the Investment Advisers Act of 1940; (vii) an employee benefit plan as defined in sections 3(3) and 3(32) of the Employment Retirement Income Security Act of 1974; and (viii) a person predominantly engaged in activities that are in the business of banking, or in activities that are financial in nature, as defined in section 4(k) of the Bank Holding Company Act of 1956. *See* 7 U.S.C. 2(h)(7)(C)(i); 15 U.S.C. 78c–3(g)(3).

[20] *See* 7 U.S.C. 2(h)(7)(C)(ii); 17 CFR 50.50; 77 FR 42560 (July 19, 2012); as recodified by 77 FR 74284 (December 13, 2012).

[21] *See* 15 U.S.C. 78c–3(g)(3)(B).

[22] On December 21, 2010, the SEC proposed to exempt security-based swaps used by small depository institutions, small Farm Credit System institutions, and small credit unions with total assets of $10 billion or less from clearing. *See* 75 FR 79992 (December 21, 2010).

[23] *See* 7 U.S.C. 2(h)(7)(C)(iii).

[24] *See* 7 U.S.C. 2(h)(7)(D); 15 U.S.C. 78c–3(g)(4). This exception does not apply to a person that is a swap dealer, security-based swap dealer, major swap participant, major security-based swap participant, an issuer that would be an investment company as defined in section 3 of the Investment Company Act of 1940 (15 U.S.C. 80a-3) but for section 3(c)(1) or 3(c)(7) of that Act, a commodity pool, or a bank holding company with over $50 billion in consolidated assets.

[25] Pub. L. 114–113, 129 Stat. 2242 (2015).

[26] Under section 705 of the Appropriations Act of 2016, a treasury affiliate may qualify for an exception from the clearing requirements only if the affiliate (i) enters into the swap to hedge or mitigate the commercial risk of the person or other affiliate of the person that is not a financial entity, and the commercial risk that the affiliate is hedging or mitigating has been transferred to the affiliate; (ii) is directly and wholly-owned by another affiliate qualified for the exception under section 2(h)(7)(D)(i) of the Commodity Exchange Act or an entity that is not a financial entity; (iii) is not indirectly majority-owned by a financial entity; (iv) is not ultimately owned by a parent company that is a financial entity; and (v) does not provide any services, financial or otherwise, to any affiliate that is a nonbank financial company supervised by the Board of Governors (as defined under section 102 of the Financial Stability Act of 2010). With respect to the treasury affiliate exception, the affiliate may not enter into any swap other than for the purpose of hedging or mitigating commercial risk; and neither the affiliate nor any person affiliated with the affiliate that is not a financial entity may enter into a swap with or on behalf of any affiliate that is a financial entity or otherwise assume, net, combine, or consolidate the risk of swaps entered into by any such financial entity, except one that is an affiliate that qualifies for the exception. Further, any swap entered into by an affiliate that qualifies for the exception shall be subject to a centralized risk management program of the affiliate, which is reasonably designed both to monitor and manage the risks associated with the swap and to identify each of the affiliates on whose behalf a swap was entered into. *See* Pub. L. 114–113, 129 Stat. 2242 (2015).

[27] For example, the treasury affiliate exception will not apply if the affiliate is a swap dealer, a security-based swap dealer, a major swap participant, a major security-based swap participant, a commodity pool, a bank holding company, a private fund (as defined in section 202(a) of the Investment Advisers Act of 1940), an employee benefit plan or government plan (as defined in paragraphs (3) and (32) of section 3 of the Employee Retirement Income Security Act of 1974), an insured depository institution, a Farm Credit System institution, a credit union, a nonbank

Since the exemption in § __.1(d) of the final rule incorporates the treasury affiliate exception by reference to section 2(h)(7)(D) of the Commodity Exchange Act and section 3C(g)(4) of the Securities Exchange Act, the exemption will by operation of law apply to qualifying non-cleared swaps and non-cleared security-based swaps of treasury affiliates, acting as either principal or agent. For this reason, no changes to the regulatory text were necessary to reflect these changes to the underlying statutes.[28]

C. Certain Cooperative Entities

Section 302 of TRIPRA provides that the initial and variation margin requirements shall not apply to a non-cleared swap in which a counterparty qualifies for an exemption issued under section 4(c)(1) of the Commodity Exchange Act from the clearing requirements of section 2(h)(1)(A) of the Commodity Exchange Act for cooperative entities as defined in such exemption.[29] The CFTC, pursuant to its authority under section 4(c)(1) of the Commodity Exchange Act, adopted a regulation that allows cooperatives that are financial entities to elect an exemption from mandatory clearing of swaps that: (1) They enter into in connection with originating loans for their members; or (2) hedge or mitigate commercial risk related to loans or swaps with their members, or arising from certain swaps with members.[30] The swaps of these cooperatives that would qualify for an exemption from clearing also would qualify pursuant to § __.1(d) for an exemption from the margin requirements of the joint final rule.

D. Compliance With Eligibility Requirements

Section 302 of TRIPRA identifies the types of non-cleared swaps or non-cleared security-based swaps with counterparties that are excluded from the margin requirements of the joint final rule by referring to specific sections of the Commodity Exchange Act and the Securities Exchange Act. These provisions, in turn, set forth clearing exceptions and exemptions for these counterparties. To qualify for such exceptions and exemptions, the counterparty must, in addition to falling within the class or type of entity exempted or excepted by the respective statutory provisions, also be entering into the swap or security-based swap to hedge or mitigate commercial risk, and must report to the applicable Commission (in a manner set forth by the applicable Commission) how it generally meets its financial obligations associated with entering into non-cleared swaps or non-cleared security-based swaps.[31]

Swaps and Security-Based Swaps Required to be Cleared

For swaps that the CFTC has determined are required to be cleared, the CFTC has adopted regulations that establish requirements by which an eligible entity may elect its option not to clear that type of swap and comply with the related substantive hedging and reporting requirements.[32] For such a swap, compliance with the CFTC regulatory requirements for a swap subject to clearing will provide the covered swap entity with sufficient information about the eligible entity and the swap to establish the swap is also exempt from the margin requirements of the joint final rule.[33] The Agencies believe that whenever a covered swap entity transacts in a swap with an eligible entity that uses the clearing exemption for that swap in compliance with these CFTC requirements, the covered swap entity needs no additional information from the eligible entity to proceed with that swap pursuant to the final rule's exemption from the margin requirements of the joint final rule.

With respect to security-based swaps, the SEC has not yet made determinations requiring any security-based swap to be cleared, and has not yet adopted final rules related to how eligibility and compliance with the associated substantive requirements can be documented.[34] For a security-based swap subject to clearing, compliance with the SEC regulatory requirements, once finalized, will provide the covered swap entity with sufficient information about the eligible entity and the security-based swap to establish that the security-based swap is also exempt from the margin requirements of the joint final rule. Until such time as determinations are finalized by the SEC, the Agencies expect that covered swap entities will take appropriate steps to establish a reasonable belief that the entity is of a type eligible for the exemption and is using the security-based swap to hedge or mitigate commercial risk, as described below for other non-cleared swaps and non-cleared security-based swaps.

Swaps and Security-Based Swaps Not Required To Be Cleared

There are also cases where a covered swap entity may enter into a non-cleared swap or non-cleared security-based swap with an eligible entity that the CFTC or SEC, respectively, does not require to be cleared. For swaps that are not subject to a CFTC or SEC clearing requirement, the Agencies expect that covered swap entities will take appropriate steps to establish a reasonable belief that the counterparty is an entity eligible for the exemption and is using the swap to hedge or

financial company supervised by the Board, or an entity engaged in the insurance business and subject to capital regulation by an insurance regulator. The Appropriations Act of 2016 further prohibited the treasury affiliate exception from applying to affiliates which are themselves affiliated with swap entities unless the CFTC or the SEC, as applicable, determines that doing so is in the public interest. *See* Pub. L. 114–113, 129 Stat. 2242 (2015).

[28] Accordingly, the Agencies find it unnecessary to provide further notice or seek further public comment regarding the effect of the Appropriations Act of 2016 on this final rule.

[29] *See* 7 U.S.C. 6(c)(1). The CFTC, pursuant to its authority under section 4(c)(1) of the Commodity Exchange Act, adopted 17 CFR 50.51, which allows cooperative financial entities that meet certain qualifications to elect not to clear certain swaps that are otherwise required to be cleared pursuant to section 2(h)(1)(A) of the Commodity Exchange Act.

[30] *See* 7 U.S.C. 6(c)(1); 17 CFR 50.51.

[31] 7 U.S.C. 2(h)(7)(A); 17 CFR 50.50(b); 15 U.S.C. 3C(g)(4). Other provisions of the Commodity Exchange Act and the Securities Exchange Act separately impose additional governance requirements on an entity that elects a clearing exemption and that is an issuer of securities registered under section 12 of, or that is required to file reports under section 15(d) of, the Securities Exchange Act of 1934. 7 U.S.C. 2(j); 15 U.S.C. 3C(i).

[32] 17 CFR 50.50(b), 50.51(c), 50.51. In addition to providing reporting requirements, these CFTC rules further define the entities that are eligible for exceptions and exemptions from the clearing requirements and define when a swap is used to hedge or mitigate commercial risk.

[33] Whenever a qualifying non-clearing entity has elected its option to not clear a swap that the CFTC has determined should be cleared, the entity's eligibility as well as its compliance with the associated hedging and reporting requirements must be demonstrated either: (1) In an annual filing by the entity reporting to an appropriate Swap Data Repository (SDR) or, if no registered SDR is available to receive the information, to the CFTC, which will be applicable to all such swaps entered into by the entity for 365 days following the date of such filing; or (2) on a swap-by-swap basis through a report filed by the eligible entity or the covered swap entity with the applicable SDR or, if no registered SDR is available to receive the information, the CFTC. The rule requires that the reporting counterparty have a reasonable basis to believe that the electing counterparty is an eligible entity that meets the associated hedging and reporting requirements. *See* 17 CFR 50.50(b)(2)–(3) and 50.51(c).

[34] In December 2010, the SEC proposed reporting requirements for a counterparty exercising an exception from clearing, which would require the entity to report to a security-based SDR that it is an eligible entity and: that the swap is being used to hedge or mitigate commercial risk; how it generally meets its financial obligations associated with entering into non-cleared security-based swaps, and, if a registered issuer of securities, whether a committee of the board has reviewed and approved the decision to enter into security-based swaps subject to the clearing exception. 75 FR 79992 (December 21, 2010).

mitigate commercial risk.[35] The final rule does not prescribe any specific procedure or standard in this regard, and instead leaves covered swap entities the flexibility to collect information specifically on these points, take cognizance of information they already have about their counterparties and their non-cleared swap and non-cleared security-based swap transactions, or a combination of both. The Agencies believe it would be reasonable for a covered swap entity to rely in good faith on reasonable representations of its counterparty in making these assessments.[36]

In addition to the entity type requirements and the hedging requirements specified in the statutory clearing exceptions and exemptions referenced under section 302 of TRIPRA, there are requirements for reporting to the relevant Commission, in the manner set forth by the Commission, when the clearing exceptions and exemptions are elected. The Agencies expect covered swap entities subject to the joint final rule to comply with any reporting requirements that the relevant Commission may impose on covered swap entities in order to permit the use of the margin exemptions pursuant to section 302 of TRIPRA.

IV. Effective Date

The Riegle Community Development and Regulatory Improvement Act of 1994 (the ''RCDRIA'') requires that the OCC, the Board, and the FDIC, in determining the effective date and administrative compliance requirements of new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions, consider, consistent with principles of safety and soundness and the public interest, any administrative burdens that such regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the benefits of such regulations.[37] In addition, new regulations by the OCC, the Board, or the FDIC that impose additional reporting, disclosures, or other new requirements on insured depository institutions generally must take effect on the first day of a calendar quarter that begins on or after the date on which the regulations are published in final form.[38] Accordingly, this final rule, which adopts the interim final rule without change, will be effective on October 1, 2016 as required under the RCDRIA.

V. Administrative Law Matters

A. Solicitation of Comments on Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act, Public Law 106–102, sec. 722, 113 Stat. 1338, 1471 (Nov. 12, 1999), requires the OCC, Board and FDIC to use plain language in all proposed and final rules published after January 1, 2000. The OCC, Board and FDIC sought to present the final rule in a simple and straightforward manner and did not receive any comments on the use of plain language.

B. Paperwork Reduction Act Analysis

Certain provisions of the final rule contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act (''PRA'') of 1995 (44 U.S.C. 3501–3521). In accordance with the requirements of the PRA, the Agencies may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for the OCC is 1557–0335, the FDIC is 3064–0204, and the Board is 7100–0364. The information collection requirements contained in this final rulemaking have been submitted to OMB for review and approval by the OCC and FDIC under section 3507(d) of the PRA and § 1320.11 of OMB's implementing regulations (5 CFR part 1320). The Board reviewed the final rule under the authority delegated to the Board by OMB. The Agencies received no comments on the PRA.

The final rule contains requirements subject to the PRA. The reporting requirements are found in § _.1(d). The final rule implements statutory language that requires certain swaps of certain counterparties to qualify for a statutory exemption or exception from clearing in order to not be subject to the initial and variation margin requirements of the joint final rule.

Proposed Information Collection

Title of Information Collection: Reporting and Recordkeeping Requirements Associated with Margin and Capital Requirements for Covered Swap Entities.

Frequency of Response: Annual, daily, and event-generated.

Affected Public: The affected public of the OCC, FDIC, and Board is assigned generally in accordance with the entities covered by the scope and authority section of their respective final rule. Businesses or other for-profit.

Respondents:

OCC: Any national bank or a subsidiary thereof, Federal savings association or a subsidiary thereof, or Federal branch or agency of a foreign bank that is registered as a swap dealer, major swap participant, security-based swap dealer, or major security-based swap participant.

FDIC: Any FDIC-insured state-chartered bank that is not a member of the Federal Reserve System or FDIC-insured state-chartered savings association that is registered as a swap dealer, major swap participant, security-based swap dealer, or major security-based swap participant.

Board: Any state member bank (as defined in 12 CFR 208.2(g)), bank holding company (as defined in 12 U.S.C. 1841), savings and loan holding company (as defined in 12 U.S.C. 1467a), foreign banking organization (as defined in 12 CFR 211.21(o)), foreign bank that does not operate an insured branch, state branch or state agency of a foreign bank (as defined in 12 U.S.C. 3101(b)(11) and (12)), or Edge or agreement corporation (as defined in 12 CFR 211.1(c)(2) and (3)) that is registered as a swap dealer, major swap participant, security-based swap dealer, or major security-based swap participant.

Abstract: This final rule implements Title III of the Terrorism Risk Insurance Program Reauthorization Act of 2015 (''TRIPRA''), which exempts from the Agencies' swap margin rules non-cleared swaps and non-cleared security-based swaps in which a counterparty qualifies for an exemption or exception from clearing under the Dodd-Frank Act. This final rule is a companion rule to the joint final rule adopted by the Agencies to implement section 731 and 764 of the Dodd-Frank Act.

Reporting Requirements

The final rule implements statutory language that requires certain swaps and security-based swaps of certain counterparties to qualify for a statutory exemption or exception from clearing in order to not be subject to the initial and variation margin requirements of the joint final rule. The reporting requirements are found in § __.1(d) pursuant to cross-references to other

[35] As noted above, this category of non-cleared swaps includes all non-cleared security-based swaps during the interim until the SEC adopts final regulations requiring clearing of security-based swaps and associated exemptions from clearing.

[36] *See* the Agencies' joint final rule at 80 FR 74858 (November 30, 2015), discussing covered swap entities' reliance in good faith on reasonable representations of a counterparty as to whether the counterparty is a financial end user with a material swaps exposure; *see also* 17 CFR 50.50(b)(2)–(3) and 50.51(c).

[37] 12 U.S.C. 4802(a).

[38] 12 U.S.C. 4802(b).

statutory provisions that set forth the conditions for an exemption from clearing. For example, TRIPRA provides that the initial and variation margin requirements of the joint final rule shall not apply to a non-cleared swap or non-cleared security-based swap in which a counterparty qualifies for an exception under section 2(h)(7)(A) of the Commodity Exchange Act or section 3C(g)(1) of the Securities Exchange Act, which includes certain reporting requirements established by the CFTC or the SEC.[39] Certain other counterparties that are exempt from clearing pursuant to other provisions are also required to meet these reporting requirements to notify the CFTC or the SEC.[40] Thus, in certain cases, the statutory exemption from clearing requires a notification to the CFTC or SEC. These counterparties may be required to meet the same notification requirements that are required for an exception or exemption from clearing in order to qualify for an exception or exemption pursuant to § __.1(d) from the initial and variation margin requirements established by the Agencies under sections 731 and 764 of the Dodd-Frank Act. Since this final rule serves to implement exemptions and exceptions by reference to existing statutory provisions, § __.1(d) imposes new reporting requirements that are required under the relevant statutory provisions.

Estimated Burden per Response: § _.1(d)—1 hour.

Annual Frequency: 1,000.

OCC

Number of respondents: 20.

Total estimated annual burden: 20,000 hours.

FDIC[41]

Number of respondents: 1.

Total estimated annual burden: 1,000 hours.

Board

Number of respondents: 50.

Proposed revisions only estimated annual burden: 50,000 hours.

Total estimated annual burden: 86,964 hours.

FCA: The FCA has determined that the final rule does not involve a collection of information pursuant to the Paperwork Reduction Act for Farm Credit System institutions because Farm Credit System institutions are Federally chartered instrumentalities of the United States and instrumentalities of the United States are specifically excepted from the definition of ''collection of information'' contained in 44 U.S.C. 3502(3).

FHFA: With respect to any regulated entity as defined in section 1303(20) of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, as amended (12 U.S.C. 4502(20)), the final rule does not contain any collection of information that requires the approval of the OMB under the PRA.

C. Regulatory Flexibility Act Analysis

Board: An initial regulatory flexibility analysis, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (''RFA''),[42] was included in the interim final rule. In the initial regulatory flexibility analysis, the Board requested comments on all aspects of the initial regulatory flexibility analysis, and, in particular, comments on its conclusion that the interim final rule would not have a significant economic impact on a substantial number of small entities. The Board also requested comments on any significant alternatives to the interim final rule that would minimize the impact of the rule on small entities. The Board has since considered the potential impact of this final rule on small entities in accordance with section 604 of the RFA and has prepared the following final regulatory flexibility analysis. Based on the Board's analysis, and for the reasons stated below, the Board believes that the final rule will not have a significant economic impact on a substantial number of small entities.

1. *Statement of the need for, and objectives of, the final rule.* As explained in detail above, this final rule implements section 302 of TRIPRA, which provides that initial and variation margin requirements will not apply to specified non-cleared swaps or non-cleared security-based swaps of certain counterparties (to a covered swap entity). The reasons and justification for the final rule are described above in the **SUPPLEMENTARY INFORMATION**.

2. *Summary of the significant issues raised by public comment on the Board's initial analysis, the Board's assessment of such issues, and a statement of any changes made as a result of such comments.* The Board did not receive comments specifically on the initial regulatory flexibility analysis contained in the interim final rule, but the Agencies did receive comments on other aspects of the rule. A full discussion of all comments received by the Agencies with respect to this rule is contained in the **SUPPLEMENTARY INFORMATION**, above.

3. *Small entities affected by the final rule.* This final rule may have an effect on the following types of small entities: (i) Covered swap entities that are subject to the joint final rule's capital and margin requirements; and (ii) certain counterparties (*e.g.,* non-financial end users and certain other small financial counterparties) that engage in swaps or security-based swaps with covered swap entities.[43]

Under Small Business Administration (the ''SBA'') regulations, the finance and insurance sector includes commercial banking, savings institutions, credit unions, other depository credit intermediation and credit card issuing entities (''financial institutions''), which generally are considered ''small'' if they have assets of $550 million or less.[44] Covered swap entities would be considered financial institutions for purposes of the RFA in accordance with SBA regulations. The Board does not expect that any covered swap entity is likely to be a small financial institution, because a small financial institution is unlikely to engage in the level of swap activity that would require it to register as a swap dealer or major swap participant.[45] None of the currently

[39] *See, e.g.,* 17 CFR 50.50(b).

[40] For example, certain exempt cooperatives must meet these reporting requirements to qualify for an exemption from clearing. *See* 17 CFR 50.51(c). Similarly, exempt treasury affiliates also must be an affiliate of a person that qualifies for an exception from clearing that notifies the CFTC or SEC how it generally meets its financial obligations associated with entering into non-cleared swaps or non-cleared security-based swaps. *See* 7 U.S.C. 2(h)(7)(D); 15 U.S.C. 78c–3(g)(4).

[41] The FDIC had initially estimated that three of its institutions might register as a swap dealer, major swap participant, security-based swap dealer or major security-based swap participant but no state non-member bank nor any state savings association has so registered, so FDIC is reducing its estimate to one as a placeholder for its information collection.

[42] *See* 5 U.S.C. 601 *et seq.*

[43] The Board notes that the RFA does not require the Board to consider the impact of the final rule, including its indirect economic effects, on small entities that are not subject to the requirements of the final rule. *See e.g., In Mid-Tex Electric Cooperative* v. *FERC,* 773 F.2d 327 (D.C. Cir. 1985); *United Distribution Cos.* v. *FERC,* 88 F.3d 1105, 1170 (D.C. Cir. 1996); *Cement Kiln Recycling Coalition* v. *EPA,* 255 F.3d 855 (D.C. Cir. 2001).

[44] *See* 13 CFR 121.201 (effective December 2, 2014); *see also* 13 CFR 121.103(a)(6) (noting factors that the SBA considers in determining whether an entity qualifies as a small business, including receipts, employees, and other measures of its domestic and foreign affiliates).

[45] The CFTC has published a list of provisionally registered swap dealers (as of February 9, 2016) and provisionally registered major swap participants (as of March 1, 2013) that does not include any small financial institutions. *See http://www.cftc.gov/LawRegulation/DoddFrankAct/registerswapdealer* and *http://www.cftc.gov/LawRegulation/DoddFrankAct/registermajorswappart.* The SEC has not provided a similar list since it only recently adopted rules to provide for the registration of security-based swap dealers and major security-based swap participants. *See* 80 FR 48963 (August 14, 2015); 17 CFR parts 240 and 249.

registered covered swap entities are small entities. The final rule would have an indirect effect on certain counterparties to non-cleared swaps and non-cleared security-based swaps. Many of these counterparties would be considered ''small'' under the SBA's regulations.[46] However, the effect of TRIPRA and the final rule will be to exempt many of the non-cleared swaps and non-cleared security-based swaps of these counterparties from the margin requirements of the Agencies' joint final rule.

4. *Projected reporting, recordkeeping and other compliance requirements of the final rule.* As described above, this final rule implements statutory language that requires certain swaps of certain counterparties to qualify for a statutory exemption or exception from the applicable clearing requirements in order to not be subject to the initial and variation margin requirements of the joint final rule. The reporting requirements are found in § _.1(d) of this final rule pursuant to cross-references to other statutory provisions that set forth the conditions for an exemption or exception from clearing. In certain cases, the statutory exemption from clearing and related regulations may require a counterparty to report information, such as how it meets its swaps obligations, to the CFTC or SEC. These counterparties may be required to meet the same notification requirements that are required for an exception or exemption from the relevant CFTC and SEC regulations. Other than this potential overlap of reporting obligations of this final rule and the relevant CFTC and SEC regulations, the Board is not aware of any other Federal rules that duplicate, overlap, or conflict with this final rule. In light of the exemptions provided for the non-cleared swaps and non-cleared security-based swaps of many small entities, the Board does not believe that the final rule would have a significant economic impact on a substantial number of small entity counterparties.

5. *Significant alternatives to the final rule.* Since the final rule was required by TRIPRA, the Board does not believe that there are any significant alternatives to the rule which would accomplish the stated objectives of the applicable statute.

[46] *See* 13 CFR 121.201. In addition to small financial institutions with assets of $550 million or less, swap counterparties could also include other small entities defined in regulations issued by the SBA, including firms within the ''Securities, Commodity Contracts, and Other Financial Investments and Related Activities'' sector with assets of $38.5 million or less and ''Funds, Trusts and Other Financial Vehicles'' with assets of $32.5 million or less.

In light of the foregoing, the Board does not believe that this final rule would have a significant economic impact on a substantial number of small entities.

FDIC: The RFA requires an agency, in connection with a notice of final rulemaking, to prepare a Final Regulatory Flexibility Act analysis describing the impact of the rule on small entities (defined by the SBA for purposes of the RFA to include banking entities with total assets of $550 million or less) or to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Using SBA's size standards, as of June 30, 2015, the FDIC supervised 3,357 small entities. The FDIC does not expect any small entity that it supervises is likely to be a covered swap entity because such entities are unlikely to engage in the level of swap activity that would require them to register as a swap entity. Because TRIPRA excludes non-cleared swaps entered into for hedging purposes by a financial institution with total assets of $10 billion or less from the requirement of the final rule, the FDIC expects that when a covered swap entity transactions non-cleared swaps with a small entity supervised by the FDIC, and such swaps are used to hedge the small entity's commercial risk, those swaps will not be subject to the final rule. The FDIC does not expect any small entity that it supervises will engage in non-cleared swaps for purposes other than hedging. Therefore, the FDIC does not believe that the interim final rule results in a significant economic impact on a substantial number of small entities under its supervisory jurisdiction.

The FDIC certifies that the interim final rule does not have a significant economic impact on a substantial number of small FDIC-supervised institutions.

OCC: The Regulatory Flexibility Act (RFA)[47] generally requires an agency that is issuing a proposed rule to prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of the proposed rule on small entities. The RFA does not apply to a rulemaking where a general notice of proposed rulemaking is not required.[48] For the reasons described above in the Supplementary Information, the OCC has previously determined that it was unnecessary to publish a notice of proposed rulemaking for this final rule. Accordingly, the RFA's requirements relating to an initial and final regulatory flexibility analysis do not apply.

[47] *See* 5 U.S.C. 601 *et seq.*

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

FCA: Pursuant to section 605(b) of the Regulatory Flexibility Act, the FCA hereby certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Each of the banks in the Farm Credit System, considered together with its affiliated associations, has assets and annual income in excess of the amounts that would qualify them as small entities. Nor does the Federal Agricultural Mortgage Corporation meet the definition of a ''small entity.'' Therefore, Farm Credit System institutions are not ''small entities'' as defined in the Regulatory Flexibility Act.

FHFA: FHFA certifies that the final rule will not have a significant economic impact on a substantial number of small entities, since none of FHFA's regulated entities comes within the meaning of a ''small entity'' as defined in the Regulatory Flexibility Act (*see* 5 U.S.C. 601(6)), and the final rule will not substantially affect any business that its regulated entities might conduct with any such small entity.

List of Subjects

12 CFR Part 45

Administrative practice and procedure, Capital, Margin requirements, National Banks, Federal Savings Associations, Reporting and recordkeeping requirements, Risk.

12 CFR Part 237

Administrative practice and procedure, Banks and banking, Capital, Foreign banking, Holding companies, Margin requirements, Reporting and recordkeeping requirements, Risk.

12 CFR Part 349

Administrative practice and procedure, Banks, Holding companies, Capital, Margin requirements, Reporting and recordkeeping requirements, Savings associations Risk.

12 CFR Part 624

Accounting, Agriculture, Banks, Banking, Capital, Cooperatives, Credit, Margin requirements, Reporting and recordkeeping requirements, Risk, Rural areas, Swaps.

12 CFR Part 1221

Government-sponsored enterprises, Mortgages, Securities.

Department of the Treasury

Office of the Comptroller of the Currency

12 CFR Chapter I

PART 45—MARGIN AND CAPITAL REQUIREMENTS FOR COVERED SWAP ENTITIES

■ Accordingly, the interim final rule amending 12 CFR part 45, which was published at 80 FR 74916 on November 30, 2015, is adopted as a final rule without change.

Board of Governors of the Federal Reserve System

12 CFR Chapter II

PART 237—SWAPS MARGIN AND SWAPS PUSH-OUT

Subpart A—Margin and Capital Requirements for Covered Swap Entities

■ Accordingly, the interim final rule amending 12 CFR part 237, subpart A which was published at 80 FR 74916 on November 30, 2015, is adopted as a final rule without change.

Federal Deposit Insurance Corporation

12 CFR Chapter III

PART 349—DERIVATIVES

■ Accordingly, the interim final rule amending 12 CFR part 349 which was published at 80 FR 74916 on November 30, 2015, is adopted as a final rule without change.

Farm Credit Administration

12 CFR Chapter VI

■ Accordingly, the interim final rule amending 12 CFR part 624 which was published at 80 FR 74916 on November 30, 2015, is adopted as a final rule without change.

Federal Housing Finance Agency

Chapter XII—Federal Housing Finance Agency

Subchapter B—Entity Regulations

PART 1221—MARGIN AND CAPITAL REQUIREMENTS FOR COVERED SWAP ENTITIES

■ Accordingly, the interim final rule amending 12 CFR part 1221 which was published at 80 FR 74916 on November 30, 2015, is adopted as a final rule without change.

Dated: June 21, 2016.

Thomas J. Curry,

Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System, July 26, 2016.

Robert deV. Frierson,

Secretary of the Board.

Dated at Washington, DC, this 21 of June 2016.

By order of the Board of Directors.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

Dated: June 22, 2016.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

Dated: June 27, 2016.

Melvin L. Watt,

Director, Federal Housing Finance Agency.

[FR Doc. 2016–18193 Filed 8–1–16; 8:45 am]

BILLING CODE 4810–33–P; 8070–01–P; 6705–01–P; 6714–01–P; 6210–01–P; 4810–33–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–4291; Airspace Docket No. 16–AGL–7]

Amendment of Class E Airspace for the following Indiana Towns; Goshen, IN; Greencastle, IN; Huntingburg, IN; North Vernon, IN; Rensselaer, IN; Tell City, IN; and Washington, IN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace extending upward from 700 feet above the surface at Virgil I. Grissom Municipal Airport, Bedford, IN; Goshen Municipal Airport, Goshen, IN; Putnam County Airport, Greencastle, IN; Huntingburg Airport, Huntingburg, IN; North Vernon Airport, North Vernon, IN; Jasper County Airport, Rensselaer, IN; Perry County Municipal Airport, Tell City, IN; and Daviess County Airport, Washington, IN. Decommissioning of non-directional radio beacons (NDBs), cancellation of NDB approaches, and implementation of area navigation (RNAV) procedures have made this action necessary for the safety and management of Instrument Flight Rules (IFR) operations at these airports. This action also updates the geographic coordinates of Goshen Municipal Airport, Putnam County Airport, North Vernon Airport, Jasper County Airport, and Perry County Municipal Airport to coincide with the FAA's aeronautical database. O'Neal Airport, Vincennes, IN, is removed from this rule as the Class E airspace area was removed in a rule published in the **Federal Register** of October 23, 2015.

DATES: Effective 0901 UTC, November 10, 2016. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: 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 Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.9Z 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: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

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 amends Class E airspace at Virgil I. Grissom Municipal Airport, Bedford, IN; Goshen Municipal Airport, Goshen, IN; Putnam County Airport, Greencastle, IN; Huntingburg Airport, Huntingburg, IN; North Vernon Airport, North Vernon, IN; Jasper County Airport, Rensselaer,

IN; Perry County Municipal Airport, Tell City, IN; and Daviess County Airport, Washington, IN.

History

On May 3, 2016, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) (81 FR 26499) Docket No. FAA–2016–4291, to modify Class E airspace at Virgil I. Grissom Municipal Airport, Bedford, IN; Goshen Municipal Airport, Goshen, IN; Putnam County Airport, Greencastle, IN; Huntingburg Airport, Huntingburg, IN; North Vernon Airport, North Vernon, IN; Jasper County Airport, Rensselaer, IN; Perry County Municipal Airport, Tell City, IN; Daviess County Airport, Washington, IN; and remove controlled airspace at O'Neal Airport, Vincennes, IN. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received. Subsequent to publication, the FAA found that Class E airspace extending upward from 700 feet above the surface at O'Neal Airport, Vincennes, IN, was previously removed in a rule published in the **Federal Register** of October 23, 2015 (80 FR 64316) Docket No. FAA–2015–2049.

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 part 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends 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 Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 modifies Class E airspace extending upward from 700 feet above the surface at the following airports:

Within a 6.5-mile radius of Virgil I. Grissom Municipal Airport, Bedford, IN;

Within a 6.8-mile radius of Goshen Municipal Airport, Goshen, IN, and updates the geographic coordinates of this airport;

Within a 6.5-mile radius of Putnam County Airport, Greencastle, IN, and updates the geographic coordinates of this airport;

Within a 6.5-mile radius of Huntingburg Airport, Huntingburg, IN, with a segment extending from the 6.5-mile radius to 11.2 miles east of the airport;

Within a 6.5-mile radius of North Vernon Airport, North Vernon, IN, and updates the geographic coordinates of this airport;

Within a 6.4-mile radius of Jasper County Airport, Rensselaer, IN, and updates the geographic coordinates of this airport;

Within a 6.4-mile radius of Perry County Municipal Airport, Tell City, IN, and updates the geographic coordinates of this airport; and

Within a 6.4-mile radius of Daviess County Airport, Washington, IN.

Airspace reconfiguration is necessary due to the decommissioning of NDBs, cancellation of NDB approaches, or implementation of RNAV procedures at the above airports. Controlled airspace is necessary for the safety and management of the standard instrument approach procedures for IFR operations at the airports.

O'Neal Airport, Vincennes, IN, is removed from this rulemaking as the airspace was removed in a previously published rulemaking (80 FR 64316, October 23, 2015), Docket No. FAA–2015–2049.

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 only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of 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.

* * * * *

AGL IN E5 Bedford, IN [Amended]

Bedford, Virgil I. Grissom Municipal Airport, IN
(Lat. 38°50′24″ N., long. 86°26′43″ W.)
Bedford, Bedford Medical Center Heliport, IN
Point In Space
(Lat. 38°51′51″ N., long. 86°31′27″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Virgil I. Grissom Municipal Airport, and within a 6-mile radius of the Bedford Medical Center Heliport point in space coordinates at lat. 38°51′51″ N., long. 86°31′27″ W.

* * * * *

AGL IN E5 Goshen, IN [Amended]

Goshen Municipal Airport, IN
(Lat. 41°31′35″ N., long. 85°47′39″ W.)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of Goshen Municipal Airport.

* * * * *

AGL IN E5 Greencastle, IN [Amended]

Greencastle, Putnam County Airport, IN
(Lat. 39°38′01″ N., long. 86°48′50″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Putnam County Airport.

* * * * *

AGL IN E5 Huntingburg, IN [Amended]

Huntingburg Airport, IN
(Lat. 38°14′57″ N., long. 86°57′13″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Huntingburg Airport and within 2 miles either side of the 091° bearing from the airport extending from the 6.5-mile radius to 11.2 miles east of the airport.

* * * * *

AGL IN E5 North Vernon, IN [Amended]

North Vernon Airport, IN
(Lat. 39°02′43″ N., long. 85°36′20″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of North Vernon Airport.

* * * * *

AGL IN E5 Rensselaer, IN [Amended]

Rensselaer, Jasper County Airport, IN
(Lat. 40°56′52″ N., long. 87°10′58″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Jasper County Airport.

* * * * *

AGL IN E5 Tell City, IN [Amended]

Tell City, Perry County Municipal Airport, IN
(Lat. 38°01′08″ N., long. 86°41′33″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Perry County Municipal Airport.

* * * * *

AGL IN E5 Washington, IN [Amended]

Washington, Daviess County Airport, IN
(Lat. 38°42′02″ N., long. 87°07′47″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Daviess County Airport.

Issued in Fort Worth, Texas, on July 25, 2016.

Walter Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2016–18229 Filed 8–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 91

[Docket No.: FAA–2015–8059; Amendment No. 91–333A]

RIN 2120–AA66

Airports/Locations: Special Operating Restrictions

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; technical amendment.

SUMMARY: This action amends the Appendix listing airports/locations with special operating restrictions in FAA's general operating and flight rules. Specifically, this action corrects the entry for Kansas City, MO (Kansas City International Airport) and updates the name of twelve (12) other airports listed in Appendix D, section 1. Additionally, this action updates the name of thirteen (13) airports listed in Appendix D, section 3, and the name of four (4) airports listed in Appendix D, section 4. The FAA is taking this action to correctly identify the airports listed in the appropriate special operating restrictions sections of the Appendix consistent with FAA aeronautical database information.

DATES: *Effective Date:* September 1, 2016.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace Policy Group, AJV–11, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–8783, email *colby.abbott@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

Title 14 of the Code of Federal Regulations (14 CFR), part 91, appendix D, sections 1, 3, and 4, list the airports where special operating restrictions apply. Specifically, section 1 lists the locations at which aircraft operating within 30 nautical miles (NM) of the listed airports, from the surface upward to 10,000 feet mean sea level (MSL), must be equipped with an altitude encoding transponder. The locations listed in this section are intended to be the Class B airspace area primary airports. Further, section 3 lists the locations at which aircraft fixed-wing Special VFR operations are prohibited and section 4 lists the locations at which solo student, sport, and recreational pilot activity is not permitted.

On April 28, 1975, the FAA issued a final rule (40 FR 18414) Docket No. 73–WA–11, FR. Doc. 75–10970, which established the Kansas City, Missouri (MO), Terminal Control Area (TCA), listing the Kansas City International Airport as the primary airport. In 1993, as a result of the Airspace Reclassification rule (56 FR 65638) Docket No. 24456, FR Doc. 91–29869, TCAs were changed to Class B airspace areas and the Kansas City, MO, TCA became the Kansas City, MO, Class B airspace area with the Kansas City International Airport listed as the primary airport. However, when the Airspace Reclassification final rule amended the regulatory text in 14 CFR 91.215(b)(2) to read ''All aircraft. In all airspace within 30 nautical miles of an airport listed in appendix D, section 1 of this part . . .'', the airports listed in Appendix D, section 1, inadvertently included Kansas City, KS (Mid-Continent International Airport) in error instead of Kansas City, MO (Kansas City International Airport). This action corrects that inadvertent error in Appendix D, section 1.

Further review of the airports listed in Appendix D, section 1, highlighted that the airport name for twelve other airports listed in the section were incorrect and had changed since originally having been included as a result of the Airspace Reclassification rule. The twelve airports include: Hartsfield-Jackson Atlanta International Airport, Baltimore/Washington International Thurgood Marshall Airport, Cincinnati/Northern Kentucky International Airport, Dallas/Fort Worth International Airport, Detroit Metropolitan Wayne County Airport, George Bush Intercontinental/Houston Airport, Minneapolis-St. Paul International/Wold-Chamberlain Airport, Newark Liberty International Airport, Louis Armstrong New Orleans International Airport, Pittsburgh International Airport, Miramar Marine Corps Air Station, and Joint Base Andrews.

Similarly, review of the airports listed in appendix D, section 3, identified that the airport name for thirteen airports listed in the section were incorrect and had changed since originally having been included as a result of the Airspace Reclassification rule. The thirteen airports include: Hartsfield-Jackson Atlanta International Airport, Baltimore/Washington International Thurgood Marshall Airport, Cincinnati/Northern Kentucky International Airport, Dallas/Fort Worth International Airport, Dallas Love Field Airport, Detroit Metropolitan Wayne County Airport, George Bush Intercontinental/Houston Airport, Louisville International Airport-Standiford Field, Minneapolis-St. Paul International/Wold-Chamberlain Airport, Newark Liberty International Airport, Louis Armstrong New Orleans International Airport, Pittsburgh International Airport, and Joint Base Andrews.

Lastly, review of the airports listed in appendix D, section 4, identified that the airport name for four airports listed in the section were incorrect and had changed since originally having been included as a result of the Airspace Reclassification rule. The four airports include: Hartsfield-Jackson Atlanta International Airport, Dallas/Fort Worth International Airport, Newark Liberty International Airport, and Joint Base Andrews.

This action administratively updates the airport names listed in Appendix D, sections 1, 3, and 4 to correctly identify the airports consistent with FAA aeronautical database information.

The Rule

The FAA is amending 14 CFR part 91, Appendix D, sections 1, 3, and 4 to correct an inadvertent error listing Kansas City, KS (Mid-Continent International Airport) instead of Kansas City, MO (Kansas City International Airport) in section 1, and update the airport names listed in sections 1, 3, and 4 to match FAA aeronautical database information. Additionally, this action corrects a typographic format error for the Chicago, IL, entry in section 1. The amendments are as follows:

Appendix D, Section 1

Change ''Atlanta, GA (The William B. Hartsfield Atlanta International Airport)'' to ''Atlanta, GA (Hartsfield-Jackson Atlanta International Airport)''.

Change ''Baltimore, MD (Baltimore Washington International Airport)'' to ''Baltimore, MD (Baltimore/Washington International Thurgood Marshall Airport)''.

Add ''Camp Springs, MD (Joint Base Andrews)'' where it falls alphabetically.

Change ''Chicago, IL Chicago-O'Hare International Airport)'' to ''Chicago, IL (Chicago-O'Hare International Airport)''.

Change ''Covington, KY (Cincinnati Northern Kentucky International Airport)'' to ''Covington, KY (Cincinnati/Northern Kentucky International Airport)''.

Change ''Dallas, TX (Dallas/Fort Worth Regional Airport)'' to ''Dallas, TX (Dallas/Fort Worth International Airport)''.

Change ''Detroit, MI (Metropolitan Wayne County Airport)'' to ''Detroit, MI (Detroit Metropolitan Wayne County Airport)''.

Change ''Houston, TX (George Bush Intercontinental Airport/Houston)'' to ''Houston, TX (George Bush Intercontinental/Houston Airport)''.

Change ''Kansas City, KS (Mid-Continent International Airport)'' to ''Kansas City, MO (Kansas City International Airport)''.

Change ''Minneapolis, MN (Minneapolis-St. Paul International Airport)'' to ''Minneapolis, MN (Minneapolis-St. Paul International/Wold-Chamberlain Airport)''.

Change ''Newark, NJ (Newark International Airport)'' to ''Newark, NJ (Newark Liberty International Airport)''.

Change ''New Orleans, LA (New Orleans International Airport-Moisant Field)'' to ''New Orleans, LA (Louis Armstrong New Orleans International Airport)''.

Change ''Pittsburgh, PA (Greater Pittsburgh International Airport)'' to ''Pittsburgh, PA (Pittsburgh International Airport)''.

Change ''San Diego, CA (Marine Corps Air Station Miramar)'' to ''San Diego, CA (Miramar Marine Corps Air Station)''.

Change ''Washington, DC (Ronald Reagan Washington National Airport and Andrews Air Force Base, MD)'' to ''Washington, DC (Ronald Reagan Washington National Airport)''.

Appendix D, Section 3

Change ''Atlanta, GA (The William B. Hartsfield Atlanta International Airport)'' to ''Atlanta, GA (Hartsfield-Jackson Atlanta International Airport)''.

Change ''Baltimore, MD (Baltimore Washington International Airport)'' to ''Baltimore, MD (Baltimore/Washington International Thurgood Marshall Airport)''.

Add ''Camp Springs, MD (Joint Base Andrews)'' where it falls alphabetically.

Change ''Covington, KY (Cincinnati Northern Kentucky International Airport)'' to ''Covington, KY (Cincinnati/Northern Kentucky International Airport)''.

Change ''Dallas, TX (Dallas/Fort Worth Regional Airport)'' to ''Dallas, TX (Dallas/Fort Worth International Airport)''.

Change ''Dallas, TX (Love Field)'' to ''Dallas, TX (Dallas Love Field Airport)''.

Change ''Detroit, MI (Metropolitan Wayne County Airport)'' to ''Detroit, MI (Detroit Metropolitan Wayne County Airport)''.

Change ''Houston, TX (George Bush Intercontinental Airport/Houston)'' to ''Houston, TX (George Bush Intercontinental/Houston Airport)''.

Change ''Louisville, KY (Standiford Field)'' to ''Louisville, KY (Louisville International Airport-Standiford Field)''.

Change ''Minneapolis, MN (Minneapolis-St. Paul International Airport)'' to ''Minneapolis, MN (Minneapolis-St. Paul International/Wold-Chamberlain Airport)''.

Change ''Newark, NJ (Newark International Airport)'' to ''Newark, NJ (Newark Liberty International Airport)''.

Change ''New Orleans, LA (New Orleans International Airport-Moisant Field)'' to ''New Orleans, LA (Louis Armstrong New Orleans International Airport)''.

Change ''Pittsburgh, PA (Greater Pittsburgh International Airport)'' to ''Pittsburgh, PA (Pittsburgh International Airport)''.

Change ''Washington, DC (Ronald Reagan Washington National Airport and Andrews Air Force Base, MD)'' to ''Washington, DC (Ronald Reagan Washington National Airport)''.

Appendix D, Section 4

Change ''Atlanta, GA (The William B. Hartsfield Atlanta International Airport)'' to ''Atlanta, GA (Hartsfield-Jackson Atlanta International Airport)''.

Add ''Camp Springs, MD (Joint Base Andrews)'' where it falls alphabetically.

Change ''Dallas, TX (Dallas/Fort Worth Regional Airport)'' to ''Dallas, TX (Dallas/Fort Worth International Airport)''.

Change ''Newark, NJ (Newark International Airport)'' to ''Newark, NJ (Newark Liberty International Airport)''.

Remove ''Andrews Air Force Base, MD''.

Administrative Procedure Act

The Administrative Procedure Act (5 U.S.C. 553(b)) requires agencies to publish a notice of proposed rulemaking and provide opportunity for comment except when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. The FAA finds that notice and the opportunity for comment are unnecessary for this action as the action merely changes the names of airports to conform to the names included in the FAA aeronautical database. The FAA also finds that not changing these names in the regulations is contrary to the public interest as not changing the names could cause confusion or errors in charts or other documents produced using the aeronautical database and regulations.

List of Subjects in 14 CFR Part 91

Air traffic control, Aircraft, Airmen, Airports, Aviation safety.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends Title 14 of the Code of Federal Regulations part 91, as follows:

PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 1. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 1155, 40101, 40103, 40105, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, 47534, articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180), (126 Stat. 11).

■ 2. Amend appendix D to part 91 as follows:

■ a. In Section 1, by revising the entries for Atlanta, GA; Baltimore, MD; Chicago, IL; Covington, KY; Dallas, TX; Detroit, MI; the first Houston, TX, entry; Minneapolis, MN; Newark, NJ; New Orleans, LA; Pittsburgh, PA; the first San Diego, CA, entry; and Washington, DC; adding entries for Camp Springs, MD, and Kansas City, MO in alphabetical order; and removing the entry for Kansas City, KS.

■ b. In Section 3, by revising the entries for Atlanta, GA; Baltimore, MD; Covington, KY; both Dallas, TX, entries; Detroit, MI; Houston, TX; Louisville, KY; Minneapolis, MN; Newark, NJ; New Orleans, LA; Pittsburgh, PA; and Washington, DC; and adding an entry for Camp Springs, MD, in alphabetical order.

■ c. In Section 4, by revising the entries for Atlanta, GA; Dallas, TX; and Newark, NJ; removing Andrews Air Force Base, MD; and adding an entry for Camp Springs, MD, in alphabetical order.

The revisions read as follows:

Appendix D to Part 91—Airports/ Locations: Special Operating Restrictions

Section 1. * * *
Atlanta, GA (Hartsfield-Jackson Atlanta International Airport)
Baltimore, MD (Baltimore/Washington International Thurgood Marshall Airport)
* * * * *
Camp Springs, MD (Joint Base Andrews)
* * * * *
Chicago, IL (Chicago-O'Hare International Airport)
* * * * *
Covington, KY (Cincinnati/Northern Kentucky International Airport)
Dallas, TX (Dallas/Fort Worth International Airport)
* * * * *
Detroit, MI (Detroit Metropolitan Wayne County Airport)
* * * * *
Houston, TX (George Bush Intercontinental/ Houston Airport)
* * * * *
Kansas City, MO (Kansas City International Airport)
* * * * *
Minneapolis, MN (Minneapolis-St. Paul International/Wold-Chamberlain Airport)
Newark, NJ (Newark Liberty International Airport)
New Orleans, LA (Louis Armstrong New Orleans International Airport)
* * * * *
Pittsburgh, PA (Pittsburgh International Airport)
* * * * *
San Diego, CA (Miramar Marine Corps Air Station)
* * * * *
Washington, DC (Ronald Reagan Washington National Airport)
* * * * *
Section 3. * * *
* * * * *
Atlanta, GA (Hartsfield-Jackson Atlanta International Airport)
Baltimore, MD (Baltimore/Washington International Thurgood Marshall Airport)
* * * * *
Camp Springs, MD (Joint Base Andrews)
* * * * *
Covington, KY (Cincinnati/Northern Kentucky International Airport)
Dallas, TX (Dallas/Fort Worth International Airport)
Dallas, TX (Dallas Love Field Airport)
* * * * *
Detroit, MI (Detroit Metropolitan Wayne County Airport)
* * * * *
Houston, TX (George Bush Intercontinental/ Houston Airport)
* * * * *
Louisville, KY (Louisville International Airport-Standiford Field)
* * * * *
Minneapolis, MN (Minneapolis-St. Paul International/Wold-Chamberlain Airport)
Newark, NJ (Newark Liberty International Airport)
* * * * *
New Orleans, LA (Louis Armstrong New Orleans International Airport)
* * * * *
Pittsburgh, PA (Pittsburgh International Airport)
* * * * *
Washington, DC (Ronald Reagan Washington National Airport)
Section 4. * * *
* * * * *
Atlanta, GA (Hartsfield-Jackson Atlanta International Airport)
* * * * *
Camp Springs, MD (Joint Base Andrews)
* * * * *
Dallas, TX (Dallas/Fort Worth International Airport)
* * * * *
Newark, NJ (Newark Liberty International Airport)
* * * * *

Issued in Washington, DC, on July 14, 2016.

Dale A. Bouffiou,

Acting Director, Office of Rulemaking.

[FR Doc. 2016–17161 Filed 8–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

International Trade Administration

19 CFR Part 351

[Docket No. 140929814–6136–02]

RIN 0625–AB02

Correction to Applicability Date for Modification of Regulations Regarding Price Adjustments in Antidumping Duty Proceedings

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

ACTION: Final rule.

SUMMARY: The Department of Commerce (the Department) is modifying the applicability date contained in the final rule published in the **Federal Register** on March 24, 2016. The original applicability date language did not convey the Department's intention, *i.e.,* to apply the newly amended regulations to all segments of proceedings initiated on or after the effective date contained in the rule. This action is necessary to ensure that there is no ambiguity in the application of the modified regulations.

DATES: *Effective date:* September 1, 2016.

Applicability date: This rule will apply to all segments of proceedings initiated on or after September 1, 2016.

FOR FURTHER INFORMATION CONTACT: Jessica Link at (202) 482–1411.

SUPPLEMENTARY INFORMATION: On March 24, 2016, the Department published a final rule in the **Federal Register** modifying 19 CFR 351.102(b)(38) and 19 CFR 351.401(c). *Modification of Regulations Regarding Price Adjustments in Antidumping Duty Proceedings,* 81 FR 15641 (March 24, 2016) (Final Rule). The **DATES** section of the Final Rule states: ''*Effective date:* April 25, 2016. *Applicability date:* This rule will apply to all proceedings initiated on or after April 25, 2016.''

On June 20, 2016, the Department published a proposed rule to correct the applicability date of the Final Rule. *See Correction to Applicability Date for Modification of Regulations Regarding Price Adjustments in Antidumping Duty Proceedings,* 81 FR 39873 (June 20, 2016). In its proposed rule, the Department explained that the applicability date in the Final Rule does not convey the Department's intention, *i.e.,* to apply the newly amended regulations to all segments of proceedings initiated on or after the effective date of the Final Rule. The Department further explained that, although ''proceedings'' can be interpreted generally to include any segment of an administrative case before Enforcement and Compliance that is initiated on or after the effective date, ''proceeding'' and ''segment of proceeding'' are defined separately in 19 CFR 351.102(b)(40) and 19 CFR 351.102(b)(47), respectively. Thus, to avoid any ambiguity and to clarify the Department's intent, the Department proposed to modify the applicability date of the Final Rule such that the Final Rule will apply to all segments of proceedings initiated on or after 30 days following the publication date of the final rule that results from this rulemaking.

The Department received no comments on the proposed rule. Thus, the Department is modifying the applicability date of the Final Rule as discussed above. As the prior applicability date was not included in the modified regulations, 19 CFR 351.102(b)(38) and 19 CFR 351.401(c), the Department is not amending its regulations. The only change to the Final Rule being addressed in this final rule is a change to the applicability date of the Final Rule.

Changes From the Proposed Rule

There are no changes from the proposed rule.

Classification

Executive Order 12866

It has been determined that this final rule is not significant for purposes of Executive Order 12866.

Paperwork Reduction Act

This final rule contains no new collection of information subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

Executive Order 13132

This final rule does not contain policies with federalism implications as that term is defined in section 1(a) of Executive Order 13132, dated August 4, 1999 (64 FR 43255 (August 10, 1999)).

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* the Chief Counsel for Regulation at the Department of Commerce certified to the Chief Counsel for Advocacy, 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 factual basis for this certification was published with the proposed rule and is not repeated here. No comments were received regarding the certification or on the economic impact of this rule more generally. As a result, the conclusion in the certification memorandum for the proposed rule remains unchanged and a final regulatory flexibility analysis is not required and one has not been prepared.

Dated: July 27, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–18305 Filed 8–1–16; 8:45 am]

BILLING CODE 3510–DS–P

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 239

Republic of Tunisia Loan Guarantees Issued Under Section 7034(o) of the Department of State, Foreign Operations, and Related Programs Appropriations Act of 2016—Standard Terms and Conditions

AGENCY: Agency for International Development (USAID).

ACTION: Final rule.

SUMMARY: This regulation prescribes the procedures and standard terms and conditions applicable to loan guarantees to be issued for the benefit of the Republic of Tunisia pursuant to Section 7034(o) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2016.

DATES: Effective August 1, 2016.

FOR FURTHER INFORMATION CONTACT: D. Bruce McPherson, Office of General Counsel, U.S. Agency for International Development, Washington, DC 20523–6601; tel. 202–712–1611, fax 202–216–3058.

SUPPLEMENTARY INFORMATION: Pursuant to Section 7034(o) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2016 (Div. K, Pub. L. 114–113), the United States of America, acting through the U.S. Agency for International Development, may issue certain loan guarantees applicable to sums borrowed by Banque Centrale de Tunisie, acting on behalf of the Republic of Tunisia (the ''Borrower''), not exceeding an aggregate total of U.S. $500 million in principal amount. Upon issuance, the loan guarantees shall ensure the Borrower's repayment of 100% of principal and interest due under such loans, and the full faith and credit of the United States of America shall be pledged for the full payment and performance of such guarantee obligations.

This rulemaking document is not subject to rulemaking under 5 U.S.C. 553 or to regulatory review under Executive Order 12866 because it involves a foreign affairs function of the United States. The provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) do not apply.

List of Subjects in 22 CFR Part 239

Foreign aid, Foreign relations, Guaranteed loans, Loan programs—foreign relations.

Authority and Issuance

■ Accordingly, part 239 is added to title 22, chapter II, of the Code of Federal Regulations, to read as follows:

PART 239—REPUBLIC OF TUNISIA LOAN GUARANTEES ISSUED UNDER SECTION 7034(o) OF THE DEPARTMENT OF STATE, FOREIGN OPERATIONS, AND RELATED PROGRAMS APPROPRIATIONS ACT OF 2016

Sec.

239.1 Purpose.
239.2 Definitions.
239.3 The Guarantee.
239.4 Guarantee eligibility.
239.5 Non-impairment of the Guarantee.
239.6 Transferability of Guarantee; Note Register.
239.7 Fiscal Agent obligations.
239.8 Event of Default; Application for Compensation; payment.
239.9 No acceleration of Eligible Notes.
239.10 Payment to USAID of excess amounts received by a Noteholder.
239.11 Subrogation of USAID.
239.12 Prosecution of claims.
239.13 Change in agreements.
239.14 Arbitration.
239.15 Notice.
239.16 Governing Law.
Appendix A to Part 239—Application for Compensation

Authority: Section 7034(o) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2016 (Div. K, Pub. L. 114–113)

§ 239.1 Purpose.

The purpose of the regulations in this part is to prescribe the procedures and standard terms and conditions applicable to loan guarantees issued for the benefit of the Borrower, pursuant Section 7034(o) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2016 (Div. K, Pub. L. 114–113). The loan guarantees will be issued as provided herein pursuant to the Loan Guarantee Agreement, dated June 6, 2016, between the United States of America and the Republic of Tunisia (the ''Loan Guarantee Agreement''). The loan guarantee will apply to sums borrowed during a period beginning on the date that the Loan Guarantee Agreement enters into force and ending thirty days after such date, not exceeding an aggregate total of five hundred million United States Dollars (U.S. $500,000,000) in principal amount. The loan guarantees shall ensure the Borrower's repayment of 100% of principal and interest due under such loans. The full faith and credit of the United States of America is pledged for the full payment and performance of such guarantee obligations.

§ 239.2 Definitions.

Wherever used in the standard terms and conditions set out in this part:

Applicant means a Noteholder who files an Application for Compensation with USAID, either directly or through the Fiscal Agent acting on behalf of a Noteholder.

Application for Compensation means an executed application in the form of Appendix A to this part which a Noteholder, or the Fiscal Agent on behalf of a Noteholder, files with USAID pursuant to § 239.8.

Borrower means Banque Centrale de Tunisie, acting on behalf of Republic of Tunisia.

Business Day means any day other than a day on which banks in New York, NY are closed or authorized to be closed or a day which is observed as a

Federal holiday in Washington, DC, by the United States Government.

Date of Application means the date on which an Application for Compensation is actually received by USAID pursuant to § 239.15.

Defaulted Payment means, as of any date and in respect of any Eligible Note, any Interest Amount and/or Principal Amount not paid when due.

Eligible Note(s) means [a] Note[s] meeting the eligibility criteria set out in § 239.4.

Fiscal Agency Agreement means the agreement among USAID, the Borrower and the Fiscal Agent pursuant to which the Fiscal Agent agrees to provide fiscal agency services in respect of the Note[s], a copy of which Fiscal Agency Agreement shall be made available to Noteholders upon request to the Fiscal Agent.

Fiscal Agent means the bank or trust company or its duly appointed successor under the Fiscal Agency Agreement which has been appointed by the Borrower with the consent of USAID to perform certain fiscal agency services for specified Eligible Note[s] pursuant to the terms of the Fiscal Agency Agreement.

Further Guaranteed Payments means the amount of any loss suffered by a Noteholder by reason of the Borrower's failure to comply on a timely basis with any obligation it may have under an Eligible Note to indemnify and hold harmless a Noteholder from taxes or governmental charges or any expense arising out of taxes or any other governmental charges relating to the Eligible Note in the country of the Borrower.

Guarantee means the guarantee of USAID issued pursuant to this part and Section 7034(o) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2016 (Div. K, Pub. L. 114–113).

Guarantee Payment Date means a Business Day not more than three (3) Business Days after the related Date of Application.

Interest Amount means for any Eligible Note the amount of interest accrued on the Principal Amount of such Eligible Note at the applicable Interest Rate.

Interest Rate means the interest rate borne by an Eligible Note.

Loss of Investment means, in respect of any Eligible Note, an amount in United States Dollars equal to the total of the:

(1) Defaulted Payment unpaid as of the Date of Application,

(2) Further Guaranteed Payments unpaid as of the Date of Application, and

(3) Interest accrued and unpaid at the Interest Rate(s) specified in the Eligible Note(s) on the Defaulted Payment and Further Guaranteed Payments, in each case from the date of default with respect to such payment to and including the date on which full payment thereof is made to the Noteholder.

Note[s] means any debt securities issued by the Borrower.

Noteholder means the owner of an Eligible Note who is registered as such on the Note Register.

Note Register means the register of Eligible Notes required to be maintained by the Fiscal Agent.

Person means any legal person, including any individual, corporation, partnership, joint venture, association, joint stock company, trust, unincorporated organization, or government or any agency or political subdivision thereof.

Principal amount means the principal amount of the Eligible Notes issued by the Borrower. For purposes of determining the principal amount of the Eligible Notes issued by the Borrower, the principal amount of each Eligible Note shall be the stated principal amount thereof.

USAID means the United States Agency for International Development or its successor.

§ 239.3 The Guarantee.

Subject to the terms and conditions set out in this part, the United States of America, acting through USAID, guarantees to Noteholders the Borrower's repayment of 100 percent of principal and interest due on Eligible Notes. Under the Guarantee, USAID agrees to pay to any Noteholder compensation in United States Dollars equal to such Noteholder's Loss of Investment under its Eligible Note; provided, however, that no such payment shall be made to any Noteholder for any such loss arising out of fraud or misrepresentation for which such Noteholder is responsible or of which it had knowledge at the time it became such Noteholder. The Guarantee shall apply to each Eligible Note registered on the Note Register required to be maintained by the Fiscal Agent.

§ 239.4 Guarantee eligibility.

(a) Eligible Notes only are guaranteed hereunder. Notes in order to achieve Eligible Note status:

(1) Must be signed on behalf of the Borrower, manually or in facsimile, by a duly authorized representative of the Borrower;

(2) Must contain a certificate of authentication manually executed by a Fiscal Agent whose appointment by the Borrower is consented to by USAID in the Fiscal Agency Agreement; and

(3) Shall be approved and authenticated by USAID by either:

(i) The affixing by USAID on the Notes of a guarantee legend incorporating these Standard Terms and Conditions signed on behalf of USAID by either a manual signature or a facsimile signature of an authorized representative of USAID or

(ii) The delivery by USAID to the Fiscal Agent of a guarantee certificate incorporating these Standard Terms and Conditions signed on behalf of USAID by either a manual signature or a facsimile signature of an authorized representative of USAID.

(b) The authorized USAID representatives for purposes of the regulations in this part whose signature(s) shall be binding on USAID shall include the USAID Chief and Deputy Chief Financial Officer, Assistant Administrator and Deputy, Bureau for Economic Growth, Education, and Environment, Director and Deputy Director, Office of Development Credit, and such other individual(s) designated in a certificate executed by an authorized USAID Representative and delivered to the Fiscal Agent. The certificate of authentication of the Fiscal Agent issued pursuant to the Fiscal Agency Agreement shall, when manually executed by the Fiscal Agent, be conclusive evidence binding on USAID that an Eligible Note has been duly executed on behalf of the Borrower and delivered.

§ 239.5 Non-impairment of the Guarantee.

After issuance of the Guarantee, the Guarantee will be an unconditional, full faith and credit obligation of the United States of America and will not be affected or impaired by any subsequent condition or event. This non-impairment of the guarantee provision shall not, however, be operative with respect to any loss arising out of fraud or misrepresentation for which the claiming Noteholder is responsible or of which it had knowledge at the time it became a Noteholder. In particular and without limitation, the Guarantee shall not be affected or impaired by:

(a) Any defect in the authorization, execution, delivery or enforceability of any agreement or other document executed by a Noteholder, USAID, the Fiscal Agent or the Borrower in connection with the transactions contemplated by this Guarantee or

(b) The suspension or termination of the program pursuant to which USAID

is authorized to guarantee the Eligible Notes.

§ 239.6 Transferability of Guarantee; Note Register.

A Noteholder may assign, transfer or pledge an Eligible Note to any Person, provided that such transfer is permitted under applicable law and regulation, including, without limitation, the Office of Foreign Asset Control (OFAC) regulations. Any such assignment, transfer or pledge shall be effective on the date that the name of the new Noteholder is entered on the Note Register required to be maintained by the Fiscal Agent pursuant to the Fiscal Agency Agreement. USAID shall be entitled to treat the Persons in whose names the Eligible Notes are registered as the owners thereof for all purposes of the Guarantee, and USAID shall not be affected by notice to the contrary.

§ 239.7 Fiscal Agent obligations.

Failure of the Fiscal Agent to perform any of its obligations pursuant to the Fiscal Agency Agreement shall not impair any Noteholder's rights under the Guarantee, but may be the subject of action for damages against the Fiscal Agent by USAID as a result of such failure or neglect. A Noteholder may appoint the Fiscal Agent to make demand for payment on its behalf under the Guarantee.

§ 239.8 Event of Default; Application for Compensation; payment.

At any time after an Event of Default, as this term is defined in an Eligible Note, any Noteholder hereunder, or the Fiscal Agent on behalf of a Noteholder hereunder, may file with USAID an Application for Compensation in the form provided in Appendix A to this part. USAID shall pay or cause to be paid to any such Applicant any compensation specified in such Application for Compensation that is due to the Applicant pursuant to the Guarantee as a Loss of Investment not later than the Guarantee Payment Date. In the event that USAID receives any other notice of an Event of Default, USAID may pay any compensation that is due to any Noteholder pursuant to the Guarantee, whether or not such Noteholder has filed with USAID an Application for Compensation in respect of such amount.

§ 239.9 No acceleration of Eligible Notes.

Eligible Notes shall not be subject to acceleration, in whole or in part, by USAID, the Noteholder or any other party. USAID shall not have the right to pay any amounts in respect of the Eligible Notes other than in accordance with the original payment terms of such Eligible Notes.

§ 239.10 Payment to USAID of excess amounts received by a Noteholder.

If a Noteholder shall, as a result of USAID paying compensation under the Guarantee, receive an excess payment, it shall refund the excess to USAID.

§ 239.11 Subrogation of USAID.

In the event of payment by USAID to a Noteholder under the Guarantee, USAID shall be subrogated to the extent of such payment to all of the rights of such Noteholder against the Borrower under the related Note.

§ 239.12 Prosecution of claims.

After payment by USAID to an Applicant hereunder, USAID shall have exclusive power to prosecute all claims related to rights to receive payments under the Eligible Notes to which it is thereby subrogated. If a Noteholder continues to have an interest in the outstanding Eligible Notes, such a Noteholder and USAID shall consult with each other with respect to their respective interests in such Eligible Notes and the manner of and responsibility for prosecuting claims.

§ 239.13 Change in agreements.

No Noteholder will consent to any change or waiver of any provision of any document contemplated by the Guarantee without the prior written consent of USAID.

§ 239.14 Arbitration.

Any controversy or claim between USAID and any Noteholder arising out of the Guarantee shall be settled by arbitration to be held in Washington, DC in accordance with the then prevailing rules of the American Arbitration Association, and judgment on the award rendered by the arbitrators may be entered in any court of competent jurisdiction.

§ 239.15 Notice.

Any communication to USAID pursuant to the Guarantee shall be in writing in the English language, shall refer to the Republic of Tunisia Loan Guarantee Number inscribed on the Eligible Note and shall be complete on the day it shall be actually received by USAID at the Office of Development Credit, Bureau for Economic Growth, Education and Environment, United States Agency for International Development, Washington, DC 20523–0030. Other addresses may be substituted for the above upon the giving of notice of such substitution to each Noteholder by first class mail at the address set forth in the Note Register.

§ 239.16 Governing law.

The Guarantee shall be governed by and construed in accordance with the laws of the United States of America governing contracts and commercial transactions of the United States Government.

Appendix A to Part 239—Application for Compensation

Application for Compensation

United States Agency for International Development

Washington, DC 20523

Ref: Guarantee dated as of ____, 20____:

Gentlemen: You are hereby advised that payment of $____ (consisting of $____ of principal, $____ of interest and $____ in Further Guaranteed Payments, as defined in § 239.2 of the Standard Terms and Conditions of the above-mentioned Guarantee) was due on _____, 20__, on $____ Principal Amount of Notes issued by Banque Centrale de Tunisie, acting on behalf of the Republic of Tunisia (the ''Borrower'') held by the undersigned. Of such amount $____ was not received on such date and has not been received by the undersigned at the date hereof. In accordance with the terms and provisions of the above-mentioned Guarantee, the undersigned hereby applies, under § 239.8 of said Guarantee, for payment of $____, representing $____, the Principal Amount of the presently outstanding Note(s) of the Borrower held by the undersigned that was due and payable on ____ and that remains unpaid, and $____, the Interest Amount on such Note(s) that was due and payable by the Borrower on ____ and that remains unpaid, and $____ in Further Guaranteed Payments,[1] plus accrued and unpaid interest thereon from the date of default with respect to such payments to and including the date payment in full is made by you pursuant to said Guarantee, at the rate of __% per annum, being the rate for such interest accrual specified in such Note. Such payment is to be made at [state payment instructions of Noteholder].

All capitalized terms herein that are not otherwise defined shall have the meanings assigned to such terms in the Standard Terms and Conditions of the above-mentioned Guarantee.

By: _____

Gayle Girod,

Assistant General Counsel
Office of the General Counsel
U.S. Agency for International Development

July 27, 2016.

[FR Doc. 2016–18192 Filed 8–1–16; 8:45 am]

BILLING CODE P

[1] In the event the Application for Compensation relates to Further Guaranteed Payments, such Application must also contain a statement of the nature and circumstances of the related loss.

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2016–0602]

Eighth Coast Guard District Annual Recurring Marine Events

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce special local regulations during the Pittsburgh Three Rivers Regatta on the Ohio River, from mile 0.0–0.5, Allegheny River mile 0.0–0.6, Monongahela River mile 0.0–0.5 extending the entire width of all three rivers. These regulations are needed to protect vessels transiting the area and event spectators from the hazards associated with a regatta on the navigable waterway. During the enforcement period, entry into, transiting, or anchoring in the regulated area is prohibited to all vessels not registered with the sponsor as participants or official patrol vessels, unless specifically authorized by the Captain of the Port (COTP) Pittsburgh or a designated representative.

DATES: The regulations in 33 CFR 100.801, Table 1, Sector Ohio Valley, No. 22 are effective from 12 noon until 11:30 p.m. daily, from August 5, 2016 through August 7, 2016.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email MST1 Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard; telephone 412–221–0807, email *Jennifer.L.Haggins@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce special local regulations for the annual Pittsburgh Three Rivers Regatta listed in 33 CFR 100.801 Table 1, Sector Ohio Valley, No. 22 from 12:00 noon until 11:30 p.m., from August 5, 2016 through August 7, 2016. Entry into the regulated area is prohibited unless authorized by the COTP or a designated representative. Persons or vessels desiring to enter into or pass through the area must request permission from the COTP or a designated representative. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

This notice of enforcement is issued under authority of 33 CFR 100.801 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Local Notice to Mariners and updates via Marine Information Broadcasts.

L. McClain, Jr.,

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

[FR Doc. 2016–18257 Filed 8–1–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0360]

Drawbridge Operation Regulation; York River, Yorktown, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation; modification.

SUMMARY: The Coast Guard has modified a temporary deviation from the operating schedule that governs the Coleman Memorial Bridge (US 17) across the York River, mile 7.0, Yorktown, VA. This modified deviation is necessary to perform additional bridge maintenance. This modified deviation allows the bridge to remain in the closed-to-navigation position.

DATES: This modified deviation is effective from 7 a.m. July 31, 2016, to 7 p.m. on August 28, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0360] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH''. Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mrs. Traci Whitfield, Bridge Administration Branch Fifth District, Coast Guard; telephone (757) 398–6629, email *Traci.G.Whitfield@uscg.mil.*

SUPPLEMENTARY INFORMATION: On May 26, 2016, the Coast Guard published a temporary deviation entitled ''Drawbridge Operation Regulation; York River, Yorktown, VA'' in the **Federal Register** (81 FR 33391). Under that temporary deviation, the bridge would remain in the closed-to-navigation position from 7 a.m. to 7 p.m. as follows: Sunday, May 22, 2016; Sunday, June 5, 2016, with an inclement weather date on Sunday, June 12, 2016; Sunday, June 19, 2016, with an inclement weather date on Sunday, June 26, 2016; and Sunday, July 10, 2016, with an inclement weather date on Sunday, July 17, 2016.

The Virginia Department of Transportation (VDOT), who owns and operates the Coleman Memorial Bridge (US 17), has requested a modified temporary deviation from the currently published deviation to complete repairs. The bridge must be in the closed-to-navigation position, for an additional two Sundays, in order to perform the complexity of mechanical work, which normally takes two weeks and cannot be accomplished when the bridge is moveable. The bridge is a single bascule span and has a vertical clearance in the closed position of seven feet above mean high water.

Under this modified temporary deviation, the bridge will continue to remain in the closed-to-navigation position from 7 a.m. to 7 p.m. as follows: July 31, 2016, with an inclement weather date on Sunday, August 7, 2016; and Sunday, August 21, 2016, with an inclement weather date on Sunday, August 28, 2016. At all other times, the bridge will operate in accordance with the operating regulations set out in 33 CFR 117.1025.

The York River is used by a variety of vessels including deep draft ocean-going vessels, U.S. government vessels, small commercial fishing vessels, recreational vessels and tug and barge traffic. The Coast Guard has carefully coordinated the restrictions with U.S. government and commercial waterway users.

Vessels able to pass through the bridge in the closed position may do so at anytime. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels unable to pass through the bridge in the closed position. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

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

Dated: July 22, 2016.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2016–18214 Filed 8–1–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0416]

RIN 1625–AA00

Safety Zone; Chesapeake Bay, Cape Charles, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters in the vicinity of the inlet of Kings Creek, on the Chesapeake Bay. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards associated with a fireworks display, which include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Hampton Roads.

DATES: This rule is effective from 8:30 p.m. on August 6, 2016, through 10:30 p.m. on August 7, 2016. This rule will be enforced from 8:30 p.m. through 10:30 p.m. on August 6, 2016, unless the fireworks display is postponed because of adverse weather, in which case this rule will be enforced from 8:30 p.m. through 10:30 p.m. on August 7, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0416 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 LCDR Barbara Wilk, Waterways Management Division Chief, Sector Hampton Roads, U.S. Coast Guard; telephone 757–668–5580, email *hamptonroadswaterway@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule. It is impracticable for us to publish an NPRM because information about the fireworks was received by the Coast Guard without sufficient time to publish a proposed rule and consider comments on it and then issue an effective rule by August 6, 2016. The Coast Guard will provide advance notifications to users of the affected waterway via marine information broadcasts and local notice to mariners.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds good cause for making it effective less than 30 days after publication in the **Federal Register**. The restriction on vessel traffic is necessary to protect life, property and the environment, on the scheduled day and rain date for the fireworks display when there are expected to be more than 2,000 spectators present. Therefore, due to the need to have a rule effective starting August 6, it is impracticable to delay the effective date of this rule until 30 days after it is published. Delaying the effective date would be contrary to the safety zone's intended objectives of protecting persons and vessels, and enhancing public and maritime safety.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Hampton Roads (COTP) has determined that potential hazards associated with fireworks display starting on August 6, 2016, with a rain date of August 7, 2016, will be a safety concern for anyone within a 280 foot radius of the launching site. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the fireworks display. The potential hazards to mariners within the safety zone include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris.

IV. Discussion of the Rule

This rule establishes a safety zone from 8:30 p.m. through 10:30 p.m. on August 6, 2016, with a rain date of August 7, 2016. This rule will only be subject to enforcement on August 7, 2016, if the scheduled August 6 fireworks display is postponed because of adverse weather. The safety zone will encompass all navigable waters of the of the inlet of Kings Creek, on the Chesapeake Bay, within a 280 foot radius of the fireworks launch site in approximate position 37°16′53″ N., 076°00′42″ W. (NAD 1983). The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during the fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, duration, and time-of-year of the safety zone. Vessel traffic will be able to safely transit around this safety zone which will impact a small designated area of the Chesapeake Bay in Cape Charles, VA for one hour. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting two hours that will prohibit entry in all navigable waters within a 280 foot radius of the launching site. 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, under the undesignated center heading Fifth Coast Guard District, temporary § 165.T05–0416 to read as follows:

§ 165.T05–0416 Safety Zone, Chesapeake Bay; Cape Charles, VA.

(a) *Definitions.* For the purposes of this section—

''*Captain of the Port''* means the Commander, Sector Hampton Roads.

''*Participants''* means individuals and vessels involved in explosives training.

''*Representative''* means any Coast Guard commissioned, warrant or petty officer who has been authorized to act on the behalf of the Captain of the Port.

(b) *Location.* The following area is a safety zone: All waters in the vicinity of the of the inlet of Kings Creek, on the Chesapeake Bay, within a 280 foot radius of the fireworks launch site in approximate position 37°16′53″ N., 076°00′42″ W. (NAD 1983).

(c) *Regulations.* (1) The general regulations governing safety zones in § 165.23, apply to the area described in paragraph (b) of this section.

(2) With the exception of participants, entry into or remaining in this safety zone is prohibited unless authorized by the Captain of the Port, Hampton Roads or his designated representatives.

(3) All vessels underway within this safety zone at the time it is implemented are to depart the zone immediately.

(4) The Captain of the Port, Hampton Roads or his representative can be contacted at telephone number (757) 668–5555.

(5) The Coast Guard and designated security vessels enforcing the safety zone can be contacted on VHF–FM marine band radio channel 13 (165.65Mhz) and channel 16 (156.8 Mhz).

(6) This section applies to all persons or vessels wishing to transit through the safety zone except participants and vessels that are engaged in the following operations: Enforcing laws, servicing aids to navigation, and emergency response vessels.

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and

enforcement of the safety zone by Federal, State, and local agencies.

(e) *Enforcement period.* This section will be enforced from 8:30 p.m. through 10:30 p.m. on August 6, 2016, with a rain date on August 7, 2016.

Dated: July 19, 2016.

Richard J. Wester,

Captain, U.S. Coast Guard, Captain of the Port Hampton Roads.

[FR Doc. 2016–18339 Filed 8–1–16; 8:45 am]

BILLING CODE 9110–04–P

POSTAL SERVICE

39 CFR Part 230

Procedures Relating to the Disposition of Property Acquired by the United States Postal Service Office of Inspector General for Use as Evidence

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: This rule establishes procedures for the disposition of abandoned property held by the United States Postal Service Office of Inspector General. The rule establishes procedures for determining the ownership of abandoned property, the advertisement of abandoned items with no apparent owner held by the Office of Inspector General, and the disposal of items declared abandoned.

DATES: *Effective:* August 2, 2016.

FOR FURTHER INFORMATION CONTACT: Gladis Griffith, Office of General Counsel, (703) 248–4683.

SUPPLEMENTARY INFORMATION: On March 30, 2016, the Postal Service published a proposed rule to establish procedures for the disposition of abandoned property held by the United States Postal Service Office of Inspector General (81 FR 17637).

In the course of conducting official investigations, Special Agents of the United States Postal Service Office of Inspector General frequently recover property lost or stolen from the mail and obtain custody of property needed for use as evidence in proceedings to enforce various provisions of the United States Code. In most cases, such property is returned to the owner at the conclusion of the investigation or any resulting administrative or judicial proceedings. In some cases, however, the owners fail to claim property, and it therefore remains in the custody of the Office of Inspector General after it is no longer needed. The objective of the proposed rule was to establish a fair and uniform procedure to identify the owners of such property, afford them an opportunity to claim its return, and in the event a valid claim is not received, treat such property as abandoned and direct that it be sold or put to official use. Apparent owners would be notified of their right to claim property, and where no apparent owner is known and the value of the property in question exceeds $200, notice would be published on the Office of Inspector General's Web site inviting the owner to submit a claim for its return.

No comments were received in response to the proposed rule. Upon further consideration, however, the Postal Service determined it would be appropriate to make non-substantive changes in proposed §§ 230.31 and 230.42 to clarify their meaning. Accordingly, in § 230.31, the definition of *Ruling Official* has been clarified; and in § 230.42, more specific instructions have been provided to special agents for the disposition and conversion of abandoned property.

List of Subjects in 39 CFR Part 230

Administrative practice and procedure, Claims, Law enforcement, Property (abandoned).

For the reasons stated in the preamble, the Postal Service amends 39 CFR part 230 as follows:

PART 230—OFFICE OF INSPECTOR GENERAL

■ 1. The authority citation for part 230 continues to read as follows:

Authority: 5 U.S.C. App.3; 39 U.S.C. 401(2) and 1001.

■ 2. Add subpart C to read as follows:

Subpart C—Rules of Procedure Relating to the Disposition of Stolen Mail Matter and Property Acquired by the Office Of Inspector General for Use as Evidence

Sec.

230.30 Scope.
230.31 Definitions.
230.32 Disposition of property of apparent owners where property is valued over $200.
230.33 Disposition of property of apparent owners where property is valued at $200 or less.
230.34 Disposition of property of unknown owners where property is valued over $200.
230.35 Disposition of property of unknown owners where property is valued at $200 or less.
230.36 Contraband and property subject to court order.
230.37 Determination of type of property.
230.38 Disposition of abandoned property; additional period for filing claims.
230.39 Submission of claims.
230.40 Determination of claims.
230.41 Reconsideration of claims.
230.42 Disposition of property declared abandoned where title vests in the government.

§ 230.30 Scope.

This subpart prescribes procedures governing the disposition of any property (real, personal, tangible, or intangible) obtained by the United States Postal Service Office of Inspector General (Office of Inspector General) for possible use as evidence after the need to retain such property no longer exists.

§ 230.31 Definitions.

The following definitions apply to this subpart:

(a) *Apparent.* That which is clear, plain, and evident.

(b) *Owner.* The person recognized by the law as having ultimate control over and the right to use property.

(c) *Claimant.* A person who submits a claim for abandoned or other unclaimed property.

(d) *Ruling official.* The official who has the authority to grant or deny a claim for abandoned or other unclaimed property, typically the Executive Special Agent in Charge of the Area Field Office where the property is located, or a designee.

§ 230.32 Disposition of property of apparent owners where property is valued over $200.

Where an apparent owner of property subject to this subpart is known, and the estimated value of the property exceeds $200, the owner shall be notified by certified mail at his last known address. The written notice shall describe the property and the procedure for filing a claim for its return (*see,* §§ 230.36 and 230.39). Such claims must be filed within 30 days from the date the written notice is postmarked. If the apparent owner of the property fails to file a timely claim, the property is considered abandoned and must be disposed of as provided in § 230.38.

§ 230.33 Disposition of property of apparent owners where property is valued at $200 or less.

Where an apparent owner of property subject to this subpart is known, and the estimated value of the property is $200 or less, the Executive Special Agent in Charge, or a designee, should attempt to return the property to the owner. If successful, the Executive Special Agent in Charge shall request the owner sign a Hold Harmless Agreement. If not, the Executive Special Agent in Charge shall vest title in the Government.

§ 230.34 Disposition of property of unknown owners where property is valued over $200.

(a) Where no apparent owner of property subject to this subpart is known, except property described in § 230.36, and the estimated value of the property exceeds $200, the Executive Special Agent in Charge, or a designee, must publish notice providing the following information:

(1) A description of the property, including model or serial numbers, if known;

(2) A statement of the location where the property was found;

(3) The name, address, and telephone number of the Executive Special Agent in Charge who has custody of the property; and

(4) A statement inviting any person who believes he or she is fully entitled to the property to submit a claim for its return with the Executive Special Agent in Charge identified in the notice. Such claim must be submitted within 30 days from the date of first publication of the notice.

(b) The notice under paragraph (a) of this section must be published for three consecutive weeks on the Office of Inspector General's Web site.

§ 230.35 Disposition of property of unknown owners where property is valued at $200 or less.

Where the owner of property subject to this subpart is unknown and the estimated value of the property is $200 or less, no notice is required, and the Executive Special Agent in Charge, or a designee, should vest title in the Government, subject to the rights of the owner to submit a valid claim as provided in § 230.38.

§ 230.36 Contraband and property subject to court order.

Claims submitted with respect to property subject to this subpart, possession of which is unlawful, must be denied, in writing, by certified mail, and the person submitting the claim must be accorded 45 days from the postmarked date to institute judicial proceedings to challenge the denial. If judicial proceedings are not instituted within 45 days, or any extension of time for good cause shown, the contraband property must be destroyed unless the Executive Special Agent in Charge, or a designee, determines that it should be placed in official use by the Office of Inspector General. Property subject to this part, the disposition of which is involved in litigation or is subject to an order of court, must be disposed of as determined by the court.

§ 230.37 Determination of type of property.

If the Office of Inspector General is unable to determine whether the personal property in its custody is abandoned or voluntarily abandoned, it shall contact the Office of Inspector General, Office of General Counsel for such a determination.

§ 230.38 Disposition of abandoned property; additional period for filing claims.

(a) Upon expiration of the time provided in §§ 230.32 and 230.34 for the filing of claims or any extension thereof, and without the receipt of a timely claim, the property described in the notice is considered abandoned and becomes the property of the Government. However, if the owner satisfies the requirements of paragraph (b) of this section, except for property described in § 230.36, such abandoned property must be returned to the owner if a valid claim is filed within three years from the date the property became abandoned, with the following qualifications:

(1) Where property has been placed in official use by the Office of Inspector General, a person submitting a valid claim under this section must be reimbursed the fair market value of the property at the time title vested in the Office of Inspector General, less costs incurred in returning or attempting to return such property to the owner; or

(2) Where property has been sold, a person submitting a valid claim under this section must be reimbursed the same amount as the last appraised value of the property prior to the sale of such property.

(b) In order to present a valid claim under paragraph (a) of this section, the claimant must establish he or she had no actual or constructive notice that he or she was entitled to file a claim pursuant to § 230.32 or § 230.34 prior to the date the property became abandoned. Publication of a notice pursuant to § 230.34 provides constructive notice, unless a claimant can demonstrate circumstances that reasonably precluded his or her access to the published notice.

§ 230.39 Submission of claims.

Claims submitted pursuant to this subpart must be submitted on Postal Service Form 1503, which may be obtained from the Executive Special Agent in Charge who has custody of the property.

§ 230.40 Determination of claims.

Upon receipt of a claim under this subpart, the Office of Inspector General must conduct an investigation to determine the merits of the claim. The results of the investigation must be submitted to the ruling official, who must approve or deny the claim by written decision, a copy of which must be forwarded to the claimant by certified mail. If the claim is granted, the conditions of relief and the procedures to be followed to obtain the relief shall be set forth. If the claim is denied, the claimant shall be advised of the reason for such denial. For claims involving firearms or contraband, the ruling official shall consult with the Office of Inspector General, Office of General Counsel prior to rendering a decision.

§ 230.41 Reconsideration of claims.

A written request for reconsideration of denied claims must be based on evidence recently developed or not previously presented. It must be submitted within 10 days of the postmarked date of the letter denying the claim. The ruling official shall advise the Asset Forfeiture Coordinator if a timely reconsideration of the denial is made. The Office of Inspector General, Office of General Counsel shall rule on the reconsideration request.

§ 230.42 Disposition of property declared abandoned where title vests in the government.

Property declared abandoned, including cash and proceeds from the sale of property subject to this part, may be shared with federal, state, or local law enforcement agencies. Abandoned property may also be destroyed, sold, or placed into official use. However, before abandoned property can be shared with another agency, sold, or placed into official use, the Executive Special Agent in Charge must confer with the Office of Inspector General, Office of General Counsel. Abandoned property that is not shared with other agencies shall be converted into a monetary instrument and deposited into the Postal Service Fund established by 39 U.S.C. 2003. The Executive Special Agent in Charge of Headquarters Operations, or a designee, in consultation with the Office of General Counsel, shall determine which accounts within the Postal Service Fund will receive the proceeds of abandoned property.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–18234 Filed 8–1–16; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2013–0561, FRL–9949–99–Region 8]

Promulgation of State Implementation Plan Revisions; Infrastructure Requirements for the 2008 Lead, 2008 Ozone, 2010 NO_2, 2010 SO_2, and 2012 $PM_{2.5}$ National Ambient Air Quality Standards; Utah

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving elements of State Implementation Plan (SIP) revisions from the State of Utah to demonstrate the State meets infrastructure requirements of the Clean Air Act (CAA) for the National Ambient Air Quality Standards (NAAQS) promulgated for ozone on March 12, 2008, lead (Pb) on October 15, 2008, nitrogen dioxide (NO_2) on January 22, 2010, sulfur dioxide (SO_2) on June 2, 2010 and fine particulate matter ($PM_{2.5}$) on December 14, 2012. The EPA is also approving 110(a)(2)(D)(ii) for the 1997 and 2006 $PM_{2.5}$ NAAQS. Finally, the EPA is approving SIP revisions the State submitted regarding state boards.

DATES: This rule is effective on September 1, 2016.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2013–0561. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. The EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Abby Fulton, Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6563, *fulton.abby@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Infrastructure requirements for SIPs are set forth in Section 110(a)(1) and (2) of the CAA. Section 110(a)(2) lists the specific infrastructure elements that a SIP must contain or satisfy.

In our proposed rule, the EPA proposed to approve and take no action on some infrastructure elements for the 2008 Pb, 2008 ozone, 2010 NO_2, 2010 SO_2 and 1997, 2006 and 2012 $PM_{2.5}$ NAAQS from the State's certifications.[1] In this rulemaking, we are taking final action to approve infrastructure elements from the State's certifications. We are also taking final action to approve new Utah Administrative Code (UAC) provisions submitted on March 14, 2016 to satisfy requirements of element (E)(ii), state boards.

II. Response to Comments

During the public comment period, we received a comment regarding regional haze in California national parks. This comment does not apply to this rulemaking.

We also received comments from the Sierra Club claiming that Utah's SIP is inadequate with respect to air monitoring and modeling requirements of Sections 110(a)(2)(B) and 110(a)(2)(K) for the 2010 SO_2 NAAQS. The Sierra Club also contends that Utah's SO_2 infrastructure SIP certification does not satisfy requirements of CAA Section 110(a)(1) and (2) because it lacks enforceable emission limits to ensure the implementation, attainment, and maintenance of the 2010 SO_2 NAAQS within Utah, as well as adequate provisions prohibiting sources within the State from emitting SO_2 in amounts which will contribute to nonattainment and interfere with maintenance of the SO_2 NAAQS in neighboring states.

Comments received from Western Resource Advocates (WRA) contend that, because of language regarding startup, shutdown, and malfunction exemptions in Utah's minor and major source permits, Utah's prevention of significant deterioration (PSD) program cannot ensure emissions will not cause or contribute to a violation of any NAAQS or PSD increment, or that Utah's minor source permitting program protects NAAQS. WRA therefore asserts that Utah's infrastructure SIP does not meet requirements of Section 110(a)(2)(A) and (C). WRA also states that Utah's infrastructure SIP does not meet the requirements of Section 110(a)(2)(F) because monitoring frequency of emissions is inadequate and that the State's SIP does not meet the public notice requirements of Section 127.

The EPA generally disagrees with the Sierra Club and WRA's comments. A separate document provides detailed responses to all significant comments received and is included in the docket associated with this action.

III. Final Action

For reasons expressed in the proposed rule and the response to comments document, the EPA is taking final action to approve infrastructure elements from the State's certifications as shown in Table 1. Elements we are taking no action on are reflected in Table 2. We are also approving new UAC rules that the State submitted on March 14, 2016 to satisfy requirements of Section 110(a)(2)(E)(ii), which pertains to state boards (Table 1).

A comprehensive summary of infrastructure elements and new UAC rules being approved into the Utah SIP through this final rule action are provided in Table 1 and Table 2.

TABLE 1—LIST OF UTAH INFRASTRUCTURE ELEMENTS AND REVISIONS THAT THE EPA IS APPROVING

Approval
December 3, 2007 submittal—1997 $PM_{2.5}$ NAAQS: (D)(ii).
September 21, 2010 submittal—2006 $PM_{2.5}$ NAAQS: (D)(ii).
January 19, 2012 submittal—2008 Pb NAAQS: (A), (C), (D)(i)(II) element 3, (D)(ii), (E), (F), (G), (H), (J), (K), (L) and (M).
June 2, 2013 submittal—2010 SO_2 NAAQS: (A), (C), (D)(i)(II) element 3, (D)(ii), (E), (F), (G), (H), (J), (K), (L) and (M).

[1] ''Where an air agency determines that the provisions in or referred to by its existing EPA approved SIP are adequate with respect to a given infrastructure SIP element (or subelement) even in light of the promulgation of a new or revised NAAQS, the air agency may make a SIP submission in the form of a certification.'' EPA's ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and (2),'' September 13, 2013, at 7.

TABLE 1—LIST OF UTAH INFRASTRUCTURE ELEMENTS AND REVISIONS THAT THE EPA IS APPROVING—Continued

Approval
January 31, 2013 submittal—2008 Ozone NAAQS: (A), (B), (C), (D)(i)(II) element 3, (D)(ii), (E), (F), (G), (H), (J), (K), (L) and (M).
January 31, 2013 submittal—2010 NO_2 NAAQS: (A), (C), (D)(i)(II) element 3, (D)(ii), (E), (F), (G), (H), (J), (K), (L) and (M).
December 4, 2015 submittal—2012 $PM_{2.5}$ NAAQS: (A), (C), (D)(i)(II) element 3, (D)(ii), (E), (F), (G), (H), (J), (K), (L) and (M).
March 14, 2016 submittal—New UAC Rules, CAA Section 128: R307–104–1, R307–104–2 and R307–104–3.

TABLE 2—LIST OF UTAH INFRASTRUCTURE ELEMENTS AND REVISIONS THAT THE EPA IS TAKING NO ACTION ON

No Action (Revision to be made in separate rulemaking action)
January 19, 2012 submittal—2008 Pb NAAQS: (B), (D)(i)(I) elements 1 and 2, (D)(i)(II) element 4.
January 31, 2013 submittal—2008 Ozone NAAQS: (D)(i)(I) elements 1 and 2, (D)(i)(II) element 4.
January 31, 2013 submittal—2010 NO_2 NAAQS: (B), (D)(i)(I) elements 1 and 2, (D)(i)(II) element 4.
June 2, 2013 submittal—2010 SO_2 NAAQS: (B), (D)(i)(I) elements 1 and 2, (D)(i)(II) element 4.
December 4, 2015 submittal—2012 $PM_{2.5}$ NAAQS: (B), (D)(i)(I) elements 1 and 2, (D)(i)(II) element 4.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the UAC discussed in section III, *Final Action* of this preamble. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

V. Statutory and Executive Orders Review

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, the 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 the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under Section 307(b)(1) of the 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 October 3, 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. This action may not be challenged later in proceedings to enforce its requirements. (See CAA Section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

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

Dated: July 19, 2016.

Shaun L. McGrath,

Acting Regional Administrator, Region 8.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart TT—Utah

■ 2. Amend § 52.2320, paragraph (c) table, by adding in numerical order, center heading ''R307–104. Conflict of Interest'' and entries ''R307–104–01'', ''R307–104–02'', and ''R307–104–03'' to read as follows:

§ 52.2320 Identification of plan.

* * * * *

(c) * * *

Rule No.	Rule title	State effective date	Final rule citation, date	Comments
*	*	*	*	*
R307–104. Conflict of Interest				
R307–104–01	Authority	6/01/2016	[Insert **Federal Register** citation], 8/02/2016.	
R307–104–02	Purpose	6/01/2016	[Insert **Federal Register** citation], 8/02/2016.	
R307–104–03	Disclosure of conflict of interest.	6/01/2016	[Insert **Federal Register** citation], 8/02/2016.	
*	*	*	*	*

* * * * *

■ 3. Amend § 52.2355 by adding paragraph (c) to read as follows:

§ 52.2355 Section 110(a)(2) infrastructure requirements.

* * * * *

(c) Gary R. Herbert, Governor, State of Utah, provided submissions to meet the infrastructure requirements for the State of Utah for the 1997 $PM_{2.5}$ NAAQS on December 3, 2007; 2006 $PM_{2.5}$ NAAQS on September 21, 2010; 2008 Pb NAAQS on January 19, 2012; 2008 ozone NAAQS on January 31, 2013; 2010 NO_2 NAAQS on January 31, 2013; 2010 SO_2 NAAQS on June 2, 2013; and 2012 $PM_{2.5}$ on December 4, 2015. The State's Infrastructure SIP is approved with respect to the 1997 and 2006 $PM_{2.5}$ NAAQS with respect to CAA Section 110(a)(1) and element (D)(ii) of Section 110(a)(2). The State's Infrastructure SIP is approved with respect to the 2008 ozone NAAQS with respect to CAA Section 110(a)(1) and the following elements of Section 110(a)(2): (A), (B), (C), (D)(i)(II) prong 3, (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M). The State's Infrastructure SIP is approved with respect to the 2008 Pb, 2010 SO_2, 2010 NO_2, and 2012 $PM_{2.5}$ NAAQS with respect to CAA Section 110(a)(1) and the following elements of Section 110(a)(2): (A), (C), (D)(i)(II) prong 3, (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M).

[FR Doc. 2016–18154 Filed 8–1–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2015–0361; FRL–9950–01–Region 4]

Air Plan Approval; Florida; Regional Haze Progress Report

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted by the State of Florida through the Florida Department of Environmental Protection (FDEP) on March 10, 2015. Florida's March 10, 2015, SIP revision (Progress Report) addresses requirements of the Clean Air Act (CAA or Act) and EPA's rules that require states to submit periodic reports describing progress towards reasonable progress goals (RPGs) established for regional haze and a determination of the adequacy of a state's existing SIP addressing regional haze (regional haze plan). EPA is approving Florida's Progress Report on the basis that it addresses the progress report and adequacy determination requirements for the first implementation period for regional haze.

DATES: This rule will be effective September 1, 2016.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2015–0361. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information 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 either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person 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 Federal holidays.

FOR FURTHER INFORMATION CONTACT: Sean Lakeman, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Mr. Lakeman can be reached by phone at (404) 562–9043 and via electronic mail at *lakeman.sean@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under the Regional Haze Rule,[1] each state is required to submit a progress

[1] Located in 40 CFR part 51, subpart P.

report in the form of a SIP revision every five years that evaluates progress towards the RPGs for each mandatory Class I Federal area (also referred to as Class I area in this rulemaking) within the state and for each mandatory Class I Federal area outside the state which may be affected by emissions from within the state. *See* 40 CFR 51.308(g). Each state is also required to submit, at the same time as the progress report, a determination of the adequacy of the state's existing regional haze plan. *See* 40 CFR 51.308(h). The first progress report is due five years after submittal of the initial regional haze plan. On March 19, 2010, FDEP submitted the State's first regional haze plan in accordance with 40 CFR 51.308(b).[2]

On March 10, 2015, FDEP submitted its regional haze progress report, reporting progress made in the first implementation period towards the RPGs for Class I Federal areas in the State and for Class I Federal areas outside the State that are affected by emissions from sources within Florida. This submittal also includes a negative declaration pursuant to 40 CFR 51.308(h)(1) that the State's regional haze plan requires no substantive revision to achieve the established regional haze visibility improvement goals for 2018. In a notice of proposed rulemaking (NPRM) published on May 24, 2016 (81 FR 32702), EPA proposed to approve Florida's Progress Report on the basis that it satisfies the requirements of 40 CFR 51.308(g) and (h). No comments were received on the May 24, 2016, proposed rulemaking. The details of Florida's submittal and the rationale for EPA's actions are further explained in the NPRM. *See* 81 FR 32702 (May 24, 2016).

II. Final Action

EPA is approving Florida's Regional Haze Progress Report SIP revision, submitted by the State on March 10, 2015, as meeting the applicable regional haze requirements set forth in 40 CFR 51.308(g) and (h).

III. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. *See* 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 CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

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

The SIP is not approved to apply on any Indian reservation land or in any other area where 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 as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

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 CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 3, 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. 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, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

Dated: July 20, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart K—Florida

■ 2. Section 52.520(e), is amended by adding the entry ''March 2015 Regional Haze Progress Report'' at the end of the table to read as follows:

§ 52.520 Identification of plan.

* * * * *

(e) * * *

[2] On August 29, 2013, EPA fully approved Florida's regional haze plan (as amended on August 31, 2010, and September 17, 2012). See 78 FR 53250.

EPA-APPROVED FLORIDA NON-REGULATORY PROVISIONS

Provision	State effective date	EPA approval date	**Federal Register** notice	Explanation
* *	*	*	* *	*
March 2015 Regional Haze Progress Report ..	3/10/2015 ...	8/2/2016	[Insert citation of publication]	

[FR Doc. 2016–18155 Filed 8–1–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 97

[FRL–9949–93–OAR]

Allocations of Cross-State Air Pollution Rule Allowances From New Unit Set-Asides for the 2016 Compliance Year

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; notice of data availability (NODA).

SUMMARY: The Environmental Protection Agency (EPA) is providing notice of emission allowance allocations to certain units under the new unit set-aside (NUSA) provisions of the Cross-State Air Pollution Rule (CSAPR) federal implementation plans (FIPs) and is responding to objections to preliminary calculations. EPA has completed final calculations for the first round of NUSA allowance allocations for the 2016 compliance year and has posted spreadsheets containing the calculations on EPA's Web site. The final allocations are unchanged from the preliminary calculations. EPA will record the allocated allowances in sources' Allowance Management System (AMS) accounts by August 1, 2016.

DATES: August 2, 2016.

FOR FURTHER INFORMATION CONTACT: Questions concerning this action should be addressed to Robert Miller at (202) 343–9077 or *miller.robertl@epa.gov* or to Kenon Smith at (202) 343–9164 or *smith.kenon@epa.gov*.

SUPPLEMENTARY INFORMATION: Under the CSAPR FIPs, a portion of each state budget for each of the four CSAPR emissions trading programs is reserved as a NUSA from which allowances are allocated to eligible units through an annual one- or two-round process. In a NODA published in the **Federal Register** on May 27, 2016 (81 FR 33636), EPA described the allocation process and provided notice of preliminary calculations for the first-round 2016 NUSA allowance allocations. EPA also described the process for submitting any objections to the preliminary calculations.

In response to the May 27 NODA, EPA received one written objection addressing CSAPR NO_X annual and NO_X ozone season allowance recordations for 2016 to Missouri's existing CSAPR units, and the number of allowances shown as available for allocation to Missouri's new units in 2016 in the May 27 NODA under those programs. Due to an allowance recordation error, two facilities in Missouri with existing units did not receive the CSAPR NO_X annual and ozone season existing unit allowance allocations specified in Missouri's approved 2016 CSAPR State Implementation Plan (SIP). This error in turn impacted the number of NUSA allowances shown in the May 27 NODA as available for allocation to Missouri's new units for 2016 under those programs. EPA corrected the recordation error to the existing units by recording a total of four additional CSAPR NO_X Annual allowances and two additional CSAPR NO_X Ozone Season allowances to two facilities in Missouri, consistent with the allocations for those facilities specified by Missouri in their 2016 CSAPR SIP. EPA in turn adjusted downward the number of allowances available for allocation in Missouri's 2016 CSAPR NO_X Annual and CSAPR NO_X Ozone Season NUSA's by four and two allowances, respectively. Since the downward correction to the number of allowances available in Missouri's 2016 NUSAs was relatively small, the number of allowances allocated to new units in Missouri in the first round was not affected.

The final unit-by-unit data and allowance allocation calculations are set forth in Excel spreadsheets titled ''CSAPR_NUSA_2016_NOx_Annual_1st_Round_Final_Data'', ''CSAPR_NUSA_2016_NOx_OS_1st_Round_Final_Data'', and ''CSAPR_NUSA_2016_SO_2_1st_Round_Final_Data'', available on EPA's Web site at *http://www.epa.gov/crossstaterule/actions.html.* The three spreadsheets show EPA's final determinations of first-round 2016 NUSA allocations under the CSAPR NO_X annual, NO_X ozone season, and SO_2 (Group 1 and Group 2) trading programs, respectively.

Pursuant to CSAPR's allowance recordation timing requirements, the allocated NUSA allowances will be recorded in sources' AMS accounts by August 1, 2016. EPA notes that an allocation or lack of allocation of allowances to a given unit does not constitute a determination that CSAPR does or does not apply to the unit. EPA also notes that NUSA allocations are subject to potential correction if a unit to which NUSA allowances have been allocated for a given compliance year is not actually an affected unit as of January 1 (or May 1 in the case of the NO_X ozone season program) of the compliance year.[1]

(Authority: 40 CFR 97.411(b), 97.511(b), 97.611(b), and 97.711(b).)

Dated: July 18, 2016.

Reid P. Harvey,

Director, Clean Air Markets Division, Office of Atmospheric Programs, Office of Air and Radiation.

[FR Doc. 2016–18152 Filed 8–1–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

EPA–HQ–OPP–2012–0843; FRL–9947–78]

Cloquintocet-mexyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cloquintocet-mexyl and its acid metabolite in or on multiple commodities which are identified and discussed later in this document when cloquintocet-mexyl is used as an inert ingredient (herbicide safener) in pesticide formulations containing the new active ingredient halauxifen-methyl (XDE-729 methyl).

[1] *See* 40 CFR 97.411(c), 97.511(c), 97.611(c), and 97.711(c).

Dow AgroSciences, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 2, 2016. Objections and requests for hearings must be received on or before October 3, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0843, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0843 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before October 3, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0843, by one of the following methods:

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 19, 2012 (77 FR 75082) (FRL–9372–6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F8085) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR 180.560 be amended by expanding the tolerances therein to cover residues of the inert ingredient (herbicide safener) cloquintocet-mexyl (acetic acid [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester; CAS Reg. No. 99607–70–2), and its acid metabolite (5-chloro-8-quinolinoxyacetic acid) when used in pesticide formulations containing the new active ingredient halauxifen-methyl (XDE-729 methyl), in or on barley grain, barley hay, barley straw, wheat forage, wheat grain, wheat hay, and wheat straw. No numerical change to the tolerances for the specific commodities was sought. That document referenced a summary of the petition prepared by Dow AgroSciences LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

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

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

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Cloquintocet-mexyl has a low order of acute oral, dermal, and inhalation toxicity. It is slightly irritating to the eyes and non-irritating to the skin. Cloquintocet-mexyl is a skin sensitizer. The chemical is not genotoxic and is not a reproductive and developmental toxicant. There is no evidence of neurotoxicity in the available studies. Cloquintocet-mexyl is classified as ''not likely to be a human carcinogen.'' The main metabolite for cloquintocet-mexyl is 5-chloro-8-quin-linoxyacetic acid, and testing on the metabolite is part of the toxicology database for cloquintocet-mexyl.

Specific information on the studies received and the nature of the adverse effects caused by cloquintocet-mexyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document Cloquintocet-Mexyl—Updated Human Health Risk Assessment from Uses of Halauxifen-methyl (PC Code 117501) in docket ID number EPA–HQ–OPP–2012–0843.

B. Toxicological Points of Departure/Levels of Concern

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

A summary of the toxicological endpoints for cloquintocet-mexyl used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CLOQUINTOCET-MEXYL FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–49 years of age).	NOAEL = 100 mg/kg/day. UF_A = 10 UF_H = 10 FQPA SF = 1x	Acute RfD = 1 mg/kg/day. aPAD = 1 mg/kg/day	Developmental toxicity study in rats (MRID 44387429). LOAEL = 400 mg/kg/day based on higher incidence of skeletal variants and decrease in fetal body weights in the high dose group.
Acute dietary (General population including infants and children).	N/A	N/A	Based on available data, a suitable endpoint was not identified for the general population because there were no effects observed in oral toxicity studies appropriate to this population that could be attributed to a single dose exposure.
Chronic dietary (All populations)	NOAEL = 4.3 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.04 mg/kg/day. cPAD = 0.04 mg/kg/day	Chronic/Oncogenicity Toxicity—Rat (MRID 44387431). LOAEL = 41.2 mg/kg/day based on thyroid hyperplasia in females.
Cancer (Oral, dermal, inhalation).	Cloquintocet-mexyl is classified as ''not likely to be carcinogenic to humans''.		

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cloquintocet-mexyl, EPA considered exposure under the petitioned-for tolerances as well as all existing cloquintocet-mexyl tolerances in 40 CFR 180.560. EPA assessed dietary exposures from cloquintocet-mexyl in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for cloquintocet-mexyl and are applicable only to females 13–49 years old in order to account for fetal effects (higher incidence of skeletal variants and decrease in fetal body weights) that were seen in the developmental toxicity study in rats. In estimating acute dietary exposure, EPA used food consumption information from the 2003–2008 National Health and Nutrition Examination Surveys (NHANES). As to residue levels in food, EPA assumed tolerance-level residues of cloquintocet-mexyl and cloquintocet acid in all forms of barley, triticale, and wheat, and assumed that all of those crops are treated (*i.e.,* 100% crop treated).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment

EPA used the food consumption data from the 2003–2008 National Health and Nutrition Examination Surveys (NHANES). As to residue levels in food, EPA assumed tolerance-level residues of cloquintocet-mexyl and cloquintocet acid in all forms of barley, triticale, and wheat, and assumed that all of those crops are treated (*i.e.,* 100% crop treated).

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that cloquintocet-mexyl does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for cloquintocet-mexyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cloquintocet-mexyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the First Index Reservoir Screening Tool (FIRST) and the Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of cloquintocet-mexyl for acute exposures are estimated to be 0.186 parts per billion (ppb) for surface water and 0.000061 ppb for ground water, chronic exposures are estimated to be 0.005 ppb for surface water and 0.000061 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. As a conservatism in the assessment, the acute drinking water estimate (0.186 ppb), rather than the chronic drinking water estimate (0.005 ppb) was used in chronic dietary assessment.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Cloquintocet-mexyl is not registered for any specific use patterns that would result in residential exposure.

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

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

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased susceptibility of in utero or post-natal exposure to rats or rabbits in the prenatal developmental studies or in rats in the 2-generation reproduction study. NOAELs for maternal/parental toxicity were either less than or equal to the NOAELs for fetal or reproductive toxicity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for cloquintocet-mexyl is sufficient for risk assessment.

ii. There is no indication that cloquintocet-mexyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that cloquintocet-mexyl results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cloquintocet-mexyl in drinking water. These assessments will not underestimate the exposure and risks posed by cloquintocet-mexyl.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to cloquintocet-mexyl will occupy <1% of the aPAD for females age 13–49, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cloquintocet-mexyl from food and water will utilize <1% of the cPAD for all subpopulations. There are no residential uses for cloquintocet-mexyl.

3. *Short-term and intermediate-term risk.* Because cloquintocet-mexyl is not registered for use in pesticide formulations that will result in residential exposure, EPA concludes that cloquintocet-mexyl will not pose a short-term or intermediate-term risk.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, cloquintocet-mexyl is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to cloquintocet-mexyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for cloquintocet-mexyl.

V. Conclusion

The residue data indicate that combined residues of cloquintocet-mexyl and cloquintocet acid are unlikely to exceed the existing tolerances for residues in barley, triticale, and wheat commodities, therefore, the existing tolerance levels remain unchanged. However, the active ingredient, halauxifen-methyl, will be added to the list of active ingredients addressed in the tolerance expression for cloquintocet-mexyl as a result of this tolerance amendment for cloquintocet-mexyl.

Therefore, 40 CFR 180.560 is amended by establishing a tolerance for the combined residues of cloquintocet-mexyl (acetic acid [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester; CAS Reg. No. 99607–70–2) and its acid metabolite (5-chloro-8-quinlinoxyacetic acid) when used as an inert ingredient (safener) in pesticide formulations containing the active ingredients clodinafop-propargyl (wheat only), dicamba (wheat only), flucarbazone-sodium (wheat only), halauxifen-methyl (wheat or barley), pinoxaden (wheat or barley), or pyroxsulam (wheat only) at 0.1 ppm in/on barley commodities (grain, hay, and straw), wheat grain, and wheat straw; at 0.2 ppm in/on wheat forage; and at 0.5 ppm in/on wheat hay.

VI. Statutory and Executive Order Reviews

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

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

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

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

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: June 28, 2016.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.560, revise the introductory text of paragraph (a) to read as follows:

§ 180.560 Cloquintocet-mexyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the inert ingredient cloquintocet-mexyl, including its metabolites and degradates, in or on the commodities in the following table when used as a safener in pesticide formulations containing the active ingredients clodinafop-propargyl (wheat only), dicamba (wheat only), flucarbazone-sodium (wheat only), halauxifen-methyl (wheat or barley), pinoxaden (wheat or barley), or pyroxsulam (wheat only). Compliance with the tolerance levels specified is to be determined by measuring the combined residues of cloquintocet-mexyl, (acetic acid [(5-

chloro-8-quinolinyl)oxy]-, 1-methylhexyl ester; CAS Reg. No. 99607–70–2) and its acid metabolite (5-chloro-8-quinolinoxyacetic acid), expressed as cloquintocet-mexyl, in or on the following commodities:

* * * * *

[FR Doc. 2016–17534 Filed 8–1–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 202, 212, 242, 246, and 252

[Docket DARS–2015–0038]

RIN 0750–AI58

Defense Federal Acquisition Regulation Supplement: Detection and Avoidance of Counterfeit Electronic Parts—Further Implementation (DFARS Case 2014–D005)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a requirement of the National Defense Authorization Act for Fiscal Year 2012, as modified by a section of the National Defense Authorization Act for Fiscal Year 2015, that addresses required sources of electronic parts for defense contractors and subcontractors.

DATES: Effective August 2, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Amy G. Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 80 FR 56939 on September 21, 2015, to further implement section 818 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2012 (Pub. L. 112–81), as modified by section 817 of the NDAA for FY 2015 (Pub. L. 113–291).

In accordance with section 818, this rule requires DoD contractors and subcontractors, except in limited circumstances, acquire electronic parts from trusted suppliers in order to further address the avoidance of counterfeit electronic parts. DoD contractors and subcontractors that are not the original component manufacturer are required by this rule to notify the contracting officer if it is not possible to obtain an electronic part from a trusted supplier. For those instances where the contractor obtains electronic parts from sources other than a trusted supplier, the contractor is responsible for inspection, test, and authentication in accordance with existing applicable industry standards.

This rule enhances DoD's ability to strengthen the integrity of the process for acquisition of electronic parts and benefits both the Government and contractors. The careful selection of suppliers and the inspection, testing, and authentication of electronic parts that are not traceable to the original manufacturer are consistent with industry risk-based processes and are steps that a prudent contractor should take notwithstanding this rule. The avoidance of the proliferation of counterfeit electronic parts in the DoD supply chain reduces the risk of critical failure of fielded systems such as aircraft, ships, and other weapon systems, thus protecting troops' lives and safety.

This rule is part of DoD's retrospective plan, completed in August 2011, under Executive Order 13563, Improving Regulation and Regulatory Review. DoD's full plan and updates can be accessed at: *http://www.regulations.gov/#!docketDetail;D=DOD-2011-OS-0036.* Eighteen respondents submitted public comments in response to the proposed rule.

II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments is provided, as follows:

A. Summary of Significant Changes From the Proposed Rule

1. Definitions

- Replaces the definition of ''authorized dealer'' with a definition of ''authorized supplier.''
- Replaces the definition of ''contract electronics manufacturer'' with a definition of ''contract manufacturer'' and a definition of ''authorized aftermarket manufacturer.'' This also results in a conforming change to the definition of ''original manufacturer.''
- Deletes the definition of ''trusted supplier'' and adds a definition of ''contractor-approved supplier.''
- Amends the definition of ''obsolete electronic part'' to utilize the newly defined term ''authorized aftermarket manufacturer.''
- Makes conforming changes throughout the rule in accordance with the added, revised, or deleted definitions.

2. Amends the following paragraphs of DFARS clause 252.246–7008, Sources of Electronic Parts, with conforming changes to DFARS subpart 246.8, as follows:

- (b)(1)—Clarifies ''in production'' and ''currently available in stock''.
- (b)(2) Introductory text—Clarifies ''not in production'' and ''not currently available in stock'' and changes ''or'' to ''and'' in the condition for use of contractor-approved suppliers, *i.e.*, ''Obtain electronic parts that are not in production by the original manufacturer or an authorized aftermarket manufacturer and not currently available in stock from a source listed in paragraph (b)(1) of this clause, from suppliers identified by the Contractor as contractor-approved suppliers . . . .''
- (b)(2)(i)—For electronic parts not in production and not currently available in stock, adds to the requirement for use of established counterfeit prevention industry standards and processes, the reference to the DoD-adopted standards at *https://assist.dla.mil*, but allows use of other appropriate standards. Use of DoD-adopted counterfeit prevention industry standards was previously required in the definition of ''trusted supplier.''
- (b)(2)(iii)—Specifies that the contracting officer is the appropriate DoD official to review and audit. This function is also added at DFARS 242.302 as a contract administration function that is delegable to the administrative contracting officer.
- (b)(3)—Moves former paragraph (d) to paragraph (b)(3), requiring prompt notification in writing, and adds the requirement that the contractor shall make documentation of the inspection, testing, and authentication of such electronic parts available to the contracting officer upon request if the contractor—
  - ○ Obtains an electronic part from a source other than any of the sources identified in paragraph (b)(1) or (b)(2) of the clause due to nonavailability from such sources, or a subcontractor (other than the original manufacturer) that refuses to accept flowdown of the clause; or
  - ○ Cannot confirm that an electronic part is new or that it has not been comingled in supplier new production or stock with used, refurbished, reclaimed, or returned parts.
- (c)(2)—Deletes contractor consideration of alternative parts if the contractor cannot establish traceability from the original manufacturer for a

specific electronic part, and makes the contractor responsible for inspection, testing, and authentication.

• (c)(3)—Requires the contractor to maintain documentation of traceability or the inspection, testing, and authentication, and adds the requirement to make such documentation available to the Government upon request.

• (d)—Adds a new paragraph (d) to address Government sources of electronic parts, to include purchases from the Federal Supply Schedule, purchases from suppliers accredited by the Defense Microelectronics Activity, or requisitioning from Government inventory/stock. Contractors and subcontractors are still required to comply with the requirements of paragraphs (b) and (c) of the clause 252.246–7008, if purchasing electronic parts from the Federal Supply Schedule or from suppliers accredited by the Defense Microelectronics Activity. However, if the contractor or subcontractor requisitions electronic parts from Government inventory/stock, then the Government is responsible for the authenticity of the parts.

• (e) Does not require clause flowdown to the original manufacturer.

B. Analysis of Public Comments

1. General Support for the Rule

Comment: Several respondents expressed support for many of the changes in the proposed rule, indicating that these are a significant step forward, are consistent with industry risk-based processes, and will help align DoD and defense contractor approaches to reduce the proliferation of counterfeit parts in the supply chain.

Response: Noted.

2. Applicability of DFARS 252.246–70XX (now 252.246–7008) and Associated Policy at Subpart 246.8

a. Contractors Not Covered by Cost Accounting Standards

Comment: Several respondents objected to the application of this rule to contractors not subject to the cost accounting standards (CAS), noting that it will apply to small businesses and acquisitions of commercial items. One respondent stated that section 818(c)(3) of the NDAA for FY 2012 does not add contractor responsibilities for avoiding counterfeit electronic parts to other than CAS-covered contractors and that DoD is overstepping Congressional intent when it applies this rule to small businesses and contracts for commercial items. The respondent states that section 818(c)(2) is only directed to contracts subject to CAS.

Response: Section 818 defines ''covered contractors'' to mean the same as the definition of the term in section 893(f)(2) of the NDAA for FY 2011, *i.e.*, a contractor that is subject to CAS under section 26 of the Office of Federal Procurement Policy Act (41 U.S.C. 422). Some portions of section 818 address covered contractors (*e.g.*, paragraph (c)(2)), and therefore only apply to contractors subject to CAS. However, paragraph (c)(3) of section 818 does not use the term ''covered contractor.'' It applies to all DoD contractors and subcontractors when obtaining electronic parts to be provided to DoD under a DoD contract. Section 818 is clear that DoD contractors and subcontractors at all tiers are responsible for detecting and avoiding counterfeit electronic parts. Thus, 252.246–7008 is consistent with the statute.

Comment: Another respondent stated the opinion that small entities not subject to CAS comprise a large portion of the counterfeit parts that directly threaten the DoD supply chain. The respondent provided several examples of non-CAS covered entities that were found by the Government to have allowed counterfeit parts to enter the DoD supply chain.

Response: Noted.

b. Small Entities

Various respondents addressed application of the rule to small entities. For analysis of applicability to small entities see the regulatory flexibility analysis at section V of this preamble.

c. Commercial Items (Including Commercially Available Off-the-Shelf Items (COTS Items)

Comment: Various respondents expressed concerns about the applicability of DFARS 252.246–7008 and associated policy to commercial item procurements, especially COTS items. One respondent expressed specific concern that the proposed expansion of coverage to commercial item contractors could result in reduced sources and increased costs for contractors. Another respondent stated that manufacturers of COTS items are independently motivated by the commercial market to assure that their products function as advertised.

Response: The Director of Defense Procurement and Acquisition Policy has determined that it is not in the best interest of the Government to exempt commercial items from the applicability of this rule. See section III of this preamble.

Comment: Several respondents expressed concerns that the proposed rule does not address the dilemma industry continually faces concerning the general lack of acceptance of counterfeit part prevention requirements flowdown by COTS electronic assembly producers and their authorized dealers. One respondent suggested providing relief from the obligation to flow down to COTS electronic assembly manufacturers.

Response: DoD has modified paragraph (b)(3) of the clause 252.246–7008 in the final rule to specify the required contractor actions if a subcontractor refuses to accept flowdown of the clause, to include notification to the contracting officer; contractor inspection, testing, and authentication of the part; and the requirement to make documentation of such inspection, testing, and authentication available to the Government upon request.

Comment: Several respondents expressed concerns that mandatory subcontract flowdown in 252.246–7008(e) for commercial items is inconsistent with Federal Acquisition Streamlining Act and that commercial item subcontracts or supplier agreements should be exempted. Another respondent stated that application of unique defense rules to commercial items where not expressly directed in the statute are prohibited without a best interests determination per 10 U.S.C. 2377. According to the respondent, in lieu of such a determination, at several points in the supplementary information, it states that ''DoD intends to determine that it is in the best interests to apply the rule to . . . .'' The respondent finds it unclear what the Department means by using the word ''intends'' rather than making the required determination or putting the cost-benefit analysis right in the rulemaking for review by the public.

Response: The provisions of the Federal Acquisition Streamlining Act (Pub. L. 103–355) with regard to applicability of laws to commercial items are now codified at 41 U.S.C. 1906 (commercial items other than COTS items) and 1907 (COTS items).

Pursuant to 41 U.S.C. 1906, acquisitions of commercial items (other than acquisitions of COTS items, which are addressed in 41 U.S.C. 1907) are exempt from a provision of law unless the law (i) contains criminal or civil penalties; (ii) specifically refers to 41 U.S.C. 1906 and states that the law applies to acquisitions of commercial items; or (iii) the Federal Acquisition Regulatory Council (FAR Council) makes a written determination and finding that it would not be in the best interest of the Federal Government to

exempt contracts (or subcontracts under a contract) for the acquisition of commercial items from the provision of law.

Pursuant to 41 U.S.C. 1907, acquisitions of COTS items are exempt from a provision of law unless the law (i) contains criminal or civil penalties; (ii) specifically refers to 41 U.S.C. 1907 and states that the law applies to acquisition of COTS items; (iii) concerns authorities or responsibilities under the Small Business Act (15 U.S.C. 644) or bid protest procedures developed under the authority of 31 U.S.C. 3551 *et seq.*; 10 U.S.C. 2305(e) and (f); or 41 U.S.C. 3706 and 3707; or (iv) if the Administrator of the Office of Federal Procurement Policy makes a written determination that it would not be in the best interest of the Federal Government to exempt acquisitions of COTS items from the provision of law.

The Director, Defense Procurement and Acquisition Policy, is the appropriate authority to make comparable determinations for regulations to be published in the DFARS, which is part of the Federal Acquisition Regulation (FAR) system of regulations. Therefore, it is not inconsistent with the Federal Acquisition Streamlining Act to apply this rule to the acquisition of commercial items (including COTS items) if the Director of Defense Procurement and Acquisition Policy has determined that it would not be in the best interest of the Government to exempt acquisitions of commercial items, including COTS items, from the provision of law relating to detection and avoidance of counterfeit parts. The Director of Defense Procurement and Acquisition Policy does not make this determination until the final rule stage, in order to allow for review and analysis of public comments received. The Director of Defense Procurement and Acquisition Policy has now made this determination (see section III of this preamble).

Comment: One respondent expressed concerns that this proposed rule is in conflict with DFARS 252.244–7000, Subcontracts for Commercial Items.

Response: The flowdown to subcontracts for commercial items is not in conflict with DFARS clause 252.244–7000, Subcontracts for Commercial Items. DFARS 252.244–7000 states that the contractor is not required to flow down the terms of any DFARS clause in a subcontract for commercial items unless so specified in the particular clause. The fact that the new clause in this rule (252.246–7008), as well as the preexisting clause 252.246–7007, specify such flowdown to subcontracts for commercial items that are for electronic parts or assemblies containing electronic parts is, therefore, in conformance with DFARS 252.244–7000.

d. Original Manufacturers

Comment: Several respondents recommended revising the clause to make it clear that the flowdown does not apply to the original manufacturers. Several respondents asserted that the flowdown to original manufacturers would be costly to both the manufacturer and the end customer and unnecessary. One respondent stated that as an authorized dealer they would not be able to flow down the requirements to the original equipment manufacturers they represent; they have distribution agreements with them that dictate by contract what each parties' responsibilities are. Another respondent suggested it would also limit the genuine products available to the Government to purchase.

Response: DoD has revised the flowdown requirement of the clause at 252.246–7008 to exclude the requirement to flow the clause down to the original manufacturer of the electronic part.

e. Electronic Parts

Comment: One respondent commented that electronic parts are not the only products, parts, or commodities within the DoD supply system that have counterfeit issues. The respondent also stated that certain parts and commodities require higher standards, such as medical products, food, munitions, and now certain electronic parts.

Response: This case addresses only the electronic parts as defined by the NDAA for FY 2012. DoD is aware of the threat of counterfeit parts, other than electronic parts, and is taking action to mitigate the threat through policy and quality assurance requirements.

f. Medical Devices

Comment: One respondent commented that the proposed rule would impose a substantial burden on manufacturers of COTS medical devices and is unnecessary to resolve concerns that may present a significant mission, security, or safety hazard. This is especially true for medical devices, which are heavily regulated by the Food and Drug Administration (FDA) and often contain one or more electronic parts. According to the respondent, DoD's application of the rule to all contractors would apply new requirements to a sizeable group of products that already have a highly effective means of addressing the concern of counterfeit electronic parts.

Furthermore, the respondent commented that the FDA is the Federal agency tasked with protecting the public health by assuring the safety, effectiveness, quality and security of drugs, vaccines, and other biological product and medical devices. The respondent considered that this will not only unduly increase the burden on manufacturers; it has the capacity to cause confusion in the marketplace and result in potential adverse implications for public health. The FDA is in the best position to strike the proper balance of interests in the health care system when establishing requirements for assuring the quality of the products it regulates, assessing the burdens these requirements place on manufacturers, and considering their impact on healthcare costs and healthcare innovation. FDA already regulates purchasing controls for medical device manufacturing, requiring each manufacturer to ensure that all purchases or otherwise received product and services conform to the specified requirements. Medical device manufacturers are required to have robust processes in place to review, investigate, and evaluate external manufacturers and suppliers. The respondent recommended that any additional requirements for FDA-regulated products should be made through the current governing agency, the FDA.

Response: This rule implements section 818 of the NDAA for FY 2012, as amended by section 817 of the NDAA for FY 2015, and prescribes the policy and procedures for preventing counterfeit electronic parts from entering the supply chain. This rule addresses concerns that DoD has encountered regarding the electronic parts, including those that are COTS items, and including medical devices. DoD recognizes the FDA's authority over drugs and medical devices. DoD recognizes that manufacturers are required to have processes in place to review, investigate, and evaluate external manufacturers and suppliers. However, DoD has a responsibility to protect the warfighter by ensuring that we are utilizing electronic products that are not counterfeit or contain counterfeit parts.

g. Raw Materials and Minerals

Comment: Several respondents are concerned that the flowdown requirement is unclear as to whether the flowdown extends to suppliers of raw materials and minerals.

Response: The clause only flows down to subcontracts that are for electronic parts or assemblies containing electronic parts. Raw materials and minerals are not electronic parts.

3. Definitions

a. ''Electronic Part''

Comment: Various respondents commented favorably on the removal of references to ''embedded software'' and ''firmware'' from the definition of ''electronic part.'' One respondent stated that this revision aligns the term's definition with the underlying substance of the material covered by the regulations. The respondent also stated that it is difficult, if not impossible, to address such elements when an express standard or protocol has not yet been adopted. Another respondent recommended that the introduction of tainted software and firmware into integrated circuits is more appropriately addressed in a separate rulemaking process. Similarly, another respondent stated that the change to the definition will rightly focus contractor attention on identifying counterfeit electronic parts as the statute requires, rather than attempting to perform quality assurance on software and firmware without any DoD guidance on how to reliably perform that function.

Response: Noted.

b. ''Trusted Supplier''/''Non-trusted Supplier''

Many respondents commented on the definition of ''trusted supplier.''

Comment: Various respondents stated that the term ''trusted supplier'' is already in use in DoD, and that duplication would lead to confusion within organizations that deal with both trusted supplier types. For reference, the other usage of trusted supplier is with the Trusted Access Program Office (TAPO), which accredits trusted foundries and suppliers through the Defense Microelectronics Activity. One respondent stated that the clause should not mention trusted suppliers at all, instead completely listing items (1) through (3) in the definition, whenever applicable.

Response: The phrase ''trusted supplier'' has been mentioned as a source of confusion since it is was first used in the NDAA for FY 2012 (section 818). The final rule published under DFARS Case 2012–D055, Detection and Avoidance of Counterfeit Parts, avoided use of the term ''trusted supplier.'' The proposed rule under this case introduced the term because it is the term consistently used in section 818 of the NDAA for FY 2012, and subsequent amendments to that statute.

However, in response to the public comments, DoD has reverted to an identification of the sources from which a contractor or subcontractor may acquire electronic parts, or items containing electronic parts, without introducing the term ''trusted supplier.'' In order to facilitate this identification of acceptable sources, DoD has introduced the definition of the term ''contractor-approved supplier'' to cover the fourth category of sources at DFARS 246.870–2(a)(1)(ii) and 252.246–7008(b)(2), which may be used only if the electronic parts are not in production and are not currently available in stock. This term reflects that this is a supplier that is not authorized to sell the manufacturer's product, but the contractor has assessed and approved this supplier.

Comment: Several respondents commented on the meaning of the term ''trusted supplier.'' One respondent agreed with the trusted supplier definition including contractor-vetted suppliers in addition to original manufacturers and authorized dealers. Several respondents disagreed with item (4) in the definition, which allows contractor-approved unauthorized distributors to be a trusted supplier. One respondent went further by claiming that item (3), unauthorized distributors who bought exclusively from the original component manufacturer or an authorized distributor, also should not be included in the definition. One respondent stated that the definition should contain an ''or'' statement that requires purchase from (1) manufacturer or (2) authorized distributor supplier types before (3) and (4) unauthorized distributors of any sort could be used. Another respondent echoed this sentiment without specifically requesting the change in definition. One respondent stated that the definition should be clarified to be consistent throughout the clause.

Response: As stated in the prior response, the term ''trusted supplier'' is no longer used or defined. However, the sources from which a contractor or subcontractor may obtain electronic parts under given circumstances are explicitly provided in section 818(c), as amended, and the statutory provisions are accurately implemented in this rule.

Comment: One respondent stated that there should also be a ''non-trusted supplier'' definition, while another respondent stated that a new definition should be developed for small and disadvantaged businesses that should not contain the word ''trust.''

Response: The term ''non-trusted supplier'' is no longer used in the final rule.

c. ''Authorized Dealer''

Comments: There were various respondents that were opposed to the use of the term ''authorized dealer'' and recommended using the term ''authorized supplier'' instead. According to the respondents, the term ''authorized supplier'' is used in all of the industry counterfeit electrical, electronic, and electromechanical parts standards, and is commonly used in the electronics industry and by DoD.

One respondent pointed out that the term ''authorized dealer'' has different meanings in DFARS 246.870–1 and 252.246–7008, and recommended that they be coordinated with each other.

Response: The term ''authorized dealer'' is not used in the electronics industry, nor is it used by DoD activities when referring to electronics sellers. In the final rule, DoD has replaced the term ''authorized dealer'' with the electronics industry's term ''authorized supplier.'' All of the commercial standards allow the use of ''authorized suppliers'' and define how they should be used.

d. Contract Electronics Manufacturer

Comment: One respondent recommended amending the definition of ''contract electronics manufacturer'' to be in line with industry use of the term. According to the respondent, industry understands a contract electronics manufacturer to be a company who builds boards or units for another company, whereas the fabrication of an electronic part ''under a contract with, or with express written authority of, the original manufacturer'' is the work of an authorized aftermarket manufacturer. According to the respondent, this definition aligns with the industry standards AS5553, AS6171, and AS6081.

The respondent therefore recommended the following definition: ''Contract electronics manufacturer'' means an organization that produces goods, using electronic parts, for other companies on a contract basis under the label or brand name of the other organization.

In addition, the respondent recommended that the concept of ''contract electronics manufacturer'' should be removed from the definition of ''original manufacturer.'' According to the respondent, the original manufacturer is regularly understood to be the original component manufacturer or the original equipment manufacturer.

Response: DoD has revised the definition of ''contract electronics

manufacturer'' consistent with the recommendation of the respondent and removed paragraph (2) from the proposed definition. The removed paragraph has been utilized as the basis for an added definition of ''authorized aftermarket manufacturer.'' This also resulted in a conforming change to the definition of ''obsolete electronic part.''

DoD also removed the term ''electronics'' from the defined term, because the other related terms of ''original manufacturer,'' original component manufacturer,'' and ''original equipment manufacturer'' are not limited to just electronic parts, even though this rule then applies those terms to the acquisition of electronic parts. Having removed the word ''electronics'' and the portion of the definition that applied to an authorized aftermarket manufacturer, DoD has retained the term ''contract manufacturer'' as part of the definition of ''original manufacturer.''

4. Supply Base Terminology

Comment: One respondent recommended that DoD define the supply base in the same way as the commercial defense industry and regulate sources of supply accordingly. According to the respondent, DoD defines the supply base in terms of (1) original equipment manufacturer primes; (2) manufacturers; and (3) dealers, distributors, or others; while the commercial defense industry uses the terms (1) original equipment manufacturer primes; (2) approved manufacturers; (3) authorized dealers/distributors; (4) dealers/brokers/others; and (5) surplus dealers. The respondent asserts that without using the commercial defense industry terms, DoD could procure certain products from potentially unauthorized sources.

Response: Since the scope of the case is limited to electronic parts, DoD has elected to define the supply base in terms commonly used by the electronics industry, rather than across the entire commercial defense industry, and has utilized the categories identified in the statute, although changing the term ''authorized dealer'' to ''authorized supplier'' to be consistent with the electronic industry usage.

5. Sources of Electronic Parts

a. Tiered Approach

The statute and this regulation provide for a tiered approach for sources of electronic parts.

- Category 1: Electronic parts that are in production or currently available in stock. The contractor shall obtain such parts from the original manufacturer, their authorized suppliers, or from suppliers that obtain such parts exclusively from the original manufacturers of the parts or their authorized dealers.
- Category 2: Electronic parts that are not in production and not currently available in stock. The contractor shall obtain such parts from suppliers identified by the contractor as contractor-approved suppliers, subject to certain conditions.
- Category 3: Electronic parts that are not in production and not available from any of the above sources; electronic parts from a subcontractor (other than the original manufacturer) that refuses to accept flowdown of DFARS 252.246–7008; or electronic parts that the contractor or subcontractor cannot confirm are new or that the electronic parts have not been comingled in supplier new production or stock with used, refurbished, reclaimed, or returned parts. The contractor may buy such electronic parts subject to certain conditions.

Comment: One respondent supported the requirement to obtain parts that are in production or currently available in stock from original manufacturers, authorized dealers, or suppliers that obtain such parts exclusively from the original manufacturers or authorized dealers.

Response: Noted.

Comment: One respondent recommended that contractors and subcontractors only be allowed to purchase from suppliers that obtain such parts exclusively from the original manufacturers of the parts or their authorized dealers only if not available from the original manufacturers or their authorized dealers. Another respondent stated that the most effective method for avoiding counterfeit electronic parts is to purchase these parts from the original manufacturer and their authorized distributors, and authorized aftermarket distributors and manufacturers (*i.e.,* ''legally authorized sources''). According to the respondent, purchasing from any other source significantly increases the likelihood of acquiring counterfeit parts.

Response: The statute unconditionally allows a contractor or subcontractor to purchase electronic parts from suppliers that obtain such parts exclusively from the original manufacturers of the parts or their authorized dealers.

Comment: One respondent suggested adding ''authorized aftermarket manufacturer'' to ''authorized dealer.''

Response: The concept of authorized aftermarket manufacturer was already included in the definition of ''authorized dealer'' (now ''authorized supplier'' in the final rule).

b. Not in Production and Not Currently Available in Stock

Comment: Several respondents requested that DoD clarify terms ''in stock'' and ''available in stock.'' One respondent noted that a part could be in production but not in stock, or not in production but available in stock. This respondent expressed concerns about the costly steps necessary to ensure compliance when a part is not acquired from a trusted supplier, so the initial analysis of the supply chain sources could be relevant to how a contractor acquires a specific part and have many assorted cost impacts. Another respondent had concerns with use of the phrase ''currently available in stock'' as it raises questions about parts that are in production but have lead times. ''Unless there is a demonstrated, immediate need for a part in production with a lead time, contractors should not have the option to seek the part from a source with a higher level of counterfeit risk.'' That respondent also had concerns with the use of the phrase ''parts that are not in production'' raising issues about obsolete parts that are not in production by the original manufacturer but may be produced on demand in a timely manner by authorized aftermarket manufacturers.

One respondent recommended that DoD must require contractors to do a more exhaustive search of the authorized supply channel before utilizing other sources. This respondent also recommended that the rule should clarify that ''not currently available in stock'' means ''not currently available in stock from original manufacturer, authorized aftermarket manufacturers, or authorized dealers.''

One respondent thought of numerous possibilities of the meaning of ''unavailable'':

- Parts might be unavailable when they exceed a certain multiple of standard pricing.
- Parts might be unavailable if they cannot be received within an acceptable lead time.
- Parts might be unavailable and out of production if the original manufacturer and no other foundry make the part.
- Parts might be unavailable and out of production because the original component manufacturer is no longer producing an electronic part yet has the ability to restart production given appropriate lead time.
- Parts that seem unavailable because they are not in production could

conceivably be available from a trusted foundry.

This respondent was concerned that parts also might change in availability and asked whether a contractor would be required to switch between sources of supply if a product later becomes available from the original manufacturer or an authorized dealer. This respondent recommended removing the triggering mechanism that use of an ''other'' trusted source requires that the parts be not in production or not currently available.

Response: The statute requires that if parts are in production or currently available in stock, the contractor or subcontractor must use a Category 1 supplier. The electronic parts may be in production and currently available in stock, in production and not currently available in stock, or not in production but currently available in stock. Therefore, even if there is a demonstrated, immediate need for a part in production with a lead time, contractors do not have the option to seek the part from other than a Category 1 source. Some of the listed technicalities with regard to potential meanings of ''unavailable'' are irrelevant, because if the part is in production, it must be bought from a Category 1 supplier, whether or not it is currently available or unavailable in stock.

DoD has modified the final rule to clarify that ''in production'' includes by the original manufacturer or by an authorized aftermarket manufacturer, and that ''currently available in stock'' means from one of the Category 1 sources.

In addition, DoD changed ''or'' to ''and'' in DFARS 246.870–2(a)(1)(ii) and at 252.246–7008(b)(2) because ''or'' includes circumstances that overlap with paragraphs (a)(1)(i) and (b)(1), respectively, and does not accurately reflect the statutory requirement to specify the sources in circumstances not covered in those paragraphs. The only remaining circumstance to be covered in paragraph (a)(1)(ii) and (b)(2) is ''not in production'' and ''not currently available in stock.''

A contractor must make a good faith effort to determine whether an electronic part is available from Category 1 sources (DFARS 246.870–2(a)(1)(i)). Any changes to a contractor's use of approved sources would require additional review by DoD. Due to the added costs that may be involved in obtaining a part from a contractor-approved supplier, a contractor is incentivized to locate a Category 1 source.

This DFARS rule does not address obsolescence management and diminishing manufacturing sources as these areas are outside the scope of this case. DFARS Case 2016–D022 will implement section 803 of the NDAA for FY 2014 to address these issues. This rule takes a risk-based approach to counterfeit prevention. The rule allows contractors to make risk-based decisions (such as testing and inspection) based on supply chain assurance measures (such as the source of the electronic part), which is all subject to review and audit by the contracting officer. DoD uses the Department of Defense Risk, Issue, and Opportunity Management Guide for Defense Acquisition Programs.

6. Contractor Identification of Contractor-Approved Suppliers

a. Selection and Use of Standards

Several respondents expressed concerns specific to the selection and use of DoD-adopted industry standards and requested that the agency identify application of standards by industry.

Comment: One respondent commented that by acknowledging that contractors can identify other suppliers as ''trusted'' if they first qualify the supplier using industry standards and processes for counterfeit prevention, the proposed rule allows for electronic parts, particularly parts for mature platforms near the end of their lifecycles, to be procured after the original manufacturers and immediate authorized dealers and distributors have ceased to manufacture and supply the parts.

Response: Noted.

Comment: One respondent questioned the meaning of ''DoD-adopted'' standards, and recommended that industry standards be the default test for the conformance of contractor-vetted trusted suppliers vice DoD-adopted standards. This respondent also mentioned an inconsistency between the requirements with regard to standards in the definition of ''trusted supplier'' and the DFARS clause at 252.246–7008(b)(2). Another respondent requested clarification as to where DoD-adopted standards are to be used versus other industry standards.

Response: A Web site was provided in the proposed rule in the definition of ''trusted supplier'' that specified DoD-adopted counterfeit prevention industry standards and processes. The following industry standards are currently DoD-adopted and could be used to satisfy contractual requirements: ISO 9001, AS9100, AS5553A, AS6462, AS6081, AS6174A, etc. The definition of ''trusted supplier'' has been deleted from the final rule. DFARS 246.870–2(a)(1)(ii)(A) and 252.246–7008(b)(2)(i) have been amended to add ''such as the DoD-adopted standards at *https://assist.dla.mil,''* but does not specifically require the use of DoD-adopted standards.

Comment: One respondent suggested changing FAR 46.203, Criteria for Use of Contract Quality Requirements, to require certification to industry standards vice compliance with industry standards.

Response: Changing the FAR is outside the scope of this case.

b. Redundant Validation

Comment: Several respondents recommended that the proposed rule be revised to eliminate redundant validation of suppliers. The respondents assert that the rule as written would require contractors to validate U.S. Government sources such as the Defense Logistics Agency and the Federal Supply Schedule as trusted suppliers. Several respondents recommend specifying that these sources be considered trusted suppliers. Another respondent recommended presuming suppliers to be ''trusted'' if the prime and subcontractors have approved processes in place to identify suppliers and provide proof that those processes have been followed. Alternately, this respondent suggested that the Government could work with industry to develop a third party accreditation program to verify that suppliers at all tiers are in compliance with established counterfeit detection and avoidance requirements and identify a pool of accredited suppliers.

Response: Contractors or subcontractors who purchase directly from another vendor (such as the Federal Supply Schedule or from suppliers accredited by the Defense Microelectronics Activity), or requisition electronic parts from the Government inventory/stock under the authority of DFARS 252.251–7000, Ordering from Government Supply Sources, are still required to comply with the requirements of DFARS 252.246–7008(b) and (c). However, the final rule has been revised at DFARS 246.870–2(a)(3)(iii)(B) and 252.246–7008(d)(3)(ii) to state that if the contractor or contractor requisitions electronic parts from the Government, the Government will be responsible for the authenticity of the parts. If any such part is subsequently found to be counterfeit or suspect counterfeit, the Government will promptly replace such part at no charge and will consider an adjustment in the contract schedule to

the extent that replacement of the counterfeit or suspect counterfeit electronic parts caused a delay in performance.

A third party accreditation program is outside the scope of this rule, which is implementing the statutory requirement to allow contractors and subcontractors to identify trusted suppliers (now termed ''contractor-approved suppliers.''

c. Review and Audit by Government

Comment: Several respondents addressed the requirement that the contractor's identification of trusted suppliers for parts not in production or not currently in stock is subject to review and audit by DoD.

One respondent commented that section 818 of the NDAA for FY 2012 only required that selection of ''trusted suppliers'' (as opposed to non-trusted suppliers) be subject to Government review and audit. One respondent questioned why contractor identified suppliers that also conform to industry standards (DoD-adopted or otherwise) are subject to review and audit by DoD officials. The respondent recommends that no additional review or audit be implemented where system oversight is compliant with DFARS part 246.

One respondent was concerned that, absent a clear standard, the due diligence required to establish a trusted supplier will vary depending on the judgment of the DoD official conducting the review and audit. This respondent recommended that the Government should establish a presumption that suppliers are trusted if the prime contractor and subcontractors have approved processes in place to identify suppliers and provide proof that those processes have been followed.

Response: Section 818 of the NDAA for FY 2012 (Pub. L. 112–81) requires, in paragraph (c)(3)(D)(iii), that the selection of additional trusted suppliers by DoD contractors is subject to review and audit by DoD officials.

Furthermore, section 885 of the NDAA for FY 2016 amends paragraph (c)(3)(D)(iii) of section 818 to require review, audit, and approval by DoD officials. This amendment will be addressed under DFARS Case 2016–D013, Amendments Related to Sources of Electronic Parts.

d. DoD Establishment of Qualification Requirements

A number of respondents commented on the need for DoD to establish qualification requirements and expressed concern about the status of DFARS Case 2015–D020, DoD Use of Trusted Suppliers for Electronic Parts.

Comment: One respondent said that the proposed rule appeared to shift the determination and risk of which suppliers to trust entirely to the contractor community, which the respondent believed is contrary to Congressional intent. The respondent asserted that the intent was for DoD and contractors to share the risk. The respondent further stated that the proposed rule does not provide detailed guidance to contractors on the factors to consider in identifying trusted suppliers.

One respondent expressed concern that there is a potential loophole for a contractor to procure electronic parts from a high-risk supplier without Government notification. A contractor might locate an obsolete, high-risk part from a poor supplier, and quickly qualify that supplier as trusted, thereby avoiding the notification requirement.

Another respondent mentioned that there is no current means to qualify a non-authorized electronic part as an original component manufacturer authorized part and purchases of electronic parts from nonauthorized sources threaten the safety and integrity of the DoD supply chain. The respondent recommended that DoD propose regulations that include DoD's use and qualification requirements for trusted suppliers, to ensure consistency with the proposed rule and the final rule in DFARS Case 2012–D055. The respondent stated that DoD should issue the rule to establish qualifications for DFARS Case 2015–D020 simultaneously with this proposed rule to avoid confusion and ensure consistency of implementation. According to the respondent, DoD has not exercised its statutory authority to identify additional trusted suppliers for contracts and subcontracts to use. The respondent encouraged DoD to clarify that the qualification requirements to be established in DFARS Case 2015–D020 may be used by contractors when implementing their trusted-supplier program as required by the proposed clause DFARS 252.246–7008, Sources of Electronic Parts.

According to one respondent DoD continues to delay regulations for use and qualification requirements of trusted suppliers. One respondent recommended that DoD accelerate resolution of DFARS Case 2015–D020 because the proposed rule requires contractors to guarantee authenticity of electronic parts acquired from the Federal Supply Schedule. Another respondent recommended that DFARS Case 2015–D020 should be aggressively developed.

Another respondent recommended delaying the proposed rule until DFARS 2015–D020 has been released so they can understand how DoD will define criteria for Trusted and Non-Trusted Suppliers.

Response: This rule implements section 818 of the NDAA for FY 2012, as amended, which provides in paragraph (c)(3)(D) that regulations to be issued by DoD shall authorize DoD contractors to identify and use ''additional trusted suppliers'' subject to certain conditions (DFARS 246.870–2(a)(1)(ii) and 252.246–7008(b)(2)). The contractor must use established counterfeit prevention industry standards, including testing, and must assume responsibility for the authenticity of the parts provided by such contractor-approved suppliers. Furthermore, DoD has the right to ''review and audit'' the contractor selection of ''contractor-approved suppliers.'' In this final rule, DoD has added this review and audit of contractor identification of contractor-approved suppliers at DFARS 242.302(S–76) as a contract administration function that is delegable to the administrative contracting officer.

This authority to identify contractor-approved suppliers is independent of section 818(c)(3)(D), which is the subject of DFARS Case 2015–D020. It would not be in the best interest of industry to delay this rule until publication of a final rule under DFARS Case 2015–D020, which has not yet been published as a proposed rule, because the ''safe harbor'' provisions of section 885(a) of the NDAA for FY 2016 are dependent upon publication of this final rule (see section II.B.9. of this preamble).

7. Traceability

Many respondents commented on the requirements for traceability from the original manufacturer to product acceptance by the Government.

Comment: Several respondents were concerned that traceability will be difficult to establish for parts used in defense systems. According to the respondents, it is likely that very large numbers of electronic parts cannot be traced back to the original manufacturer or authorized dealer.

Response: The rule expects that traceability is not always possible and provides that the contractor is responsible for inspection, testing, and authentication, in accordance with existing industry standards, if the contractor cannot establish traceability from the original manufacturer for a specific part.

Comment: Several respondents question the benefit of maintaining end-to-end traceability compared to the cost. One respondent opposes serialized end-to-end traceability throughout the supply chain because the costs of such traceability are prohibitively high as compared to the incremental benefit in increased quality assurance. According to one respondent, there will be increased costs associated with implementation and recordkeeping, which could be significant for smaller businesses. One respondent noted that traceability does not necessarily prove that an electronic component is genuine or that the component has been properly packaged, stored or handled in accordance with the original component manufacturer's specifications and that traceability documents and technologies are subject to counterfeiting.

Response: DoD has accounted for the recordkeeping requirements related to traceability in the regulatory flexibility analysis and the Office of Management and Budget clearance of the information collection requirement. While DoD acknowledges the burden associated with this requirement and that establishing such traceability does not guarantee the authenticity of all parts, nevertheless DoD considers the costs associated with this burden to be justified in comparison to the harm that can result from introduction of counterfeit parts into the DoD supply chain.

Comment: One respondent stated that the requirements of the proposed rule do not appear to be based upon risk. One respondent, however, agreed with the proposed rule allowing for risk-based processes including testing and inspections when buying parts from other than an original equipment manufacturer or original component manufacturer, their authorized dealers, or suppliers that purchase parts exclusively from the original equipment manufacturers, original component manufacturer, or their authorized dealers.

Another respondent stated that the proposed rule adopts an approach recommended by industry subject matter experts. Where traceability to the original manufacturer cannot be established, the contractor or subcontractor must complete an evaluation that includes use of alternative parts, and apply its risk-based systems, including tests and inspections commensurate with risk.

Response: First, the requirement in DFARS 252.246–7007, Contractor Counterfeit Electronic Part Detection and Avoidance System, states in paragraph (c)(4) that the system shall address risk-based processes that enable tracking of electronic parts from the original manufacturer to product acceptance by the Government. Then in paragraph (c) of DFARS 252.246–7008, it again states that the contractor shall have risk-based processes (taking into consideration the consequences of failure of an electronic part) that enable tracking from the original manufacturer. The level of inspection, testing, and authentication that the contractor would perform if unable to track an electronic part from the original manufacturer would also be commensurate with the criticality of the part. The final rule removes the requirement for contractor consideration of alternative parts. That should be a Government decision.

Comment: Several other respondents stated that industry does not ordinarily maintain this kind of serialized end-to-end traceability for electronic parts and recommended that the rule should conform to industry standards (such as SAE AS5533) for maintaining traceability of electronic parts.

One respondent stated that many legacy systems now require electronic parts not available from trusted suppliers as defined here, and pursuant to the requirement of section 803 of the NDAA for FY 2014 to issue guidance on sourcing for obsolete parts, the Department should provide instructions on how to make such determinations of risk and what criteria should reasonably support the contractor's determination. Another respondent requests more explanation as to the required ''determination of risk'' assessments that contractors, and their supply chains, will need to undertake.

Another respondent was appreciative that this rule allows the industry to enable the traceability without proscribing the method, so that the industry is able to use processes that maintain the traceability without the added expense and bureaucracy of specific documents and systems.

Response: DoD is willing to bear the expense associated with maintaining traceability to the extent feasible in order to improve detection and avoidance of counterfeit parts in the DoD supply chain. The final rule provides a course of action for the contractor if traceability cannot be established, *i.e.,* the contractor is responsible for inspection, testing, and authentication in accordance with existing applicable industry standards.

Regulations to implement section 803 of the NDAA for FY 2014 are still pending (DFARS Case 2016–D022).

Comment: One respondent asked whether traceability will be a contract deliverable to the Government.

Response: In the final rule, the clause requires that the contractor and subcontractors maintain documentation regarding traceability and make such documentation available to the Government upon request.

8. Purchases From Other Suppliers

a. Notification

Several respondents provided comments on the notification requirement of the proposed rule, which required the contractor to notify the contracting officer when buying from a Category 3 source (see DFARS 252.246–7008(b)(3)).

Comment: Several respondents questioned what is meant by ''not possible to obtain an electronic part from a trusted supplier.'' According to one respondent, it was unclear on whether the term ''not possible'' intends to preclude contractors and subcontractors from taking price and schedule impact into account in evaluating the relative risks of purchasing a particular part from a trusted supplier versus an other than trusted supplier.

Response: DoD has clarified the wording of DFARS 252.246–7008(b)(3)(i)(A), replacing ''not possible to obtain'' with ''due to nonavailability,'' for increased consistency with the statute and DFARS 246.870–2(a)(2)(i).

Comment: One respondent questioned how, when, or to whom subcontractors are supposed to provide the required notification.

Response: Since the clause flows down to all tiers, subcontractors will provide the required notification up the chain to the prime contractor.

Comment: One respondent commented that the notification requirements would present a significant challenge in cases where a subcontractor would not accept counterfeit avoidance and detection requirements included in DFARS clause 252.246–7007, Contractor Counterfeit Electronic Part Detection and Avoidance System, particularly when dealing with COTS electronic assembly providers.

Response: DoD has revised the rule to address the issues raised regarding flowdown clause acceptance of DFARS 252.246–7008, Sources of Electronic Parts, by the subcontractors (see section II.B.2.c. of this preamble), which should sufficiently resolve the concerns of the respondent.

Comment: Several respondents requested clarification on what is required to be provided in the notice to the contracting officer, when such notice is to be issued, and where in the

chain of custody the notice is to originate.

Response: The final rule has been amended at DFARS 252.246–7008(b)(3)(ii)(A) to require prompt notification to the contracting officer in writing. There is no requirement for content of the notice beyond the common sense facts necessary to convey the circumstances to the contracting officer—what part is being bought, from whom, and why. The notice originates with whatever entity (prime contractor or subcontractor) is making the purchase, and is passed up to the contracting officer through the intervening subcontract tiers and the prime contractor. Documentation of inspection, testing, and authentication of such electronic parts is only required to be furnished to the Government upon request.

Comment: One respondent referenced the outstanding ''Expanded Reporting'' FAR case that proposed addressing counterfeit electronic part reporting through the GIDEP mechanism but that case has been held in abeyance for reasons unknown to industry. The respondent requested that DOD ensure that any notice requirements in the new clause are distinguished from other requirements to report counterfeits to the GIDEP portal after discovery.

Response: DoD has noted the comments regarding the FAR Case 2013–002, Expanded Reporting Requirements. The notice in this case will not conflict with GIDEP reporting, because this notice is not a notice of a nonconforming part, but notice of contracting with a potentially higher-risk supplier.

b. Is DoD approval required?

Comments: One respondent commented that the proposed notification requirement does not address whether the contractor or subcontractor is free to purchase the part from an other-than-trusted supplier once the required notification has been given to the contracting officer or whether they cannot proceed with the purchase until it has received some form of approval from the contracting officer. Confirmation of the intent was requested to be included in the rule.

Response: The rule does not require approval for use of Category 3 sources.

9. Safe Harbor

Comment: Several respondents requested a safe harbor under various circumstances:

One respondent recommended that the DFARS be amended to reflect the ''safe harbor'' of buying from ''legally authorized sources'' (*i.e.,* original manufacturer and their authorized distributors, and authorized aftermarket distributors and manufacturers) and that the processes/procedures for detecting and avoiding counterfeit electronic parts only be used for acquisitions from unauthorized sources (*i.e.,* sources other than ''legally authorized sources'').

One respondent requested that the Defense Acquisition Regulation Council should address whether, and the extent to which, an agency's approval following a required notification would act as a safe harbor for any counterfeit problems that were subsequently encountered with the parts that had been approved.

One respondent recommended that, because traceability is considered an element of the contractor process of acquiring parts where the prime is not a trusted supplier and also part of the detection and avoidance system requirements, DoD provide a safe harbor from liability or contract breach if the contractor acquires an electronic part to support a legacy system and has performed a good faith risk determination in lieu of end-to-end traceability, but the part is determined to be counterfeit at some point in the future after delivery to DoD.

This respondent also noted that section 885(a) of the NDAA for FY 2016 provides a ''conditional safe harbor from strict liability from damage caused by counterfeit electronic parts provided the contractor has a detection and avoidance system, provides timely notice of a counterfeit in the supply chain to DoD, and acquires the parts from a trusted supplier.'' This respondent also requested that DoD ensure that any rules be conformed with all legislative changes made to the law since enactment of the NDAA for FY 2012 and that allow for an understandable and cost efficient implementation.

Response: The language of section 818 of the NDAA for FY 2012, as revised by section 885(a) of the NDAA for FY 2016, exclusively addresses allowable costs for counterfeit parts or suspect counterfeit parts and the cost of rework or corrective action that may be required to remedy the use or inclusion of such parts, and does not provide a safe harbor from liability or harm or damage that may result from the undetected use or inclusion of counterfeit parts. Section 885(a) is being implemented under DFARS Case 2016–D009.

Contractor developed risk-based processes utilizing industry standards or their internal processes/controls, are the responsibility of the contractors' discretion. Any failure of the contractor counterfeit electronic part detection and avoidance system will require remedial action.

DoD does not currently approve the acquisition of parts from any particular source.

10. Cost Allowability

Comment: One respondent asked for clarification that the costs associated with any new supply chain security measures are allowable. According to the respondent, the rule is silent as to who will bear the added costs of implementing serialized traceability or of the non-recurring engineering associated with utilizing alternate parts or of the testing necessary to establish authenticity. Any new costs associated with the final rule should be clearly stated as allowable.

Response: The implementation costs associated with compliance with DFARS 252.246–7008 are not unlike any other costs anticipated to be incurred by the contractor or subcontractor to perform the requirements of a contract. Whether a cost is allowable and allocable is generally governed by FAR part 31. Unless a cost is explicitly unallowable, whether a cost is allowable depends on factors such as reasonableness, allocability, CAS standards (and approved disclosure statements), if applicable, otherwise, generally accepted accounting principles and practices appropriate to the particular circumstances, and the terms of the contract. It is unnecessary to address the allowability of costs incurred under every contract requirement. In accordance with FAR 31.201–4, a cost is allocable if it is assignable or chargeable to one or more cost objectives on the basis of relative benefits received or other equitable relationship. Subject to these conditions a cost is allocable to a Government contract if it is (a) incurred specifically for the contract; (b) benefits both the contract and other work, and can be distributed to them in reasonable proportion to the benefits received; or (c) is necessary to the overall operation of the business, although a direct relationship to any particular cost objective cannot be shown.

11. Regulatory Flexibility Analysis

See the comments and responses relating to impact on small business in the summary of the Final Regulatory Flexibility Analysis in section V of this preamble.

12. Information Collection Requirement

Several respondents commented on the information collection requirement.

Comment: One respondent expressed detailed concerns about the necessity

and practical utility of the proposed rule. The respondent was concerned about significantly expanding contractors' tracking, collection, and reporting obligations. Subcontractors may not have such information readily available and may be reluctant to share this information up the supply chain. The respondent also had serious concerns about security and protection of the information. The respondent encouraged DoD to consider whether it is necessary to collect all this data at all tiers and to pass the data up through the supply chain to the Government, before any reportable instance of counterfeit or suspect counterfeit electronic parts.

The respondent also believed that DoD may already have access to a lot of this data, because DoD has access to databases of thousands of suppliers that provide parts to its acquisition system. The respondent considered that the handful of additional suppliers that may be identified will not provide much return on investment.

Response: The only definite reporting requirement in the rule is to provide notification to the Government if using a Category 3 supplier. This notification is a statutory requirement. Documentation on traceability or inspection, testing, and validation need only be provided to the Government upon request. This approach is considered necessary by subject matter experts within DoD to implement the statutory requirement and to detect and avoid counterfeit parts within the supply chain.

Comment: One respondent did not believe that the Government estimated collection time and costs capture all that contractors must do to comply.

- Hours per response (1 hour per response): Appears to assume that all information is already in a database or otherwise easily accessible and that a single person at a single facility will be able to generate such a report.
- Frequency of report (1 per year): The proposed rule requires that contractors must notify the contracting officer when they cannot obtain covered parts from a trusted supplier in each instance, or at least on a lot basis. This requirement is event-driven, potentially arising on multiple occasions during any given year.
- Number of respondents (1,000): In view of the statement in the **Federal Register** that the rule will cover 33,000 small entities in addition to the large CAS-covered businesses, the respondent considers the estimate of 1,000 respondents too low.

Another respondent suggested that the information collection portion of the proposed rule be re-estimated to reflect the suggested flowdown requirements to create a more accurate assessment of the true costs of the rule.

Response: The estimated information collection burden in the proposed rule related only to the required notification when using other than a ''trusted supplier.'' This should be quite rare, since it only occurs when an item is out of production, not currently available in stock, and not available from a contractor-approved supplier. However, the estimates have been adjusted to acknowledge that in many cases information for such notification may have to be provided by a lower tier subcontractor to the prime contractor.

In addition, the final rule makes explicit the requirement to maintain documentation with regard to traceability or inspection, testing and authentication and make the documentation available upon request. This is not an added burden for contractors and subcontractors, but an acknowledgement of a burden that was implicit in the proposed rule. These requirements have been calculated for subcontractors, as well as prime contractors. The final information collection requirement estimates are summarized as follows:

Requirement	Respondents	Responses	Total reporting hours	Annual reporting burden ($)
252.246–7008 (c)(3)(ii)	5,049	50,490	41,310	1,900,260
252.246–7008 (b)(3)(ii)	1,575	2,550	2,550	117,300
Total Reporting Burden	6,624	53,040	43,860	$2,017,560

Recordkeeping	Recordkeepers	Recordkeeping hours	Annual record-keeping burden
252.246–7008	78,773	2,363,190	$75,622,080

Comment: The respondent urged reconsideration not only of the estimate of the burdens, but consideration of how the rule might be revised so as to reduce the burdens on industry and the Government.

Response: DoD has not been able to identify a viable alternative that would meet the objectives of the rule and comply with the statutory requirements. The notification requirement is statutory. The data on traceability or inspection, testing, and validation need only be provided to the Government upon request.

Comment: One respondent asked for the elimination of the requirement for information collection concerning detection and avoidance of counterfeit electronic parts for products regulated by the FDA.

Response: See response in section II.B.2.f. of this preamble.

C. Other Changes

1. Revised the definition of ''original component manufacturer'' to replace ''is pursuing, or has obtained the intellectual property rights'' with ''is entitled to any intellectual property rights.'' There may not be any intellectual property rights associated with an item or the manufacturer may have the rights on the basis of a trade secret without having filed for a patent.

2. Moved DFARS 246.870–2(a)(1)(iii) to paragraph (a)(3), so that it is also applicable to (a)(2) of that section.

3. Corrected the reference at DFARS 246.870–2(a)(2) from ''paragraph (c)'' to ''paragraph (b)(3)(ii) through (b)(3)(iv)'' of the clause at 252.246–7008.

4. Amended DFARS 246.870–2(b)(2)(v) to reference 246.870–2(a), rather than replicate the suppliers to be used under certain conditions. This is consistent with DFARS 252.246–7007(c)(5), as amended in this final rule.

5. Amended DFARS 252.246–7007(b) to add notification to the contractor that an additional consequence of an unacceptable counterfeit electronic part detection and avoidance system may be a negative impact on the allowability of costs of counterfeit electronic parts or suspect counterfeit electronic parts and the cost of rework or corrective action

that may be required to remedy the use or inclusion of such parts, with a cross-reference to the cost principle at DFARS 231.205–71, while deleting the cross-reference to the cost principle at 252.246–7008(b)(2)(ii). The cost principle addresses CAS-covered contractors, which makes a cross-reference to that principle more appropriate in 252.246–7007, which applies only to CAS-covered contractors.

Also amended paragraph (c)(4) to change ''Processes'' to ''Risk-based processes,'' for consistency with DFARS 252.246–7008(c)(1) and referenced the clause at 252.246–7008(c) for details on the notification requirement (comparable to the cross-reference in the 252.246–7007(5)).

6. Moved paragraph (d) of DFARS 252.246–7008 to paragraph (b)(3) of the clause, restructured, and clarified the wording for increased consistency with the statute and DFARS 246.870–2(a)(2).

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Items, Including COTS Items

This rule applies the requirements of section 818(c)(3) of the NDAA for FY 2012, as amended, to contracts at or below the SAT, and to contracts for the acquisition of commercial items, including COTS items.

A. Applicability to Contracts at or Below the Simplified Acquisition Threshold

41 U.S.C. 1905 governs the applicability of laws to contracts or subcontracts in amounts not greater than the simplified acquisition threshold. It is intended to limit the applicability of laws to such contracts or subcontracts. 41 U.S.C. 1905 provides that if a provision of law contains criminal or civil penalties, or if the FAR Council makes a written determination that it is not in the best interest of the Federal Government to exempt contracts or subcontracts at or below the SAT, the law will apply to them. The Director, Defense Procurement and Acquisition Policy (DPAP), is the appropriate authority to make comparable determinations for regulations to be published in the DFARS, which is part of the FAR system of regulations.

B. Applicability to Contracts for the Acquisition of Commercial Items, Including COTS Items

41 U.S.C. 1906 governs the applicability of laws to contracts for the acquisition of commercial items, and is intended to limit the applicability of laws to contracts for the acquisition of commercial items. 41 U.S.C. 1906 provides that if a provision of law contains criminal or civil penalties, or if the FAR Council makes a written determination that it is not in the best interest of the Federal Government to exempt commercial item contracts, the provision of law will apply to contracts for the acquisition of commercial items. Likewise, 41 U.S.C. 1907 governs the applicability of laws to COTS items, with the Administrator for the Office of Federal Procurement Policy the decision authority to determine that it is in the best interest of the Government to apply a provision of law to acquisitions of COTS items in the FAR. The Director, DPAP, is the appropriate authority to make comparable determinations for regulations to be published in the DFARS, which is part of the FAR system of regulations.

C. Determination

The Director, DPAP, has determined that it is in the best interest of the Government to apply the requirements of section 818(c)(3) of the NDAA for FY 2012, as amended, to contracts at or below the SAT and to contracts for the acquisition of commercial items, including COTS items. Counterfeit electronic parts, regardless of dollar value, can seriously disrupt the DoD supply chain, harm weapon system integrity, and endanger troops' lives. Even low dollar value electronic parts can cause critical failure of fielded systems, such as aircraft, ships, and other weapon systems. Furthermore, studies have shown that a large proportion of proven counterfeit electronic parts were initially purchased as commercial items, including COTS items. Therefore, exempting contracts and subcontracts below the SAT or for acquisition of commercial (including COTS) items from application of the statute would severely decrease the intended effect of the statute and increase the risk of receiving counterfeit parts, which may present a significant mission, security, or safety hazard.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Regulatory Flexibility Act

A final regulatory flexibility analysis (FRFA) has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq*. The FRFA is summarized as follows:

This final rule further implements section 817 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2014 (Pub. L. 112–81), which amended section 818 of the NDAA for FY 2012. The objective of this rule is to avoid acquisition of counterfeit electronic parts by requiring DoD contractors and subcontractors, except in limited circumstances, to buy electronic parts from the original manufacturers, their authorized supplier, or suppliers that obtain such parts exclusively from the original manufacturer of the parts or their authorized suppliers, in accordance with section 818(c)(3) of the National Defense Authorization Act for FY 2012.

A. Applicability to Small Business Entities

Comment: Several respondents recommended that DoD should not apply this rule to small entities, citing the burdens imposed. However, other respondents were very supportive of DoD for establishing requirements on contracts at all tiers and applying to small entities, because counterfeit parts purchased within the supply chain from small entities comprise a large portion of the counterfeit parts that directly threaten the DoD supply chain.

Response: The law does not exempt small businesses from the statutory requirements. (See response to in section II.B.2.a. of this preamble.)

B. Burden Imposed

Comment: Several respondents, including the Office of Advocacy of the Small Business Administration, noted that the increased costs associated with implementation and recordkeeping could be significant for small businesses. Another respondent suggested that DoD weigh the cost and benefits of information collected from contractors when implementing these rules. Most small and some mid-sized companies would not have the resources, experience, and infrastructure necessary to keep up a database of information related to this rule.

Response: The Government recognizes that the cost of compliance to

the DFARS requirement for obtaining electronic parts from trusted sources may deter some small businesses and even suppliers of commercial items and COTS (where the Government is not a major portion of sales). However, the receipt of counterfeit parts represents an unacceptable risk to the Government. The clause requires small businesses and commercial item suppliers to put in place risk-based processes that take into consideration the consequences of failure.

Comment: The Office of Advocacy stated that the cost of compliance will serve to deter small businesses from participating as prime and subcontractors in the Federal Acquisition process. More specifically, the Office of Advocacy, found it unclear, for parts that are in production, who will absorb the higher costs of restrictions on sources of electronic parts. The Office of Advocacy stated that this was of concern to small businesses. For parts that are not in production, the Office of Advocacy found it unclear how the small business owner is to provide documentation to the prime contractor or the contracting officer whether the part is in production or not. The Office of Advocacy also cites lack of guidance on cost or process or acceptable procedures for the small business to follow.

Response: The Government recognizes that the cost of compliance to the DFARS requirement for obtaining electronic parts from trusted sources may deter some small businesses and even suppliers of commercial items and COTS (where the Government is not a major portion of sales). However, the receipt of counterfeit parts represents an unacceptable risk to the Government. With regard to cost allowability, the implementation costs associated with compliance with DFARS 252.246–7008 are not unlike any other costs anticipated to be incurred by the contractor or subcontractor to perform the requirements of a contract (see section II.B.10. of this preamble). With regard to the costs of counterfeit electronic parts and suspect counterfeit electronic parts, and the cost of rework or corrective action that may be required to remedy the use or inclusion of such parts, section 818(c)(2)(B), as amended by the section 885 of the NDAA for FY 2016, will make such costs allowable if the contractor obtains such parts in accordance with the regulations to be published under this case; discovers the counterfeit parts or suspect counterfeit parts; and provides timely notice to the Government (see DFARS Case 2016–D010).

With regard to parts that are not in production, the final rule has added clarification about necessary recordkeeping and documentation that shall be provided upon request (by the next high tier for a subcontractor or by the Government for the prime contractor). There is no requirement to provide documentation of whether the part is in productions. If the part can be obtained from a contractor-approved supplier and the contractor can establish traceability to the original manufacturer, then there is only need to provide documentation of the traceability upon request. If traceability cannot be established, then the contractor is required to maintain documentation of the required inspection, testing, and authentication, and make such documentation available upon request (see DFARS 252.246–7008(b)(3)(ii) and (c)(3)).

The responsibility of the contractor in paragraph (c)(2), if the contractor cannot establish traceability, has been simplified to be comparable to the requirement in paragraph (b)(3)(ii) (if the contractor buys for a source other than what the statute terms a ''trusted supplier''), *i.e.,* the contractor is responsible for inspection, testing, and authentication in accordance with existing applicable industry standards.

C. Estimates of Burden

Comment: The Office of Advocacy recommended that DoD should provide more clarity in the Initial Regulatory Flexibility Analysis (IRFA) as to the actual numbers of small businesses affected by the rule and the cost of compliance for small entities as prime and as subcontractors. The Office of Advocacy questioned whether COTS small businesses were included in the estimates.

The Office of Advocacy further stated that DoD should have more accurate data on subcontractors, citing the DoD Comprehensive Subcontracting Test Program.

Response: DoD has revised the estimated number of small business entities affected by the rule from 33,000 to 52,168. The supporting statement for the information collection requirement in the proposed rule only addressed the burden associated with the notification if the contractor is using a source other than a ''trusted supplier.'' The final rule makes explicit the requirement to maintain documentation with regard to traceability or inspection, testing, and authentication and make it available upon request (see section II.B.12. of this preamble). This is not an added burden for contractors and subcontractors but an acknowledgement of a burden that was implicit in the proposed rule.

DoD does not have access to subcontract the subcontract data necessary to provide an accurate assessment of the impact of this rule. There are only about ten entities enrolled in the DoD Comprehensive Subcontracting Data Test Program. DoD also considered the data in the Electronic Subcontracting Reporting System. This system accumulates data by prime contractor to assess whether the prime contractor is meeting its subcontracting goals—it does not provide data on whether the subcontracts being reported contain electronic parts.

D. Alternatives

Comment: According to the Office of Advocacy, DoD has not explored workable alternatives that will allow the Government to achieve its objectives. The Office of Advocacy suggested several alternatives for consideration:

- Support an Insurance Pool for small businesses, due to lack of clarity as to what constitutes a counterfeit part and who has ultimate liability.
- Use DoD testing resources to assist small firms in validating the authenticity of electronic parts or provide through the Mentor-Protege program a structure that would validate and test electronic parts for small subcontractors.
- Phase in compliance for COTS companies and small business subcontractors at certain dollar thresholds.

Response: Supporting an insurance pool for small businesses is outside the scope of this rule.

DoD does not have sufficient resources to take on the responsibility for validating the authenticity of electronic parts for small businesses. Furthermore, this would shift responsibility for compliance away from the prime contractor. 10 U.S.C. 2302 Note, which governs the DoD Mentor-Protege Pilot Program, addresses forms of assistance in paragraph (f) that a mentor firm may provide. This includes ''assistance, by using mentor firm personnel in engineering and technical matters such as production, inventory control, and quality assurance.'' It appears that this could cover a request by a small protégé firm for assistance by the mentor in compliance with this clause.

The detection and avoidance of counterfeit parts is too important to delay implementation. A low dollar value undetected counterfeit part from a small business or a COTS item can have equally disastrous consequences as

higher dollar value part that is not a COTS item or provided by a small business. Not only is this a requirement of the law, but the criticality of levying this requirements on all vendors is to meet operational mission requirements and prevent loss of life. However, the final rule has been revised to provide a procedure for notification, inspection, testing, and authentication of an electronic part if a subcontractor refuses to accept flowdown of the clause at DFARS 252.246–7008.

Based on Federal Procurement Data System data for FY 2015, DoD estimates that this rule will apply to approximately 52,168 small entities that have DoD prime contracts or subcontracts for electronic parts, including end items, components, parts, or assemblies containing electronic parts; or services, if the contractor will supply electronic parts or components, parts, or assemblies containing electronic parts as part of the service.

In addition to the requirements to acquire electronic components from trusted suppliers (in the rule: Original manufacturers, authorized suppliers, suppliers that obtain parts exclusively from original manufacturers or authorized suppliers, and contractor-approved suppliers), contractors and subcontractors that are not the original manufacturer or authorized supplier are required have a risk-based process to trace electronic parts from the original manufacturer to product acceptance by the Government. If that is not feasible, the Contractor shall have a process to complete an evaluation that includes consideration of alternative parts or utilization of tests and inspections commensurate with the risk. If it is not possible to obtain an electronic part from a trusted supplier, the contractor is required to notify the contracting officer. The contractor is responsible for inspection, testing, and authentication, in accordance with existing applicable industry standards, of electronic parts obtained from sources other than a trusted supplier. Notifying the contracting officer if it is not possible to obtain an electronic part from a trusted supplier, or responding to requests for documentation on traceability or inspection, testing, and validation of electronic parts would probably involve a mid-level of executive involvement. Recordkeeping is estimated to be function performed by personnel approximately equivalent to a Government GS–9 step 5 level.

DoD was unable to identify any significant alternatives that would reduce the economic impact on small entities and still fulfill the requirements of the statute and the objectives of the rule to detect and avoid counterfeit parts in the DoD supply chain. It is not possible to exempt small entities or acquisition of commercial items (including COTS items) from application of this rule or phase in the applicability to such entities, without an unacceptable increase in the risk to of counterfeit parts in the supply chain. (See response to the Office of Advocacy of the Small Business Administration comments on alternatives in this FRFA.) DoD also considered (with the addition of this DFARS clause 252.246–7008, which is applicable to all subcontractors that provide electronic parts, including small businesses) whether the requirements of DFARS 252.247–7007 for a formal system to detect and avoid counterfeit parts could be made inapplicable to small businesses that are subcontractors to a CAS-covered prime contractor. This alternative was not acceptable to DoD policy experts.

VI. Paperwork Reduction Act

This rule contains information collection requirements under the Paperwork Reduction Act (44 U.S.C. chapter 35). The Office of Management and Budget (OMB) has assigned OMB Control Number 0704–0541, entitled ''Detection and Avoidance of Counterfeit Parts—Further Implementation.''

List of Subjects in 48 CFR Parts 202, 212, 242, 246, and 252

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 202, 212, 242, 246, and 252 are amended as follows:

■ 1. The authority citation for parts 202, 212, 242, 246, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 202—DEFINITIONS OF WORDS AND TERMS

■ 2. Amend section 202.101 by—

■ a. Adding, in alphabetical order, the definitions for ''authorized aftermarket manufacturer,'' ''contract manufacturer,'' ''contractor-approved supplier,'' ''original component manufacturer,'' ''original equipment manufacturer,'' and ''original manufacturer'';

■ b. Amending the definition of ''electronic part'' by removing the second sentence; and

■ c. Revising the definition of ''obsolete electronic part''.

The additions and revision read as follows:

202.101 Definitions.

Authorized aftermarket manufacturer means an organization that fabricates an electronic part under a contract with, or with the express written authority of, the original component manufacturer based on the original component manufacturer's designs, formulas, and/or specifications.

* * * * *

Contract manufacturer means a company that produces goods under contract for another company under the label or brand name of that company.

* * * * *

Contractor-approved supplier means a supplier that does not have a contractual agreement with the original component manufacturer for a transaction, but has been identified as trustworthy by a contractor or subcontractor.

* * * * *

Obsolete electronic part means an electronic part that is no longer available from the original manufacturer or an authorized aftermarket manufacturer.

Original component manufacturer means an organization that designs and/or engineers a part and is entitled to any intellectual property rights to that part.

Original equipment manufacturer means a company that manufactures products that it has designed from purchased components and sells those products under the company's brand name.

Original manufacturer means the original component manufacturer, the original equipment manufacturer, or the contract manufacturer.

* * * * *

PART 212—ACQUISITION OF COMMERCIAL ITEMS

■ 3. Amend section 212.301 by adding new paragraph (f)(xix)(C) to read as follows:

212.301 Solicitation provisions and contract clauses for the acquisition of commercial items.

* * * * *

(f) * * *

(xix) * * *

(C) Use the clause at 252.246–7008, Sources of Electronic Parts, as prescribed in 246.870–3(b), to comply with section 818(c)(3) of Public Law 112–81, as amended by section 817 of the National Defense Authorization Act for Fiscal Year 2015 (Pub. L. 113–291).

PART 242—CONTRACT ADMINISTRATION AND AUDIT SERVICES

■ 4. Amend section 242.302(a) by adding a new paragraph (S–76) to read as follows:

242.302 Contract administration functions.

(a) * * *

(S–76) Review and audit contractor identification of contractor-approved suppliers for the acquisition of electronic parts, as identified in the clause at 252.246–7008, Sources of Electronic Parts.

* * * * *

PART 246—QUALITY ASSURANCE

■ 5. Revise section 246.870 heading to read as follows:

246.870 Contractor counterfeit electronic part detection and avoidance.

246.870–1 [Redesignated as 246.870–0]

■ 6. Redesignate section 246.870–1 as 246.870–0.

■ 7. In newly redesignated section 246.870–0, revise paragraph (a) to read as follows:

246.870–0 Scope.

* * * * *

(a) Partially implements section 818(c) and (e) of the National Defense Authorization Act for Fiscal Year 2012 (Pub. L. 112–81), as amended by section 817 of the National Defense Authorization Act for Fiscal Year 2015 (Pub. L. 113–291); and

* * * * *

■ 8. Add section 246.870–1 to read as follows:

246.870–1 Definition.

Authorized supplier, as used in this subpart, means a supplier, distributor, or an aftermarket manufacturer with a contractual arrangement with, or the express written authority of, the original manufacturer or current design activity to buy, stock, repackage, sell, or distribute the part.

■ 9. Revise section 246.870–2 to read as follows:

246.870–2 Policy.

(a) *Sources of electronic parts.* (1) Except as provided in paragraph (a)(2) of this section, the Government requires contractors and subcontractors at all tiers, to—

(i) Obtain electronic parts that are in production by the original manufacturer or an authorized aftermarket manufacturer or currently available in stock from—

(A) The original manufacturers of the parts;

(B) Their authorized suppliers; or

(C) Suppliers that obtain such parts exclusively from the original manufacturers of the parts or their authorized suppliers; and

(ii) Obtain electronic parts that are not in production by the original manufacturer or an authorized aftermarket manufacturer, and that are not currently available in stock from a source listed in paragraph (a)(1)(i) of this section, from suppliers identified by the Contractor as contractor-approved suppliers, provided that—

(A) For identifying and approving such contractor-approved suppliers, the contractor uses established counterfeit prevention industry standards and processes (including inspection, testing, and authentication), such as the DoD-adopted standards at *https://assist.dla.mil;*

(B) The contractor assumes responsibility for the authenticity of parts provided by such contractor-approved suppliers (see 231.205–71); and

(C) The selection of such contractor-approved suppliers is subject to review and audit by the contracting officer.

(2) The Government requires contractors and subcontractors to comply with the notification, inspection, testing, and authentication requirements of paragraph (b)(3)(ii) through (b)(3)(iv) of the clause at 252.246–7008, Sources of Electronic Parts, if the contractor—

(i) Obtains an electronic part from—

(A) A source other than any of the sources identified in paragraph (a)(1) of this section, due to nonavailability from such sources; or

(B) A subcontractor (other than the original manufacturer) that refuses to accept flowdown of this clause; or

(ii) Cannot confirm that an electronic part is new or not previously used and that it has not been comingled in supplier new production or stock with used, refurbished, reclaimed, or returned parts.

(3) Contractors and subcontractors are still required to comply with the requirements of paragraphs (a)(1) or (2) of this section, as applicable, if—

(i) Authorized to purchase electronic parts from the Federal Supply Schedule;

(ii) Purchasing electronic parts from suppliers accredited by the Defense Microelectronics Activity; or

(iii) Requisitioning electronic parts from Government inventory/stock under the authority of the clause at 252.251–7000, Ordering from Government Supply Sources.

(A) The cost of any required inspection, testing, and authentication of such parts may be charged as a direct cost.

(B) The Government is responsible for the authenticity of the requisitioned electronic parts. If any such part is subsequently found to be counterfeit or suspect counterfeit, the Government will—

(*1*) Promptly replace such part at no charge; and

(*2*) Consider an adjustment in the contract schedule to the extent that replacement of the counterfeit or suspect counterfeit electronic parts caused a delay in performance.

(b) *Contractor counterfeit electronic part detection and avoidance system.* (1) Contractors that are subject to the cost accounting standards and that supply electronic parts or products that include electronic parts, and their subcontractors that supply electronic parts or products that include electronic parts, are required to establish and maintain an acceptable counterfeit electronic part detection and avoidance system. Failure to do so may result in disapproval of the purchasing system by the contracting officer and/or withholding of payments (see 252.244–7001, Contractor Purchasing System Administration).

(2) *System criteria.* A counterfeit electronic part detection and avoidance system shall include risk-based policies and procedures that address, at a minimum,the following areas (see the clause at 252.246–7007, Contractor Counterfeit Electronic Part Detection and Avoidance System):

(i) The training of personnel.

(ii) The inspection and testing of electronic parts, including criteria for acceptance and rejection.

(iii) Processes to abolish counterfeit parts proliferation.

(iv) Processes for maintaining electronic part traceability.

(v) Use of suppliers in accordance with paragraph (a) of this section.

(vi) The reporting and quarantining of counterfeit electronic parts and suspect counterfeit electronic parts.

(vii) Methodologies to identify suspect counterfeit electronic parts and to rapidly determine if a suspect counterfeit electronic part is, in fact, counterfeit.

(viii) Design, operation, and maintenance of systems to detect and avoid counterfeit electronic parts and suspect counterfeit electronic parts.

(ix) Flow down of counterfeit detection and avoidance requirements.

(x) Process for keeping continually informed of current counterfeiting information and trends.

(xi) Process for screening the Government-Industry Data Exchange

Program (GIDEP) reports and other credible sources of counterfeiting information.

(xii) Control of obsolete electronic parts.

■ 10. Amend section 246.870–3 by—
■ a. Revising the section heading;
■ b. Redesignating paragraphs (a)(1) through (3) as paragraph (a)(1)(i) through (iii), respectively;
■ c. Redesignating paragraph (a) as paragraph (a)(1);
■ d. In newly redesignated paragraph (a)(1), removing ''paragraph (b)'' and adding ''paragraph (a)(2)'' in its place;
■ e. In newly redesignated paragraph (a)(1)(iii), removing ''Services where'' and adding ''Services, if'' in its place;
■ f. Resdesignating paragraph (b) as paragraph (a)(2);
■ g. In newly redesignated paragraph (a)(2), removing ''set-aside'' and adding ''set aside'' in its place; and
■ h. Adding new paragraph (b).

The addition reads as follows:

246.870–3 Contract clauses.

* * * * *

(b) Use the clause at 252.246–7008, Sources of Electronic Parts, in solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial items, when procuring—

(1) Electronic parts;

(2) End items, components, parts, or assemblies containing electronic parts; or

(3) Services, if the contractor will supply electronic parts or components, parts, or assemblies containing electronic parts as part of the service.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 11. Amend section 252.246–7007 by—
■ a. In the introductory text, removing ''246.870–3'' and adding ''246.870–3(a)'' in its place;
■ b. Removing the clause date ''(MAY 2014)'' and adding ''(AUG 2016)'' in its place;
■ c. In paragraph (a)—
■ i. Adding in alphabetical order the definitions of ''authorized aftermarket manufacturer,'' ''authorized supplier,'' ''contract manufacturer,'' ''contractor-approved supplier,'' ''original component manufacturer,'' ''original equipment manufacturer,'' and ''original manufacturer''; and
■ ii. Amending the definition of ''electronic part'' by removing the second sentence; and
■ iii. Revising the definition of ''obsolete electronic part'' and
■ d. Revising paragraph (b);
■ e. Revising paragraphs (c)(4) and (5); and
■ f. Revising paragraph (e).

The additions and revisions read as follows:

252.246–7007 Contractor Counterfeit Electronic Part Detection and Avoidance System.

* * * * *

(a) * * *

Authorized aftermarket manufacturer means an organization that fabricates a part under a contract with, or with the express written authority of, the original component manufacturer based on the original component manufacturer's designs, formulas, and/or specifications.

Authorized supplier means a supplier, distributor, or an aftermarket manufacturer with a contractual arrangement with, or the express written authority of, the original manufacturer or current design activity to buy, stock, repackage, sell, or distribute the part.

Contract manufacturer means a company that produces goods under contract for another company under the label or brand name of that company.

Contractor-approved supplier means a supplier that does not have a contractual agreement with the original component manufacturer for a transaction, but has been identified as trustworthy by a contractor or subcontractor.

* * * * *

Obsolete electronic part means an electronic part that is no longer available from the original manufacturer or an authorized aftermarket manufacturer.

Original component manufacturer means an organization that designs and/or engineers a part and is entitled to any intellectual property rights to that part.

Original equipment manufacturer means a company that manufactures products that it has designed from purchased components and sells those products under the company's brand name.

Original manufacturer means the original component manufacturer, the original equipment manufacturer, or the contract manufacturer.

* * * * *

(b) *Acceptable counterfeit electronic part detection and avoidance system.* The Contractor shall establish and maintain an acceptable counterfeit electronic part detection and avoidance system. Failure to maintain an acceptable counterfeit electronic part detection and avoidance system, as defined in this clause, may result in disapproval of the purchasing system by the Contracting Officer and/or withholding of payments and affect the allowability of costs of counterfeit electronic parts or suspect counterfeit electronic parts and the cost of rework or corrective action that may be required to remedy the use or inclusion of such parts (see DFARS 231.205–71).

(c) * * *

(4) Risk-based processes that enable tracking of electronic parts from the original manufacturer to product acceptance by the Government, whether the electronic parts are supplied as discrete electronic parts or are contained in assemblies, in accordance with paragraph (c) of the clause at 252.246–7008, Sources of Electronic Parts (also see paragraph (c)(2) of this clause).

(5) Use of suppliers in accordance with the clause at 252.246–7008.

* * * * *

(e) The Contractor shall include the substance of this clause, excluding the introductory text and including only paragraphs (a) through (e), in subcontracts, including subcontracts for commercial items, for electronic parts or assemblies containing electronic parts.

* * * * *

■ 12. Add section 252.246–7008 to read as follows:

252.246–7008 Sources of Electronic Parts.

As prescribed in 246.870–3(b), use the following clause:

SOURCES OF ELECTRONIC PARTS (AUG 2016)

(a) *Definitions.* As used in this clause—

Authorized aftermarket manufacturer means an organization that fabricates a part under a contract with, or with the express written authority of, the original component manufacturer based on the original component manufacturer's designs, formulas, and/or specifications.

Authorized supplier means a supplier, distributor, or an aftermarket manufacturer with a contractual arrangement with, or the express written authority of, the original manufacturer or current design activity to buy, stock, repackage, sell, or distribute the part.

Contract manufacturer means a company that produces goods under contract for another company under the label or brand name of that company.

Contractor-approved supplier means a supplier that does not have a contractual agreement with the original component manufacturer for a transaction, but has been identified as trustworthy by a contractor or subcontractor.

Electronic part means an integrated circuit, a discrete electronic component (including, but not limited to, a transistor, capacitor, resistor, or diode), or a circuit assembly (section 818(f)(2) of Pub. L. 112–81).

Original component manufacturer means an organization that designs and/or engineers a part and is entitled to any intellectual property rights to that part.

Original equipment manufacturer means a company that manufactures products that it has designed from purchased components and sells those products under the company's brand name.

Original manufacturer means the original component manufacturer, the original equipment manufacturer, or the contract manufacturer.

(b) *Selecting suppliers.* In accordance with section 818(c)(3) of the National Defense Authorization Act for Fiscal Year 2012 (Pub. L. 112–81), as amended by section 817 of the National Defense Authorization Act for Fiscal Year 2015 (Pub. L. 113–291), the Contractor shall—

(1) First obtain electronic parts that are in production by the original manufacturer or an authorized aftermarket manufacturer or currently available in stock from—

(i) The original manufacturers of the parts;

(ii) Their authorized suppliers; or

(iii) Suppliers that obtain such parts exclusively from the original manufacturers of the parts or their authorized suppliers;

(2) If electronic parts are not available as provided in paragraph (b)(1) of this clause, obtain electronic parts that are not in production by the original manufacturer or an authorized aftermarket manufacturer, and that are not currently available in stock from a source listed in paragraph (b)(1) of this clause, from suppliers identified by the Contractor as contractor-approved suppliers, provided that—

(i) For identifying and approving such contractor-approved suppliers, the Contractor uses established counterfeit prevention industry standards and processes (including inspection, testing, and authentication), such as the DoD-adopted standards at *https://assist.dla.mil*;

(ii) The Contractor assumes responsibility for the authenticity of parts provided by such contractor-approved suppliers; and

(iii) The Contractor's selection of such contractor-approved suppliers is subject to review and audit by the contracting officer; or

(3)(i) Take the actions in paragraphs (b)(3)(ii) through (b)(3)(iv) of this clause if the Contractor—

(A) Obtains an electronic part from—

(*1*) A source other than any of the sources identified in paragraph (b)(1) or (b)(2) of this clause, due to nonavailability from such sources; or

(*2*) A subcontractor (other than the original manufacturer) that refuses to accept flowdown of this clause; or

(B) Cannot confirm that an electronic part is new or previously unused and that it has not been comingled in supplier new production or stock with used, refurbished, reclaimed, or returned parts.

(ii) If the contractor obtains an electronic part or cannot confirm an electronic part pursuant to paragraph (b)(3)(i) of this clause—

(A) Promptly notify the Contracting Officer in writing. If such notification is required for an electronic part to be used in a designated lot of assemblies to be acquired under a single contract, the Contractor may submit one notification for the lot, providing identification of the assemblies containing the parts (*e.g.*, serial numbers);

(B) Be responsible for inspection, testing, and authentication, in accordance with existing applicable industry standards; and

(C) Make documentation of inspection, testing, and authentication of such electronic parts available to the Government upon request.

(c) *Traceability.* If the Contractor is not the original manufacturer of, or authorized supplier for, an electronic part, the Contractor shall—

(1) Have risk-based processes (taking into consideration the consequences of failure of an electronic part) that enable tracking of electronic parts from the original manufacturer to product acceptance by the Government, whether the electronic part is supplied as a discrete electronic part or is contained in an assembly;

(2) If the Contractor cannot establish this traceability from the original manufacturer for a specific electronic part, be responsible for inspection, testing, and authentication, in accordance with existing applicable industry standards; and

(3)(i) Maintain documentation of traceability (paragraph (c)(1) of this clause) or the inspection, testing, and authentication required when traceability cannot be established (paragraph (c)(2) of this clause) in accordance with FAR subpart 4.7; and

(ii) Make such documentation available to the Government upon request.

(d) *Government sources.* Contractors and subcontractors are still required to comply with the requirements of paragraphs (b) and (c) of this clause, as applicable, if—

(1) Authorized to purchase electronic parts from the Federal Supply Schedule;

(2) Purchasing electronic parts from suppliers accredited by the Defense Microelectronics Activity; or

(3) Requisitioning electronic parts from Government inventory/stock under the authority of 252.251–7000, Ordering from Government Supply Sources.

(i) The cost of any required inspection, testing, and authentication of such parts may be charged as a direct cost.

(ii) The Government is responsible for the authenticity of the requisitioned parts. If any such part is subsequently found to be counterfeit or suspect counterfeit, the Government will—

(A) Promptly replace such part at no charge; and

(B) Consider an adjustment in the contract schedule to the extent that replacement of the counterfeit or suspect counterfeit electronic parts caused a delay in performance.

(e) *Subcontracts.* The Contractor shall include the substance of this clause, including this paragraph (e), in subcontracts, including subcontracts for commercial items that are for electronic parts or assemblies containing electronic parts, unless the subcontractor is the original manufacturer.

(End of clause)

[FR Doc. 2016–17956 Filed 8–1–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 225 and 252

[Docket DARS–2016–0021]

RIN 0750–AI97

Defense Federal Acquisition Regulation Supplement: New Qualifying Countries—Japan and Slovenia (DFARS Case 2016–D023)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to add Japan and Slovenia as qualifying countries.

DATES: Effective August 2, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Jo Ann Reilly, telephone 571–372–6176.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is amending the DFARS to add Japan and Slovenia as qualifying countries. The Secretary of Defense recently signed reciprocal defense procurement agreements with these countries. These agreements were placed into force on June 4, 2016, for Japan and June 21, 2016, for Slovenia. The agreements remove discriminatory barriers to procurements of supplies and services produced by industrial enterprises of the other country to the extent mutually beneficial and consistent with national laws, regulations, policies, and international obligations. These agreements do not cover construction or construction material. Japan and Slovenia are already designated countries under the World Trade Organization Government Procurement Agreement.

II. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items.

This rule only updates the list of qualifying countries in the DFARS by adding the newly qualifying countries of Japan and Slovenia. The definition of ''qualifying country'' is updated in each of the following clauses; however, this revision does not impact the clause prescriptions for use, or applicability at or below the simplified acquisition threshold, or applicability to commercial items. The clauses are:

DFARS 252.225–7001, Buy American and Balance of Payments Program; DFARS 252.225–7002, Qualifying Country Sources as Subcontractors; DFARS 252.225–7012, Preference for Certain Domestic Commodities; DFARS 252.225–7017, Photovoltaic Devices; DFARS 252.225–7021, Trade Agreements; and DFARS 252.225–7036, Buy American—Free Trade Agreements—Balance of Payments Program.

III. Publication of This Final Rule for Public Comment Is Not Required by Statute

The statute that applies to the publication of the Federal Acquisition Regulation (FAR) is 41 U.S.C. 1707 entitled ''Publication of Proposed Regulations.'' Paragraph (a)(1) of the statute requires that a procurement policy, regulation, procedure or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because it does not constitute a significant DFARS revision within the meaning of FAR 1.501–1 and does not have a significant cost or administrative impact on contractors or offerors. Japan and Slovenia are added to the list of 23 other countries that have similar reciprocal defense procurement agreements with DoD. These requirements affect only the internal operating procedures of the Government.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply to this rule because this final rule does not constitute a significant DFARS revision within the meaning of FAR 1.501–1, and 41 U.S.C. 1707 does not require publication for public comment.

VI. Paperwork Reduction Act

The rule affects the certification and information collection requirements in the clause 252.225–7021, Trade Agreements, currently approved under OMB Control Number 0704–229, entitled ''DFARS Part 225, Foreign Acquisition, and related clauses,'' in accordance with the Paperwork Reduction Act (44 U.S.C. chapter 35). The impact, however, is negligible because it merely shifts the category under which items from Japan and Slovenia must be listed.

List of Subjects in 48 CFR Parts 225 and 252

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 225 and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 225 and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 225—FOREIGN ACQUISITION

225.003 [Amended]

■ 2. Section 225.003 is amended in paragraph (10), the definition of ''qualifying country'', by adding, in alphabetical order, the countries of ''Japan'' and ''Slovenia'', respectively.

225.872–1 [Amended]

■ 3. Section 225.872–1 is amended in paragraph (a) by adding, in alphabetical order, the countries of ''Japan'' and ''Slovenia'', respectively.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.225–7001 [Amended]

■ 4. Section 252.225–7001 is amended by—

■ a. In the clause heading, removing the date ''(NOV 2014)'' and adding ''(AUG 2016)'' in its place;

■ b. In paragraph (a), the definition of ''qualifying country'', adding, in alphabetical order, the countries of ''Japan'' and ''Slovenia'', respectively; and

■ c. In the Alternate I clause heading—

■ i. Removing the date ''(NOV 2014)'' and adding ''(AUG 2016)'' in its place; and

■ ii. In paragraph (a), the definition of ''qualifying country'', adding, in alphabetical order, the countries of ''Japan'' and ''Slovenia'', respectively.

252.225–7002 [Amended]

■ 5. Section 252.225–7002 is amended by—

■ a. In the clause heading, removing the date ''(DEC 2012)'' and adding ''(AUG 2016)'' in its place; and

■ b. In paragraph (a), the definition of ''qualifying country'', adding, in alphabetical order, the countries of ''Japan'' and ''Slovenia'', respectively.

252.225–7012 [Amended]

■ 6. Section 252.225–7012 is amended by—

■ a. In the clause heading, removing the date ''(FEB 2013)'' and adding ''(JUL 2016)'' in its place; and

■ b. In paragraph (a), the definition of ''qualifying country'', adding, in alphabetical order, the countries of ''Japan'' and ''Slovenia'', respectively.

252.225–7017 [Amended]

■ 7. Section 252.225–7017 is amended by—

■ a. In the clause heading, removing the date ''(JUN 2016)'' and adding ''(AUG 2016)'' in its place; and

■ b. In paragraph (a), the definition of ''qualifying country'', adding, in alphabetical order, the countries of ''Japan'' and ''Slovenia'', respectively.

252.225–7021 [Amended]

■ 8. Section 252.225–7021 is amended by—

■ a. In the clause heading, removing the date ''(JUN 2015)'' and adding ''(AUG 2016)'' in its place; and

■ b. In paragraph (a), the definition of ''qualifying country'', adding, in alphabetical order, the countries of ''Japan'' and ''Slovenia'', respectively; and

■ c. In the Alternate II clause heading—

■ i. Removing the date ''(JUN 2015)'' and adding ''(AUG 2016)'' in its place; and

■ ii. In paragraph (a), the definition of ''qualifying country'', adding, in alphabetical order, the countries of ''Japan'' and ''Slovenia'', respectively.

252.225–7036 [Amended]

■ 9. Section 252.225–7036 is amended by—

■ a. In the clause heading, removing the date ''(NOV 2014)'' and adding ''(AUG 2016)'' in its place; and

■ b. In paragraph (a), the definition of ''qualifying country'', adding, in

alphabetical order, the countries of ''Japan'' and ''Slovenia'', respectively; and

■ c. In the Alternate I clause heading—

■ i. Removing the date ''(NOV 2014)'' and adding ''(AUG 2016)'' in its place; and

■ ii. In paragraph (a) definition of ''qualifying country'', adding, in alphabetical order, the countries of ''Japan'' and ''Slovenia'', respectively.

■ d. In the Alternate II clause heading—

■ i. Removing the date ''(NOV 2014)'' and adding ''(AUG 2016)'' in its place; and

■ ii. In paragraph (a), the definition of ''qualifying country'', adding, in alphabetical order, the countries of ''Japan'' and ''Slovenia'', respectively.

■ e. In the Alternate III clause heading—

■ i. Removing the date ''(NOV 2014)'' and adding ''(AUG 2016)'' in its place; and

■ ii. In paragraph (a), the definition of ''qualifying country'', adding, in alphabetical order, the countries of ''Japan'' and ''Slovenia'', respectively.

■ f. In the Alternate IV clause heading—

■ i. Removing the date ''(NOV 2014)'' and adding ''(AUG 2016)'' in its place; and

■ ii. In paragraph (a), the definition of ''qualifying country'', adding, in alphabetical order, the countries of ''Japan'' and ''Slovenia'', respectively.

■ g. In the Alternate V clause heading—

■ i. Removing the date ''(NOV 2014)'' and adding ''(AUG 2016)'' in its place; and

■ ii. In paragraph (a), the definition of ''qualifying country'', adding, in alphabetical order, the countries of ''Japan'' and ''Slovenia'', respectively.

[FR Doc. 2016–17958 Filed 8–1–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 245 and 252

[Docket DARS–2016–0023]

Defense Federal Acquisition Regulation Supplement; Technical Amendments

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is making technical amendments to the Defense Federal Acquisition Regulation Supplement (DFARS) to provide needed editorial changes.

DATES: Effective August 2, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer L. Hawes, Defense Acquisition Regulations System, OUSD(AT&L)DPAP(DARS), Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060. Telephone 571–372–6115; facsimile 571–372–6094.

SUPPLEMENTARY INFORMATION: This final rule amends the DFARS as follows—

1. Updates the direction to contracting officers at DFARS 245.402–70 to review the guidance in DFARS Procedures, Guidance, and Information (PGI) for oversight and surveillance of contractor-acquired property; and

2. In DFARS clause 252.225–7021, Trade Agreements-Alternate II, corrects paragraph (a) definition of ''designated country'' to include the country of Croatia. DFARS final rule 2013–D005, Clauses with Alternates—Foreign Acquisition, published at 79 FR 65816 on November 5, 2014, created separate prescriptions for each foreign-related basic clause and provision, as well as each of its alternate clauses and provisions. In addition, the rule stated the full text of each clause or provision alternate. In the restatement of the full text of DFARS 252.225–7021-Alternate II, the country of Croatia was inadvertently omitted.

List of Subjects in 48 CFR 245 and 252

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 245 and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 245 and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 245—GOVERNMENT PROPERTY

■ 2. Revise section 245.402–70 to read as follows:

245.402–70 Policy.

Review the guidance at PGI 245.402–70 with regard to oversight and surveillance of contractor-acquired property.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.225–7021 [Amended]

■ 3. Amend section 252.225–7021 by, in the Alternate II clause—

a. Removing the clause date ''(JUN 2016)'' and adding ''(AUG 2016)'' in its place; and

b. In paragraph (a) definition of ''designated country'' in paragraph (i), adding, in alphabetical order, the country of ''Croatia''.

[FR Doc. 2016–17959 Filed 8–1–16; 8:45 am]

BILLING CODE 5001–06–P

SURFACE TRANSPORTATION BOARD

49 CFR Part 1002

[Docket No. EP 542 (Sub-No. 24)]

Regulations Governing Fees for Services Performed in Connection with Licensing and Related Services—2016 Update

AGENCY: Surface Transportation Board.

ACTION: Final rules.

SUMMARY: The Board updates for 2016 the fees that the public must pay to file certain cases and pleadings with the Board. In this update, the following results are obtained: 18 fees increased by $50 or less, 15 fees increased by $100 to $199, 23 fees increased by $200 to $300, 19 fees increased by more than $300, and the remaining 58 fees will be maintained at their current level.

DATES: These rules are effective September 1, 2016.

FOR FURTHER INFORMATION CONTACT: David T. Groves, (202) 245–0327, or Andrea Pope-Matheson (202) 245–0363. [TDD for the hearing impaired: 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: The Board's regulations at 49 CFR 1002.3 provide for an annual update of the Board's entire user-fee schedule. Fees are generally revised based on the cost study formula set forth at 49 CFR 1002.3(d). As compared with the 2015 fee update, the 2016 fee changes adopted here reflect a combination of a 1.46% across-the-board increase to salary costs; no change in publication cost levels; increases to two of the three Board Overhead cost factors; and a slight decrease to the third Board Overhead cost factor from its comparable 2015 level, resulting from the mechanical application of the update formula in 49 CFR 1002.3(d). Results from the formula application indicate that justified fee amounts in this 2016 update decision either remain unchanged (58 fee items), increase by $50 or less (18 fee items), increase by $300 or less (38 fee items) or increase over $300 (19 fee items) from their respective 2015 update levels. No *new* fee items are proposed in this proceeding. However, there is an expansion of existing fee item 98 to now include monthly and quarterly Waybill

request data. Therefore, the Board finds that notice and comment are unnecessary for this proceeding. *See Regulations Governing Fees for Servs.—1990 Update,* 7 I.C.C.2d 3 (1990); *Regulations Governing Fees for Servs.—1991 Update,* 8 I.C.C.2d 13 (1991); *Regulations Governing Fees for Servs.—1993 Update,* 9 I.C.C.2d 855 (1993).

Additional information is contained in the Board's decision. To obtain a free copy of the full decision, visit the Board's Web site at *http://www.stb.dot.gov* or call (202) 245–0245. [Assistance for the hearing impaired is available through Federal Information Relay Services (FIRS): (800) 877–8339.]

List of Subjects in 49 CFR Part 1002

Administrative practice and procedure, Common carriers, and Freedom of information.

Decided: July 27, 2016.

By the Board, Chairman Elliott, Vice Chairman Miller, and Commissioner Begeman.

Tia L. Delano,

Clearance Clerk.

For the reasons set forth in the preamble, title 49, chapter X, part 1002, of the Code of Federal Regulations is amended as follows:

PART 1002—FEES

■ 1. The authority citation for part 1002 continues to read as follows:

Authority: 5 U.S.C. 552(a)(4)(A) and 553; 31 U.S.C. 9701 and 49 U.S.C. 1321(a). Section 1002.1(g)(11) is also issued under 5 U.S.C. 5514 and 31 U.S.C. 3717.

■ 2. Section 1002.1 is amended by revising paragraphs (d), (f)(1), and (g)(6) and (7) to read as follows:

§ 1002.1 Fees for records search, review, copying, certification, and related services.

* * * * *

(d) Photocopies of tariffs, reports, and other public documents, at the rate of $1.50 per letter or legal size exposure. A minimum charge of $7.50 will be made for this service.

* * * * *

(f) * * *

(1) A fee of $74.00 per hour for professional staff time will be charged when it is required to fulfill a request for ADP data.

* * * * *

(g) * * *

(6) The search and review hourly fees will be based upon employee grade levels in order to recoup the full, allowable direct costs attributable to their performance of these functions. They are as follows:

Grade	Rate	Grade	Rate
GS–1	$12.43	GS–9	$29.02
GS–2	13.53	GS–10	31.95
GS–3	15.25	GS–11	35.11
GS–4	17.12	GS–12	42.08
GS–5	19.15	GS–13	50.04
GS–6	21.35	GS–14	59.13
GS–7	23.72	GS–15 and over	69.56
GS–8	26.27		

(7) The fee for photocopies shall be $1.50 per letter or legal size exposure with a minimum charge of $7.50.

* * * * *

■ 3. In 1002.2, paragraph (f) is revised to read as follows:

§ 1002.2 Filing fees.

* * * * *

(f) *Schedule of filing fees.*

Type of Proceeding	Fee
PART I: Non-Rail Applications or Proceedings to Enter Into a Particular Financial Transaction or Joint Arrangement:	
(1) An application for the pooling or division of traffic	$4,800.
(2)(i) An application involving the purchase, lease, consolidation, merger, or acquisition of control of a motor carrier of passengers under 49 U.S.C. 14303.	2,200.
(ii) A petition for exemption under 49 U.S.C. 13541 (other than a rulemaking) filed by a non-rail carrier not otherwise covered.	3,500.
(iii) A petition to revoke an exemption filed under 49 U.S.C. 13541(d)	2,900.
(3) An application for approval of a non-rail rate association agreement. 49 U.S.C. 13703.	30,400.
(4) An application for approval of an amendment to a non-rail rate association agreement:	
(i) Significant amendment	5,000.
(ii) Minor amendment	100.
(5) An application for temporary authority to operate a motor carrier of passengers. 49 U.S.C. 14303(i)	550.
(6) A notice of exemption for transaction within a motor passenger corporate family that does not result in adverse changes in service levels, significant operational changes, or a change in the competitive balance with motor passenger carriers outside the corporate family.	1,800.
(7)–(10) [Reserved].	
PART II: Rail Licensing Proceedings other than Abandonment or Discontinuance Proceedings:	
(11) (i) An application for a certificate authorizing the extension, acquisition, or operation of lines of railroad. 49 U.S.C. 10901.	8,000.
(ii) Notice of exemption under 49 CFR 1150.31–1150.35	1,900.
(iii) Petition for exemption under 49 U.S.C. 10502	13,800.
(12) (i) An application involving the construction of a rail line	82,100.
(ii) A notice of exemption involving construction of a rail line under 49 CFR 1150.36	1,900.
(iii) A petition for exemption under 49 U.S.C. 10502 involving construction of a rail line	82,100.
(iv) A request for determination of a dispute involving a rail construction that crosses the line of another carrier under 49 U.S.C. 10902(d).	300.
(13) A Feeder Line Development Program application filed under 49 U.S.C. 10907(b)(1)(A)(i) or 10907(b)(1)(A)(ii).	2,600.

Type of Proceeding	Fee
(14) (i) An application of a class II or class III carrier to acquire an extended or additional rail line under 49 U.S.C. 10902.	6,800.
(ii) Notice of exemption under 49 CFR 1150.41—1150.45	1,900.
(iii) Petition for exemption under 49 U.S.C. 10502 relating to an exemption from the provisions of 49 U.S.C. 10902.	7,200.
(15) A notice of a modified certificate of public convenience and necessity under 49 CFR 1150.21–1150.24.	1,800.
(16) An application for a land-use-exemption permit for a facility existing as of October 16, 2008 under 49 U.S.C. 10909.	6,600.
(17) An application for a land-use-exemption permit for a facility not existing as of October 16, 2008 under 49 U.S.C. 10909.	23,300.
(18)–(20) [Reserved]	
PART III: Rail Abandonment or Discontinuance of Transportation Services Proceedings:	
(21) (i) An application for authority to abandon all or a portion of a line of railroad or discontinue operation thereof filed by a railroad (except applications filed by Consolidated Rail Corporation pursuant to the Northeast Rail Service Act [Subtitle E of Title XI of Pub. L. 97–35], bankrupt railroads, or exempt abandonments).	24,400.
(ii) Notice of an exempt abandonment or discontinuance under 49 CFR 1152.50	4,000.
(iii) A petition for exemption under 49 U.S.C. 10502	6,900.
(22) An application for authority to abandon all or a portion of a line of a railroad or operation thereof filed by Consolidated Rail Corporation pursuant to Northeast Rail Service Act.	500.
(23) Abandonments filed by bankrupt railroads	2,000.
(24) A request for waiver of filing requirements for abandonment application proceedings	2,000.
(25) An offer of financial assistance under 49 U.S.C. 10904 relating to the purchase of or subsidy for a rail line proposed for abandonment.	1,700.
(26) A request to set terms and conditions for the sale of or subsidy for a rail line proposed to be abandoned.	24,900.
(27) (i) A request for a trail use condition in an abandonment proceeding under 16 U.S.C.1247(d)	300.
(ii) A request to extend the period to negotiate a trail use agreement	500.
(28)–(35) [Reserved]	
PART IV: Rail Applications to Enter Into a Particular Financial Transaction or Joint Arrangement:	
(36) An application for use of terminal facilities or other applications under 49 U.S.C. 11102	20,800.
(37) An application for the pooling or division of traffic. 49 U.S.C. 11322	11,200.
(38) An application for two or more carriers to consolidate or merge their properties or franchises (or a part thereof) into one corporation for ownership, management, and operation of the properties previously in separate ownership. 49 U.S.C. 11324:	
(i) Major transaction	1,641,600.
(ii) Significant transaction	328,300.
(iii) Minor transaction	8,100.
(iv) Notice of an exempt transaction under 49 CFR 1180.2(d)	1,800.
(v) Responsive application	8,100.
(vi) Petition for exemption under 49 U.S.C. 10502	10,300.
(vii) A request for waiver or clarification of regulations filed in a major financial proceeding as defined at 49 CFR 1180.2(a).	6,000.
(39) An application of a non-carrier to acquire control of two or more carriers through ownership of stock or otherwise. 49 U.S.C. 11324:	
(i) Major transaction	1,641,600.
(ii) Significant transaction	328,300.
(iii) Minor transaction	8,100.
(iv) A notice of an exempt transaction under 49 CFR 1180.2(d)	1,400.
(v) Responsive application	8,100.
(vi) Petition for exemption under 49 U.S.C. 10502	10,300.
(vii) A request for waiver or clarification of regulations filed in a major financial proceeding as defined at 49 CFR 1180.2(a).	6,000.
(40) An application to acquire trackage rights over, joint ownership in, or joint use of any railroad lines owned and operated by any other carrier and terminals incidental thereto. 49 U.S.C. 11324:	
(i) Major transaction	1,641,600.
(ii) Significant transaction	328,300.
(iii) Minor transaction	8,100.
(iv) Notice of an exempt transaction under 49 CFR 1180.2(d)	1,200.
(v) Responsive application	8,100.
(vi) Petition for exemption under 49 U.S.C. 10502	10,300.
(vii) A request for waiver or clarification of regulations filed in a major financial proceeding as defined at 49 CFR 1180.2(a).	6,000.
(41) An application of a carrier or carriers to purchase, lease, or contract to operate the properties of another, or to acquire control of another by purchase of stock or otherwise. 49 U.S.C. 11324:	
(i) Major transaction	1,641,600.
(ii) Significant transaction	328,300.
(iii) Minor transaction	8,100.
(iv) Notice of an exempt transaction under 49 CFR 1180.2(d)	1,500.
(v) Responsive application	8,100.
(vi) Petition for exemption under 49 U.S.C. 10502	7,200.
(vii) A request for waiver or clarification of regulations filed in a major financial proceeding as defined at 49 CFR 1180.2(a).	6,000.

Type of Proceeding	Fee
(42) Notice of a joint project involving relocation of a rail line under 49 CFR 1180.2(d)(5)	2,600.
(43) An application for approval of a rail rate association agreement. 49 U.S.C. 10706	76,800.
(44) An application for approval of an amendment to a rail rate association agreement. 49 U.S.C. 10706:	
(i) Significant amendment	14,200.
(ii) Minor amendment	100.
(45) An application for authority to hold a position as officer or director under 49 U.S.C. 11328	850.
(46) A petition for exemption under 49 U.S.C. 10502 (other than a rulemaking) filed by rail carrier not otherwise covered.	8,800.
(47) National Railroad Passenger Corporation (Amtrak) conveyance proceeding under 45 U.S.C. 562	300.
(48) National Railroad Passenger Corporation (Amtrak) compensation proceeding under Section 402(a) of the Rail Passenger Service Act.	300.
(49)–(55) [Reserved].	
PART V: Formal Proceedings:	
(56) A formal complaint alleging unlawful rates or practices of carriers:	
(i) A formal complaint filed under the coal rate guidelines (Stand-Alone Cost Methodology) alleging unlawful rates and/or practices of rail carriers under 49 U.S.C. 10704(c)(1).	350.
(ii) A formal complaint involving rail maximum rates filed under the Simplified-SAC methodology	350.
(iii) A formal complaint involving rail maximum rates filed under the Three Benchmark methodology.	150.
(iv) All other formal complaints (except competitive access complaints)	350.
(v) Competitive access complaints	150.
(vi) A request for an order compelling a rail carrier to establish a common carrier rate	300.
(57) A complaint seeking or a petition requesting institution of an investigation seeking the prescription or division of joint rates or charges. 49 U.S.C. 10705.	9,700.
(58) A petition for declaratory order:	
(i) A petition for declaratory order involving a dispute over an existing rate or practice which is comparable to a complaint proceeding.	1,000.
(ii) All other petitions for declaratory order	1,400.
(59) An application for shipper antitrust immunity. 49 U.S.C. 10706(a)(5)(A)	7,700.
(60) Labor arbitration proceedings	300.
(61) (i) An appeal of a Surface Transportation Board decision on the merits or petition to revoke an exemption pursuant to 49 U.S.C. 10502(d).	300.
(ii) An appeal of a Surface Transportation Board decision on procedural matters except discovery rulings.	400.
(62) Motor carrier undercharge proceedings	300.
(63) (i) Expedited relief for service inadequacies: A request for expedited relief under 49 U.S.C. 11123 and 49 CFR part 1146 for service emergency.	300.
(ii) Expedited relief for service inadequacies: A request for temporary relief under 49 U.S.C. 10705 and 11102, and 49 CFR part 1147 for service inadequacy.	300.
(64) A request for waiver or clarification of regulations except one filed in an abandonment or discontinuance proceeding, or in a major financial proceeding as defined at 49 CFR 1180.2(a).	650.
(65)–(75) [Reserved].	
PART VI: Informal Proceedings:	
(76) An application for authority to establish released value rates or ratings for motor carriers and freight forwarders of household goods under 49 U.S.C. 14706.	1,300.
(77) An application for special permission for short notice or the waiver of other tariff publishing requirements.	100.
(78) The filing of tariffs, including supplements, or contract summaries	1 per page. (27 min. charge.)
(79) Special docket applications from rail and water carriers:	
(i) Applications involving 25,000 or less	75.
(ii) Applications involving over 25,000	150.
(80) Informal complaint about rail rate applications	650.
(81) Tariff reconciliation petitions from motor common carriers:	
(i) Petitions involving 25,000 or less	75.
(ii) Petitions involving over 25,000	150.
(82) Request for a determination of the applicability or reasonableness of motor carrier rates under 49 U.S.C. 13710(a)(2) and (3).	250.
(83) Filing of documents for recordation. 49 U.S.C. 11301 and 49 CFR 1177.3(c)	45 per document.
(84) Informal opinions about rate applications (all modes)	250.
(85) A railroad accounting interpretation	1,200.
(86) (i) A request for an informal opinion not otherwise covered	1,600.
(ii) A proposal to use on a voting trust agreement pursuant to 49 CFR 1013 and 49 CFR 1180.4(b)(4)(iv) in connection with a major control proceeding as defined at 49 CFR 1180.2(a).	5,600.
(iii) A request for an informal opinion on a voting trust agreement pursuant to 49 CFR 1013.3(a) not otherwise covered.	550.
(87) Arbitration of Certain Disputes Subject to the Statutory Jurisdiction of the Surface Transportation Board under 49 CFR 1108:	
(i) Complaint	75.
(ii) Answer (per defendant), Unless Declining to Submit to Any Arbitration	75.
(iii) Third Party Complaint	75.
(iv) Third Party Answer (per defendant), Unless Declining to Submit to Any Arbitration	75.
(v) Appeals of Arbitration Decisions or Petitions to Modify or Vacate an Arbitration Award	150.

Type of Proceeding	Fee
(88) Basic fee for STB adjudicatory services not otherwise covered	300.
(89)–(95) [Reserved].	
PART VII: Services:	
(96) Messenger delivery of decision to a railroad carrier's Washington, DC, agent	35 per delivery.
(97) Request for service or pleading list for proceedings	26 per list.
(98) Processing the paperwork related to a request for the Carload Waybill Sample to be used in an STB or State proceeding that:	
(i) Annual request does not require a **Federal Register** notice:	
(a) Set cost portion	150.
(b) Sliding cost portion	52 per party.
(ii) Annual request does require a FR notice:.	
(a) Set cost portion	400.
(b) Sliding cost portion	52 per party.
(iii) Quarterly request does not require a FR notice:	
(a) Set cost portion	44.
(b) Sliding cost portion	13 per party.
(iv) Quarterly request does require a FR notice:	
(a) Set cost portion	225.
(b) Sliding cost portion	13 per party.
(v) Monthly request does not require a FR notice:	
(a) Set cost portion	14.
(b) Sliding cost portion	4 per party.
(vi) Monthly request does require a FR notice:	
(a) Set cost portion	180.
(b) Sliding cost portion	4 per party.
(99) (i) Application fee for the STB's Practitioners' Exam	200.
(ii) Practitioners' Exam Information Package	25.
(100) Carload Waybill Sample data:	
(i) Requests for Public Use File for all years prior to the most current year Carload Waybill Sample data available, provided on CD–R.	250 per year.
(ii) Specialized programming for Waybill requests to the Board	116 per hour.

* * * * *

[FR Doc. 2016–18295 Filed 8–1–16; 8:45 am]

BILLING CODE 4915–01–P

Proposed Rules

Federal Register
Vol. 81, No. 148
Tuesday, August 2, 2016

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

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[REG–131418–14]

RIN 1545–BN27

Reporting for Qualified Tuition and Related Expenses; Education Tax Credits

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations that revise the rules for reporting qualified tuition and related expenses under section 6050S on a Form 1098–T, ''Tuition Statement,'' and conforms the regulations to the changes made to section 6050S by the Protecting Americans from Tax Hikes Act of 2015. This document also seeks to amend the regulations on the education tax credits under section 25A generally as well as to conform the regulations to changes made to section 25A by the Trade Preferences Extension Act of 2015 and the Protecting Americans from Tax Hikes Act of 2015. The proposed regulations affect certain higher educational institutions required to file Form 1098–T and taxpayers eligible to claim an education tax credit. This document also provides notice of a public hearing on these proposed regulations.

DATES: Written or electronic comments must be received by October 31, 2016. Outlines of topics to be discussed at the public hearing scheduled for November 30, 2016 must be received by October 31, 2016.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–131418–14), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8:00 a.m. and 4:00 p.m. to CC:PA:LPD:PR (REG–131418–14), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224. Alternatively, taxpayers may submit comments electronically via the Federal eRulemaking Portal at *www.regulations.gov* (IRS REG–131418–14).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Gerald Semasek of the Office of Associate Chief Counsel (Procedure and Administration) for the proposed regulations under sections 6050S and 6724, (202) 317–6845, and Sheldon Iskow of the Office of Associate Chief Counsel (Income Tax and Accounting) for the proposed regulations under section 25A, (202) 317–4718; concerning the submission of comments and requests for a public hearing, Regina Johnson, (202) 317–6901 (not toll-free calls).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been approved by the Office of Management and Budget through Form 1040 (OMB No. 1545–0074), Form 8863 (OMB No. 1545–0074) and Form 1098–T (OMB No. 1545–1574) in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Notice and an opportunity to comment on the proposed changes to burden hours for the forms related to this proposed rule will be published in a separate notice in the **Federal Register**.

Background

This document contains proposed regulations to amend the Income Tax Regulations (26 CFR part 1) under section 25A of the Internal Revenue Code (Code) and the Procedure and Administration Regulations (26 CFR part 301) under section 6050S, to reflect the amendments to sections 25A and 6724 under the Trade Preferences Extension Act of 2015 (Pub. L. 114–27 (129 Stat. 362 (2015)) (TPEA) and the amendments to sections 25A and 6050S under the Protecting Americans from Tax Hikes Act of 2015 (Pub. L. 114–113 (129 Stat. 2242 (2015)) (PATH). Furthermore, the document contains proposed regulations to amend the Income Tax Regulations under section 25A to update the definition of qualified tuition and related expenses in § 1.25A–2(d) to reflect the changes made by the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5 (123 Stat. 115) (ARRA)), to clarify the prepayment rule in § 1.25A–5(e), and to clarify the rule for refunds in § 1.25A–5(f).

1. Section 25A—Education Tax Credits

The Taxpayer Relief Act of 1997 (Pub. L. 105–34 (111 Stat. 788) (TRA '97)) added section 25A to provide students and their families with two new nonrefundable tax credits to help pay for college (education tax credits). Pursuant to TRA '97, section 25A allowed eligible taxpayers to claim either the Hope Scholarship Credit or the Lifetime Learning Credit (LLC) for qualified tuition and related expenses paid during the taxable year for an academic period beginning during the taxable year. In general, either the student or the parent who claims a dependency exemption for the student may claim a credit for the student's qualified tuition and related expenses. Section 25A(f)(1) defines ''qualified tuition and related expenses'' as tuition and fees required for enrollment or attendance at an eligible educational institution (institution). Section 25A(f)(2) generally defines an ''eligible educational institution'' as an institution described in the Higher Education Act of 1965 that is eligible to participate in federal college financial aid programs. Section 25A(g)(4) provides that amounts paid during the taxable year for enrollment during an academic period beginning within the first three months of the following taxable year are treated as amounts paid for an academic period beginning during the taxable year. Section 25A(g)(5) provides that no credit is allowed for any expenses for which a deduction is allowed under another provision of the Code.

Final regulations under section 25A were published in the **Federal Register** (67 FR 78687) on December 26, 2002. Section 1.25A–2(d)(1) of these regulations defines ''qualified tuition and related expenses'' to mean tuition and fees required for the enrollment or attendance of a student for courses of instruction at an institution. Section 1.25A–2(d)(2)(i) provides that only fees required to be paid to the institution as a condition of the student's enrollment

or attendance at the institution are treated as qualified tuition and related expenses for purposes of section 25A. Under this rule, fees for books, supplies, and equipment used in a course of study are required fees only if the fees must be paid to the institution for the enrollment or attendance of the student at the institution. See § 1.25A–2(d)(2)(ii). In addition, § 1.25A–5(e)(1) provides that an education tax credit is allowed only for payments of qualified tuition and related expenses for an academic period beginning in the same taxable year as the year the payment is made. Section 1.25A–5(e)(2) provides that qualified tuition and related expenses paid during one taxable year for an academic period beginning in the first three months of the taxable year following the taxable year in which the payment is made will be treated as paid for an academic period beginning in the same taxable year as the year the payment is made (prepayment rule).

Section 1.25A–5(f) provides rules for refunds of qualified tuition and related expenses. If qualified tuition and related expenses are paid and a refund of these expenses is received in the same taxable year, qualified tuition and related expenses for the taxable year are reduced by the amount of the refund. Section 1.25A–5(f)(1). If a taxpayer receives a refund of qualified tuition and related expenses in the current taxable year (current year) that were paid in the prior taxable year (prior year) before the taxpayer files his/her federal income tax return for the prior year, the taxpayer reduces the qualified tuition and related expenses for the prior year by the refund amount. Section 1.25A–5(f)(2). However, if the taxpayer receives the refund after filing his/her federal income tax return for the prior year, the taxpayer must increase the tax imposed for the current year by the recapture amount. Section 1.25A–5(f)(3)(i). The recapture amount is calculated in the manner provided in § 1.25A–5(f)(3)(ii). Sections 1.25A–5(f)(4) and (f)(5) provide that refunds of loan proceeds and receipt of excludable educational assistance are treated as refunds for purposes of § 1.25A–5(f)(1), (2), and (3), as appropriate.

In 2009, ARRA enacted section 25A(i), which expanded the Hope Scholarship Credit with the American Opportunity Tax Credit (AOTC) for taxable years beginning after 2008. The definition of ''qualified tuition and related expenses'' for purposes of the AOTC is broader than the definition of qualified tuition and related expenses for the Hope Scholarship Credit and the LLC because it includes expenses paid for course materials. See section 25A(i)(3).

2. Section 222—Deduction for Qualified Expenses

Section 431(a) of the Economic Growth and Tax Relief Reconciliation Act of 2001, Public Law 107–16 (115 Stat. 38) added section 222, which generally allows a deduction for qualified tuition and related expenses paid by a taxpayer during the taxable year subject to certain dollar and income limitations. Section 222(b) provides that no deduction is allowed if the taxpayer claims an education tax credit for the student.

3. Section 6050S—Information Reporting for Eligible Educational Institutions

TRA '97 also added section 6050S to require eligible educational institutions to file information returns and to furnish written statements to assist taxpayers and the IRS in determining whether a taxpayer is eligible for an education tax credit under section 25A, as well as other education tax benefits. These returns and statements are made on Form 1098–T, ''Tuition Statement.'' Prior to the enactment of PATH, section 6050S(b)(2)(B)(i) permitted institutions to report either the aggregate amount of payments received or the aggregate amount billed for qualified tuition and related expenses during the calendar year for individuals enrolled for any academic period. Institutions also must report the aggregate amount of scholarships or grants received for an individual's costs of attendance that the institution administered and processed during the calendar year. See section 6050S(b)(2)(B)(ii). Section 6050S(b)(2)(B)(iii) requires that institutions must separately report adjustments (that is, refunds of payments or reductions in charges) made during the calendar year to qualified tuition and related expenses that were reported in a prior calendar year and that institutions also must separately report adjustments (that is, refunds or reductions) made during the calendar year to scholarships that were reported in a prior calendar year. Section 6050S(b)(2)(D) requires that the information return include other information as the Secretary may prescribe.

In addition, sections 6050S(a)(2) and (a)(3) require any person engaged in a trade or business of making payments to any individual under an insurance agreement as reimbursements or refunds of qualified expenses (an insurer) or who receives from any individual $600 or more of interest during the calendar year on qualified education loans to file information returns and to furnish written information statements. Section 6050S(b)(2) provides that these information returns must contain the name, address, and TIN of any individual with respect to whom these payments were made or received, the aggregate amount of reimbursements or refunds (or similar amounts paid to such individuals during the calendar year by an insurer), the aggregate amount of interest received for the calendar year from the individual, and such other information as the Secretary may prescribe.

Section 6050S(d) provides that every person required to make a return under section 6050S(a) must furnish a written statement to each individual whose name is set forth on the return showing the name, address, and phone number of the person required to make the return and the amounts described in section 6050S(b)(2)(B). For taxable years beginning after June 29, 2015, all of the information required by section 6050S(b)(2), not just the amounts, must be included on the written statement. The written statement must be furnished by January 31 of the year following the year for which the return is required to be made.

Final regulations under section 6050S were published in the **Federal Register** (67 FR 77678) in the same Treasury Decision as the final regulations for section 25A on December 19, 2002. The section 6050S regulations provide exceptions to the reporting requirements for educational institutions for students who are nonresident aliens, for noncredit courses, for certain billing arrangements, and in cases where qualified tuition and related expenses are paid entirely with scholarships or grants. These regulations also set forth the specific information that institutions must report to the IRS, as well as information that the institution must include with the statement furnished to the student. These regulations also include requirements regarding the time and manner for soliciting the student's TIN.

4. Sections 6721, 6722 and 6724—Information Reporting Penalties and Penalty Relief

Section 6721 imposes a penalty on an eligible educational institution that fails to timely file correct information returns with the IRS. Section 6722 imposes a penalty on an educational institution that fails to timely furnish correct written statements to the student. Generally, the penalty under section 6721 and section 6722 is $100 per failure, with an annual maximum

penalty of $1.5 million. The penalty is increased to $250 per failure and the annual maximum penalty is increased to $3 million for returns required to be filed and statements required to be made after December 31, 2015. However, section 6724(a) provides that the penalty under section 6721 or 6722 may be waived if it is shown that the failure was due to reasonable cause and not due to willful neglect.

Section 301.6724–1(a)(2) provides that the penalty is waived for reasonable cause only if the filer establishes that: (1) Either there are significant mitigating factors with respect to the failure or that the failure arose from events beyond the filer's control and (2) the filer acted in a responsible manner both before and after the failure. In the case of a missing or incorrect TIN, § 301.6724–1(d)(2) provides that the filer acted in a responsible manner if the filer satisfies the solicitation requirements in § 301.6724–1(e) (regarding a missing TIN) or (f) (regarding an incorrect TIN).

Section 1.6050S–1(e)(3) provides that the rules regarding reasonable cause under § 301.6724–1 do not apply in the case of failure to include a correct TIN on a Form 1098–T. Instead, § 1.6050S–1(e)(3) provides special rules for institutions to establish reasonable cause for a failure to include a correct TIN on Form 1098–T.

Section 1.6050S–1(e)(3)(i) provides that reasonable cause for a failure to include a correct TIN on the Form 1098–T may be established if (1) the failure arose from events beyond the institution's control, such as a failure of the individual to furnish a correct TIN, and (2) the institution acted in a responsible manner before and after the failure. Section 1.6050S–1(e)(3)(ii) provides that if the institution does not have the student's correct TIN in its records, acting in a responsible manner means making a single solicitation for the TIN by December 31 of the calendar year for which the payment is made, the amount is billed, or a reimbursement is made. Section 1.6050S–1(e)(3)(iii) also provides for the manner by which an educational institution should request the individual's TIN. The solicitation must be done in writing and must clearly notify the individual that the law requires the individual to furnish a TIN so that it may be included on an information return filed by the institution. The solicitation may be made on Form W–9S, ''Request for Student's or Borrower's Taxpayer Identification Number and Certification,'' or the institution may develop its own form and incorporate it into other forms customarily used by the institution, such as financial aid forms. In the instance that an institution does not have a student's TIN in its records and the student does not provide the TIN in response to a solicitation described in § 1.6050S–1(e), the institution must file and furnish the Form 1098–T, leaving the space for the TIN blank.

5. TPEA Amendments to Sections 25A, 222 and 6724

Section 804(a) of TPEA amended section 25A by adding a new subparagraph (g)(8), which provides that, for taxable years beginning after June 29, 2015, except as provided by the Secretary, a taxpayer may not claim an education tax credit under section 25A unless the taxpayer receives a statement furnished by an eligible educational institution that contains all of the information required in section 6050S(d)(2) (that is, the recipient's copy of the Form 1098–T). Section 804(b) similarly amends section 222(d) to provide that, for taxable years beginning after June 29, 2015, except as provided by the Secretary, a taxpayer may not claim a deduction for qualified tuition and related expenses unless the taxpayer receives the recipient's copy of the Form 1098–T. For purposes of both the education tax credit and the deduction, a taxpayer who claims a student as a dependent will be treated as receiving the statement if the student receives the statement.

Section 805 of TPEA amends section 6724 by adding a new subsection (f), which provides that no penalty will be imposed under section 6721 or 6722 against an eligible educational institution solely by reason of failing to include the individual's TIN on a Form 1098–T or related statement if the institution contemporaneously certifies under penalties of perjury in the form and manner prescribed by the Secretary that it has complied with the standards promulgated by the Secretary for obtaining the individual's TIN. The provision applies to returns required to be made and statements required to be furnished after December 31, 2015.

6. PATH Amendments to Sections 25A, 222 and 6050S

a. AOTC Permanent and Section 222 Extended

Section 102(a) of PATH amends section 25A(i) to make the AOTC permanent. Section 153(a) of PATH amends section 222(e) to retroactively extend the deduction for qualified tuition and related expenses for taxable years beginning after December 31, 2014, and ending on or before December 31, 2016.

b. Amendments to Section 25A

Section 206(a)(2) of PATH amends section 25A(i) to provide that the AOTC is not allowed if the student's TIN and the TIN of the taxpayer claiming the credit is issued after the due date for filing the return for the taxable year. Pursuant to section 206(b)(1), this amendment is effective for returns (including an amended return) filed after December 18, 2015. Section 206(b)(2) of PATH provides, however, that this amendment does not apply to any return (other than an amendment to any return) for a taxable year that includes the date of enactment of PATH (December 18, 2015) if the return is filed on or before the due date for such return.

Section 211(a) of PATH amends section 25A(i) to provide that the AOTC is not allowed if the return does not include the employer identification number (EIN) of any institution to which the qualified tuition and related expenses were paid with respect to the student. This amendment is effective for taxable years beginning after December 31, 2015.

c. Amendments to Section 6050S

Section 211(b) of PATH amends section 6050S(b)(2) to require eligible educational institutions and insurers to report their EIN on the return and statement. This amendment is effective for expenses paid after December 31, 2015, for education furnished in academic periods beginning after such date.

Section 212 of PATH amends section 6050S(b)(2)(B)(i) to eliminate the option for eligible educational institutions to report aggregate qualified tuition and related expenses billed for the calendar year. Accordingly, for expenses paid after December 31, 2015, for education furnished in academic periods beginning after such date, eligible educational institutions are required to report aggregate payments of qualified tuition and related expenses received during the calendar year.

Explanation of Provisions

1. Changes To Implement TPEA and PATH

a. Changes to Section 25A and Section 222

Both TPEA and PATH add new requirements for claiming education tax benefits. Under TPEA, the student is required to receive a Form 1098–T in order to claim the LLC or the AOTC or claim the deduction under section 222. Under PATH, the ability to claim the AOTC is further limited. First, the

taxpayer can claim the AOTC only if the taxpayer includes, on his/her return for which the credit is claimed, the EIN of any educational institution to which qualified tuition and related expenses are paid. Second, the taxpayer can claim the AOTC only if the TIN of the student and the TIN of the taxpayer, on the return for which the credit is claimed, are issued on or before the due date of the original return.

i. Form 1098–T Requirement Under TPEA

Form 1098–T assists taxpayers in determining whether they are eligible to claim education tax credits under section 25A or the deduction for qualified tuition and related expenses under section 222. However, before TPEA, there was no requirement that the taxpayer (or the taxpayer's dependent if the taxpayer's dependent is the student) receive a Form 1098–T to claim these tax benefits.

Section 804 of TPEA changes the requirements for a taxpayer to claim education tax benefits under section 25A or section 222. For qualified tuition and related expenses paid during taxable years beginning after June 29, 2015, TPEA provides that, unless the Secretary provides otherwise, a taxpayer must receive a Form 1098–T to claim either a credit under section 25A or a deduction under section 222.

The proposed regulations reflect these changes. Specifically, the proposed regulations add a new paragraph (f) to § 1.25A–1 to require that for taxable years beginning after June 29, 2015, unless an exception applies, no education tax credit is allowed unless the taxpayer (or the taxpayer's dependent) receives a Form 1098–T. However, the proposed regulations explain that the amount reported on the Form 1098–T may not reflect the total amount of qualified tuition and related expenses that the taxpayer has paid during the taxable year because certain expenses are not required to be reported on the Form 1098–T. For example, under § 1.25A–2(d)(3), expenses for course materials paid to a vendor other than an eligible educational institution are eligible for the AOTC. However, because these expenses are not paid to an eligible educational institution, these expenses are not required to be reported on a Form 1098–T. Accordingly, a taxpayer who meets the requirements in § 1.25A–1(f) regarding the Form 1098–T requirement to claim the credit and who can substantiate payment of qualified tuition and related expenses may include these unreported expenses in the computation of the amount of the education tax credit allowable for the taxable year even though the expenses are not reported on a Form 1098–T.

Proposed § 1.25A–1(f)(2)(i) provides an exception to the Form 1098–T requirement in § 1.25A–1(f)(1) if the student has not received a Form 1098–T by the later of (a) January 31 of the taxable year following the taxable year to which the education credit relates or (b) the date the federal income tax return claiming the education tax credit is filed. This exception only applies if the taxpayer or taxpayer's dependent (i) has requested, in the manner prescribed in publications, forms and instructions, or published guidance, the eligible educational institution to furnish the Form 1098–T after January 31 of the year following the taxable year to which the education tax credit relates but on or before the date the return is filed claiming the education tax credit, and (ii) has cooperated fully with the eligible educational institution's efforts to obtain information necessary to furnish the statement. Proposed § 1.25A–1(f)(2)(ii) provides that the receipt of a Form 1098–T is not required if the reporting rules under section 6050S and related regulations provide that the eligible educational institution is exempt from providing a Form 1098–T to the student (for example, non-credit courses). Proposed § 1.25A–1(f)(2)(iii) also provides that the IRS may provide additional exceptions in published guidance of general applicability, see § 601.601(d)(2). The proposed regulations under § 1.25A–1(f) apply to education tax credits claimed for taxable years beginning after June 29, 2015.

Until the proposed regulations under §§ 1.25A–1(f) and 1.6050S–1(a) are published in the **Federal Register** as final regulations, a taxpayer (or the taxpayer's dependent) (other than a non-resident alien) who does not receive a Form 1098–T because its institution is exempt from furnishing a Form 1098–T under current § 1.6050S–1(a)(2) may claim an education tax credit under section 25A(a) if the taxpayer (1) is otherwise qualified, (2) can demonstrate that the taxpayer (or the taxpayer's dependent) was enrolled at an eligible educational institution, and (3) can substantiate the payment of qualified tuition and related expenses. Section 804(b) of TPEA also amends section 222 to require a Form 1098–T to claim a deduction for qualified tuition and related expenses for taxable years beginning after June 29, 2015. Rules similar to those in proposed § 1.25A–1(f), including the exceptions, apply for purposes of section 222.

ii. Identification Requirements for AOTC Under PATH

Section 206(a)(2) of PATH amends section 25A(i) to provide that the AOTC is not allowed if the student's TIN or the TIN of the taxpayer claiming the credit is issued after the due date for filing the return for the taxable year. This amendment is generally effective for any return or amended return filed after December 18, 2015. The proposed regulations reflect this change. Specifically, the proposed regulations add new § 1.25A–1(e)(2)(i), which provides that, for any federal income tax return (including an amended return) filed after December 18, 2015, no AOTC is allowed unless the student's TIN and the taxpayer's TIN are issued on or before the due date (including an extension, if timely requested) for filing the return for that taxable year.

Section 211 of PATH amends section 25A(i) to provide that the AOTC is not allowed unless the taxpayer's return includes the EIN of any institution to which the qualified tuition and related expenses were paid with respect to the student. The proposed regulations reflect this change by adding new § 1.25A–1(e)(2)(ii).

b. Changes to Section 6050S Reporting To Conform With TPEA 1098–T Requirement

i. Exceptions To Reporting Requirement and Clarifying Changes

Currently, the regulations under section 6050S include exceptions to reporting. For instance, under § 1.6050S–1(a)(2)(i), institutions are not required to file a Form 1098–T with the IRS or provide a Form 1098–T to a nonresident alien, unless the individual requests a Form 1098–T. Under § 1.6050S–1(a)(2)(ii), institutions are not required to report information with respect to courses for which no academic credit is awarded. In addition, reporting is not required with respect to individuals whose qualified tuition and related expenses are paid entirely with scholarships under § 1.6050S–1(a)(2)(iii) or individuals whose qualified tuition and related expenses are paid under a formal billing arrangement under § 1.6050S–1(a)(2)(iv).

The exceptions in §§ 1.6050S–1(a)(2)(i), (iii), and (iv) to reporting on Form 1098–T are inconsistent with the TPEA, which generally requires a student to receive a Form 1098–T from the educational institution to claim a section 25A education credit. With these exceptions, a significant number of taxpayers claiming the credit will not have a Form 1098–T, which would frustrate the explicit purpose of TPEA.

Therefore, the proposed regulations remove these exceptions.

Removal of the exceptions in §§ 1.6050S–1(a)(2)(i), (iii), and (iv) also assists students. Students to whom these exceptions apply are deprived of important information that they need to determine their eligibility for education tax credits. The Form 1098–T provides students with the amount of tuition paid (or billed for calendar year 2016 only), the amount of scholarships and grants that the institution administered and processed, and an indication of whether the student was enrolled at least a half time for an academic period. Students who do not receive a Form 1098–T cannot use the information that would be provided on the form to assist them in determining the proper amount of education credits they may claim. Further, removal of these exceptions will improve the IRS's ability to use the Form 1098–T to verify whether taxpayers should be allowed the education tax benefits that are claimed. In addition, removal of these exceptions would improve the IRS's ability to determine whether the institutions are complying with their reporting obligations.

The proposed regulations would not remove the exception to reporting under § 1.6050S–1(a)(2)(ii) for courses for which no academic credit is awarded. Treasury and the IRS understand that in many cases fees for these courses are charged outside of the financial systems used for students who are taking courses for credit. In addition, given that non-credit courses would not be eligible for the AOTC (or Hope Credit) and would only be eligible for the LLC if the student is taking the course to acquire or improve job skills, reporting expenses paid for non-credit courses could cause confusion and unintended non-compliance.

Treasury and the IRS believe that students benefit from receipt of the Form 1098–T because the information on the form assists the student in determining eligibility for education tax benefits that make higher education more affordable. Reporting that does not provide useful information to students and the IRS, however, unduly burdens institutions and the IRS and could confuse students about whether they are eligible to claim education tax benefits. Therefore, Treasury and the IRS are asking for comments regarding exceptions to the reporting under section 6050S. Specifically, comments are requested regarding the exception to reporting for students who are nonresident aliens, including how an institution determines that a student is a nonresident alien and experience administering the existing exception. Comments are also requested regarding whether the exception for noncredit courses should be retained, and if so, whether there should be any changes to the exception.

The proposed regulations also revise the information that institutions are required to report on the Form 1098–T in an effort to provide more precise information for students to use when determining eligibility for and the amount of an education tax credit and for the IRS to use to verify compliance with the requirements for claiming the education tax credits. For instance, the current regulations under § 1.6050S–1(b)(2)(ii)(D) require that the Form 1098–T include an indication of whether amounts reported relate to an academic period that begins in the first three months of the next calendar year pursuant to the prepayment rule in § 1.25A–5(e)(2). The proposed regulations revise this section to include a requirement that the amount paid that relates to an academic period that begins in the first three months of the next calendar year be specifically stated on the Form 1098–T. This will assist the IRS in identifying credits claimed in two years for the same qualified tuition and related expenses.

In addition, the proposed regulations add a new paragraph (I) to § 1.6050S–1(b)(2)(ii) to require the institution to indicate the number of months that a student was a full-time student during the calendar year. The proposed regulations also add to that paragraph a definition of what constitutes a month. This information will assist the IRS in determining whether a parent properly claimed the student as a dependent and, therefore, properly claimed the credit for the student's qualified tuition and related expenses. See § 1.25A–1(f) for rules relating to claiming the credit in the case of a dependent.

The proposed regulations clarify § 1.6050S–1(b)(2)(v) regarding the rules for determining the amount of payments received for qualified tuition and related expenses. This clarification is intended to provide a uniform rule for all institutions to determine whether a payment received by an institution should be reported on a Form 1098–T as qualified tuition and related expenses in the current year. Under the proposed rule, payments received during a calendar year are treated first as payments of qualified tuition and related expenses up to the total amount billed by the institution for qualified tuition and related expenses for enrollment during the calendar year and then as payments of expenses other than qualified tuition and related expenses for enrollment during the calendar year. A similar rule applies in the case of payments received during the calendar year with respect to enrollment in an academic period beginning during the first three months of the next calendar year. In that case, the payments received by the institution with respect to the amount billed for enrollment in an academic period beginning during the first three months of the next calendar year are treated as payments of qualified tuition and related expenses for the calendar year in which the payments are received. Examples have been added to § 1.6050S–1(b)(2)(vii) to illustrate these rules. Treasury and the IRS request comments regarding these rules, including alternative approaches and recommendations for addressing other issues that should be covered by these rules.

The proposed regulations also revise § 1.6050S–1(c)(1)(iii) regarding the instructions accompanying the Form 1098–T that the institution must furnish to students. The proposed regulations add a new paragraph (D) to § 1.6050S–1(c)(1)(iii) to require institutions to include a paragraph in the instructions informing students that they may be able to optimize their federal tax benefits by taking a portion of a scholarship or grant into income. This new paragraph will alert students about their ability to optimize their federal education tax benefits by allocating all or a portion of their scholarship or grant to pay the student's actual living expenses (if permitted by the terms of the scholarship or grant) by including such amounts in income on the student's tax return if the student is required to file a return. By including such amounts in income, the scholarship or grant is no longer tax free, and the student is not required to reduce qualified tuition and related expenses by the amount paid with the now taxable scholarship or grant. See section 25A(g)(2) and § 1.25A–5(c)(3) for rules regarding allocation of scholarships and grants between qualified tuition and related expenses and other expenses. Minor revisions have also been made to the other paragraphs required to be included in instructions, including addition of the name of the form (Form 1098–T) on which reporting occurs and specific identification of Publication 970, ''Tax Benefits for Education,'' as a resource for taxpayers.

The proposed regulations also provide a definition of ''administered and processed'' for purposes of determining which scholarships and grants an institution is required to report on the Form 1098–T. The current regulations

do not have a definition of this term, and the lack of a definition has resulted in uncertainty and inconsistent reporting. The proposed regulations resolve this by adding a definition of ''administered and processed'' to § 1.6050S–1(e)(1)(i). Under this definition, a scholarship or grant is administered and processed by an institution if the institution receives payment of an amount (whether by cash, check, or other means of payment) that the institution knows or reasonably should know, is a scholarship or grant, regardless of whether the institution is named as the payee or a co-payee of the amount and regardless of whether, in the case of a payment other than in cash, the student endorses the check or other means of payment for the benefit of the institution. Pell Grants are provided as an example of a scholarship or grant that is treated as administered and processed by an institution.

ii. PATH Eliminates Option To Report Amount Billed

These proposed regulations also implement the amendment to section 6050S(b)(2)(B)(i) under PATH, which eliminates the option for eligible educational institutions to report the aggregate amount billed for qualified tuition and related expenses for expenses paid after December 31, 2015, for education furnished in academic periods beginning after such date. Eligible educational institutions have informed the IRS that they cannot implement the necessary changes in technology to enable reporting of aggregate payments of qualified tuition and expenses for the first year in which the statutory amendment applies, calendar year 2016. Therefore, in Announcement 2016–17, I.R.B. 2016–20, the IRS stated that it will not impose penalties under section 6721 or 6722 against an eligible educational institution required to file 2016 Forms 1098–T solely because the institution reports the aggregate amount billed for qualified tuition and expenses rather than the aggregate payments of qualified tuition and related expenses received. Thus, for calendar year 2016, no penalties will be imposed if an educational institution fails to implement the PATH's amendment to section 6050S(b)(2)(B)(i) and continues to report the amount billed.

The proposed regulations reflect the PATH amendment by eliminating the option to report the amount billed. These regulations are proposed to be effective on publication of final regulations in the **Federal Register**. In the interim, the limited penalty relief in Announcement 2016–17 will apply to allow educational institutions to report the amount billed for calendar year 2016.

iii. No Change Required To Implement EIN Reporting Requirement

Current regulations under § 1.6050S–1(b)(2)(ii)(A) require that the eligible educational institution report its name, address, and TIN on the Form 1098–T. Accordingly, the amendment to section 6050S(b)(2) by section 211(b) of PATH requiring eligible educational institution and insurers to report their EIN does not require a change to the regulations.

c. Changes To Implement New Section 6724(f)

Section 1.6050S–1(f)(4) of the proposed regulations reflects the enactment of section 6724(f) by section 805 of TPEA. Under section 6724(f), the IRS may not impose information reporting penalties under section 6721 and section 6722 against an eligible educational institution for failure to include a correct TIN on the Form 1098–T if the institution certifies compliance with IRS standards for soliciting TINs. Relief under section 6724(f) applies only to eligible educational institutions and does not apply to insurers required to file Forms 1098–T under section 6050S(a)(2).

The IRS generally sends penalty notices to taxpayers who fail to file information returns when required or who file incorrect information returns. Filers seeking penalty relief based on reasonable cause must respond to the penalty notice with a statement explaining how the filer qualifies for relief. Under section 6724(f), however, no penalty under section 6721 or 6722 is imposed in the first instance if the educational institution contemporaneously makes a true and accurate certification under penalties of perjury in such form and manner as may be prescribed by the Secretary that it complied with the standards promulgated by the Secretary to obtain the student's TIN. Section 6724(f) is effective for returns required to be filed and statements required to be furnished after December 31, 2015.

Standards for obtaining the student's TIN are set forth in § 1.6050S–1(e)(3)(ii) and (iii) of the existing regulations. These regulations are proposed to be redesignated as § 1.6050S–1(f)(3)(ii) and (iii). Under these standards, the institution does not have to solicit a student's TIN, but may use the TIN that it has in its records. If the institution does not have the student's correct TIN in its records, then it must solicit the TIN in the time and manner described in redesignated § 1.6050S–1(f). To implement section 6724(f), § 1.6050S–1(f)(4) of the proposed regulations has been added to provide that for returns required to be filed and statements required to be furnished after December 31, 2015, the IRS will not impose a penalty against an institution under section 6721 or 6722 for failure to include the student's correct TIN on the return or statement if the institution certifies to the IRS under penalties of perjury in the form and manner prescribed by the Secretary in publications, forms and instructions, or other published guidance at the time of filing of the return that the institution complied with the requirements in § 1.6050S–1(f)(3)(ii) and (iii). However, the proposed regulations make clear that the certification will not protect the institution from penalty if the IRS determines subsequently that the requirements of § 1.6050S–1(f)(3)(ii) and (iii) were not satisfied or if the failure to file correct information returns relates to something other than a failure to provide the correct TIN for the student. In addition, a cross-reference is proposed to be added to the regulations under section 6724 to alert taxpayers that the rules for penalty relief for eligible educational institutions with respect to reporting obligations under section 6050S are contained in § 1.6050S–1(f).

d. Penalty Relief Under Section 6724(f) for Calendar Year 2015 Forms 1098–T

Section 6724(f) requires the IRS to develop procedures enabling an eligible educational institution to avoid imposition of the section 6721 and section 6722 penalty for failure to include a student's correct TIN on the Form 1098–T by certifying under penalties of perjury at the time of filing or furnishing the form that the institution complied with the IRS standards for obtaining a student's TIN. In Announcement 2016–03, I.R.B. 2016–4, the IRS stated that it will not impose penalties under section 6721 or 6722 against an eligible educational institution required to file Forms 1098–T for calendar year 2015 solely because the student's TIN is missing or incorrect.

2. Other Changes to Regulations Under Section 25A and Section 6050S

The proposed regulations also update and clarify the regulations under section 25A. The proposed regulations update § 1.25A–2(d) to reflect the changes made by ARRA allowing students to claim the AOTC for expenses paid for course materials (such as books, supplies, and equipment) required for enrollment or attendance, whether or not the course

materials are purchased from the institution. Prior to ARRA, the term ''qualified tuition and related expenses'' included tuition and fees, but did not include course materials, such as books, unless the cost of these materials was a fee that was required to be paid to the institution as a condition of attendance or enrollment. See section 25A(f)(1) and § 1.25A–2(d)(2)(ii).

When Congress enacted the AOTC in 2009, it expanded the definition of qualified tuition and related expenses for purposes of the AOTC to include expenses paid for course materials. See H.R. Conf. Rep. 111–16, 111th Cong., 1st Sess. p. 525 (February 29, 2009). Course materials are qualified expenses only for the AOTC and not for the LLC. See Tax Increase Prevention Act of 2014 (Pub. L. 113–295, 128 Stat. 4010). The proposed regulations update § 1.25A–2(d) to provide that, for purposes of claiming the AOTC for tax years beginning after December 31, 2008, the definition of qualified tuition and related expenses includes not only tuition and fees required for enrollment or attendance at an eligible educational institution, but also expenses paid for course materials needed for enrollment or attendance at an eligible educational institution. Accordingly, after ARRA, for purposes of claiming the Hope Scholarship Credit and LLC, qualified tuition and related expenses continue to exclude the cost of books, supplies, and equipment if they can be purchased from any vendor. However, for purposes of claiming the AOTC, qualified tuition and related expenses includes the cost of course materials such as books, supplies and equipment that is needed for meaningful attendance or enrollment in a course of study, whether or not the materials are purchased from the institution. The proposed regulations provide an example that illustrates that for purposes of the AOTC qualified tuition and related expenses includes the cost of course material, including books, even if a taxpayer purchases these materials from a vendor other than the institution.

In addition, the proposed regulations add a new section under section 6050S to eliminate uncertainty in the reporting requirements that may result from these proposed amendments to § 1.25A–2(d). Under proposed § 1.6050S–1(a)(2)(i), an institution is not required to report the amount paid or billed for books, supplies, and equipment unless the amount is a fee that must be paid to the eligible educational institution as a condition of enrollment or attendance under § 1.25A–2(d)(2)(ii).

The proposed regulations also clarify the example in § 1.25A–5(e)(2)(ii) regarding the prepayment rule. Under § 1.25A–5(e)(2)(i), if qualified tuition and related expenses are paid during one taxable year for an academic period that begins during the first three months of the taxpayer's next taxable year (that is, in January, February, or March of the next taxable year for calendar year taxpayers), an education tax credit is allowed for the qualified tuition and related expenses only in the taxable year in which the taxpayer pays the expenses. The Treasury Department and the IRS are aware that there is some uncertainty regarding the application of the prepayment rule to amounts paid in the prior year and the current year for an academic period beginning during the current year. The proposed regulations clarify the proper treatment in this situation by expanding the Example in § 1.25A–5(e)(2)(ii) to illustrate that a student who pays part of a semester's tuition in Year 1, and the remainder in Year 2, may claim a credit for Year 1, for the portion of the tuition paid in December Year 1 and a separate credit for Year 2 for the portion of the tuition paid in February Year 2.

The proposed regulations also clarify the rules under § 1.25A–5(f) regarding a refund of qualified tuition and related expenses received from an eligible educational institution. The current regulations do not address the situation where the taxpayer receives a refund in the current taxable year of qualified tuition and related expenses for an academic period beginning in the current taxable year for which payments were made during the prior taxable year under the prepayment rule and payments were made during the current taxable year. To address this situation, the proposed regulations provide that the taxpayer may allocate the refund in any proportion to reduce qualified tuition and related expenses paid in either taxable year, except that the amount of the refund allocated to a taxable year may not exceed the qualified tuition and related expenses paid in the taxable year for the academic period to which the refund relates. The sum of the amounts allocated to each taxable year cannot exceed the amount of the refund. The proposed regulations add an example to illustrate this rule.

Proposed Effective and Applicability Dates

These regulations are proposed to take effect when published in the **Federal Register** as final regulations.

Statement of Availability of IRS Documents

IRS published guidance cited in this preamble is published in the Internal Revenue Bulletin and is available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS Web site at *http://www.irs.gov.*

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations.

It is hereby certified that the collection of information in this notice of proposed rulemaking will not have a significant economic impact on a substantial number of small entities within the meaning of section 601(6) of the Regulatory Flexibility Act (5 U.S.C. chapter 6). The type of small entities to which the regulations may apply are small eligible educational institutions (generally colleges and universities eligible to receive federal financial aid for education under the Higher Education Act of 1965). This certification is based on the fact that few, if any, new eligible educational institutions will be subject to reporting and the changes made by this notice of proposed rulemaking require little, if any, additional time for compliance by institutions currently subject to reporting requirements. The collection of information in this regulation implements the statute and should not require eligible educational institutions to collect information that is not already maintained by the institution. Eligible educational institutions have been subject to information reporting under section 6050S since 1998, and the obligations under the existing final regulations that are the foundation for these proposed regulations are already in place. Any additional information returns required to be filed under this notice of proposed rulemaking should result in few, if any, new eligible educational institutions being subject to reporting that were not already required to file Forms 1098–T. Only eligible educational institutions, not all educational institutions, are subject to these reporting rules. For this purpose, an eligible educational institution means an institution described in section 481 of the Higher Education Act of 1965 (20 U.S.C. 1088) as in effect on the date of enactment (August 5, 1997), and which is eligible to participate in a program under title IV of such act (generally colleges and universities whose students are eligible to receive

federal financial aid for higher education). See sections 25A(f)(2) and 6050S(e). Further, this notice of proposed rulemaking contains modifications that should simplify compliance and thereby reduce the time needed to comply with the information reporting obligations under section 6050S. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act is not required. Pursuant to section 7805(f) of the Code, this proposed regulation has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses. The Internal Revenue Service invites the public to comment on this certification.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the **DATES** and **ADDRESSES** headings. The Treasury Department and the IRS request comments on all aspects of the proposed rules. All comments will be available at *www.regulations.gov* or upon request.

A public hearing has been scheduled for November 30, 2016 at 10:00 a.m. in the IRS Auditorium, Internal Revenue Service Building, 1111 Constitution Avenue NW., Washington, DC 20224. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed onto the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit written or electronic comments by October 31, 2016 and an outline of the topics to be discussed and the time to be devoted to each topic (a signed original and eight (8) copies) by October 31, 2016. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these proposed regulations is Gerald Semasek of the Office of Associate Chief Counsel (Procedure and Administration) for the proposed regulations under section 6050S and section 6724 and Sheldon Iskow of the Office of Associate Chief Counsel (Income Tax and Accounting) for the proposed regulations under section 25A.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 301 are proposed to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

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

■ **Par. 2.** Section 1.25A–0 is amended by:
■ 1. Revising the entry for § 1.25A–1(e)(1) introductory text.
■ 2. Adding entries for § 1.25A–1(e)(1), (2), and (3).
■ 3. Revising the entries for § 1.25A–1(f) introductory text and (f)(2).
■ 4. Adding entries for § 1.25A–1(f)(3) and (4).
■ 5. Revising the entries for § 1.25A–1(g) and (h).
■ 6. Adding an entry for § 1.25A–1(i).
■ 7. Revising the entries for §§ 1.25A–2(d)(3), (4), (5), and (6).
■ 8. Adding entries for §§ 1.25A–2(d)(7) and (e).
■ 9. Revising the entry for § 1.25A–2(f)(6).
■ 10. Adding entries for §§ 1.25A–5(f)(7) and (g).

The revisions and additions read as follows:

§ 1.25A–0 Table of Contents.

* * * * *

§ 1.25A–1 Calculation of Education Tax Credit and General Eligibility Requirements

* * * * *

(e) Identification requirements.
(1) In general.
(2) Additional identification requirements for the American Opportunity Tax Credit.
(i) TIN must be issued on or before the due date of the original return.
(ii) Return must include the eligible educational institution's employer identification number (EIN).
(3) Effective/applicability dates.
(f) Statement requirement.

* * * * *

(2) Exceptions.
(3) Transition rule.
(4) Effective/applicability date.
(g) Claiming the credit in the case of a dependent.
(h) Married taxpayers.
(i) Nonresident alien taxpayers and dependents.

§ 1.25A–2 Definitions

* * * * *

(d) * * *
(3) Course materials for the American Opportunity Tax Credit for taxable years beginning after December 31, 2008.
(4) Personal expenses.
(5) Treatment of a comprehensive or bundled fee.
(6) Hobby courses.
(7) Examples.
(e) Effective/applicability date.

* * * * *

§ 1.25A–5 Special Rules Relating to Characterization and Timing of Payments

* * * * *

(f) * * *
(6) Treatment of refunds where qualified tuition and related expenses paid in two taxable years for the same academic period.
(7) Examples.
(g) Effective/applicability date.

■ **Par. 3.** Section 1.25A–1 is amended by:
■ 1. Revising paragraph (e).
■ 2. Redesignating paragraphs (f), (g), and (h) as paragraphs (g), (h), and (i), respectively.
■ 3. Adding a new paragraph (f).
■ 4. In newly redesignated paragraph (g)(2), removing the language ''(f)'' and adding ''(g)'' in its place.

The revisions and additions read as follows:

§ 1.25A–1 Calculation of education tax credit and general eligibility requirements.

* * * * *

(e) *Identification requirements*—(1) *In general.* No education tax credit is allowed unless a taxpayer includes on the federal income tax return claiming the credit the name and the taxpayer identification number (TIN) of the student for whom the credit is claimed. For rules relating to assessment for an omission of a correct taxpayer identification number, see section 6213(b) and (g)(2)(J).

(2) *Additional identification requirements for the American*

Opportunity Tax Credit (AOTC)—(i) *TIN must be issued on or before the due date of the original return.* For any federal income tax return (including an amended return) filed after December 18, 2015, no AOTC is allowed unless the TIN of the student and the TIN for the taxpayer claiming the credit are issued on or before the due date, or the extended due date if the extension request is timely filed, for filing the return for the taxable year for which the credit is claimed.

(ii) *Return must include the eligible educational institution's employer identification number (EIN).* For taxable years beginning after December 31, 2015, no AOTC is allowed unless the taxpayer includes the EIN of each eligible educational institution to which qualified tuition and related expenses were paid.

(3) *Applicability dates.* (i) Except as provided in paragraphs (e)(3)(ii) and (iii) of this section, this paragraph (e) applies on or after December 26, 2002.

(ii) Paragraph (e)(2)(i) of this section applies to federal income tax returns (including amended returns) filed after December 18, 2015.

(iii) Paragraph (e)(2)(ii) of this section applies to taxable years beginning after December 31, 2015.

(f) *Statement requirement*—(1) *In general.* Except as provided in paragraph (f)(2) of this section, for taxable years beginning after June 29, 2015, no education tax credit is allowed unless the taxpayer (or the taxpayer's dependent) receives a statement furnished by an eligible educational institution, as defined in § 1.25A–2(b), containing all of the information required under § 1.6050S–1(b)(2). The amount of qualified tuition and related expenses reported on the statement furnished by an eligible educational institution may not reflect the total amount of the qualified tuition and related expenses paid during the taxable year for which a taxpayer may claim an education tax credit. A taxpayer that substantiates payment of qualified tuition and related expenses that are not reported on Form 1098–T, ''Tuition Statement'', may include those expenses in computing the amount of the education tax credit allowable for the taxable year.

(2) *Exceptions.* Paragraph (f)(1) of this section does not apply—

(i) If the taxpayer or the taxpayer's dependent:

(A) Has not received such a statement from an eligible educational institution required to furnish such statement under section 6050S and the regulations thereunder as of January 31 of the year following the taxable year to which the education tax credit relates or the date the return is filed claiming the education tax credit, whichever is later;

(B) Has requested, in the manner prescribed in forms, instructions, or in other published guidance, the eligible educational institution to furnish the Form 1098–T after January 31 of the year following the taxable year to which the education tax credit relates but on or before the date the return is filed claiming the education tax credit; and

(C) Has cooperated fully with the eligible educational institution's efforts to obtain information necessary to furnish the statement;

(ii) If the eligible educational institution is not required to furnish a statement to the student under section 6050S and the regulations thereunder; or

(iii) As otherwise provided in published guidance of general applicability, see § 601.601(d)(2) of this chapter.

(3) *Applicability date.* Paragraph (f) of this section applies to credits claimed for taxable years beginning after June 29, 2015.

* * * * *

■ **Par. 4.** Section 1.25A–2 is amended by:

■ 1. Revising paragraphs (d)(2)(i) and (ii).

■ 2. In paragraph (d)(2)(iii), removing the language ''(d)(3)'' and adding ''(d)(4)'' in its place.

■ 3. Redesignating paragraphs (d)(3), (4), (5), and (6) as paragraphs (d)(4), (5), (6), and (7), respectively.

■ 4. Adding a new paragraph (d)(3).

■ 5. In newly redesignated paragraph (d)(5), by removing the language ''(d)(3)'' and adding ''(d)(4)'' in its place.

■ 6. In newly redesignated paragraph (d)(7), revising *Example 2,* redesignating *Examples 3, 4, 5,* and *6,* as *Examples 4, 5, 6,* and *7,* and adding a new *Example 3.*

■ 7. Adding paragraph (e).

The revisions and additions read as follows:

§ 1.25A–2 Definitions.

* * * * *

(d) * * *

(2) *Required fees*—(i) *In general.* Except as provided in paragraphs (d)(3) and (4) of this section, the test for determining whether any fee is a qualified tuition and related expense is whether the fee is required to be paid to the eligible educational institution as a condition of the student's enrollment or attendance at the institution.

(ii) *Books, supplies, and equipment.* For taxable years beginning before January 1, 2009, for purposes of the Hope Scholarship Credit, and for taxable years beginning after December 31, 1997, for purposes of the Lifetime Learning Credit, qualified tuition and related expenses include fees for books, supplies, and equipment used in a course of study only if the fees must be paid to the eligible educational institution for the enrollment or attendance of the student at the institution. For taxable years beginning after December 31, 2008, see paragraph (d)(3) of this section for rules relating to books, supplies and equipment for purposes of the American Opportunity Tax Credit.

* * * * *

(3) *Course materials for the American Opportunity Tax Credit for taxable years beginning after December 31, 2008.* For taxable years beginning after December 31, 2008, the term ''qualified tuition and related expenses'' for purposes of the American Opportunity Tax Credit under section 25A(i) includes the amount paid for course materials (such as books, supplies, and equipment) required for enrollment or attendance at an eligible educational institution. For this purpose, ''required for enrollment or attendance'' means that the course materials are needed for meaningful attendance or enrollment in a course of study, regardless of whether the course materials are purchased from the institution.

* * * * *

(7) * * *

Example 2. First-year students attending College W during 2008 are required to obtain books and other materials used in its mandatory first-year curriculum. The books and other reading materials are not required to be purchased from College W and may be borrowed from other students or purchased from off-campus bookstores, as well as from College W's bookstore. College W bills students for any books and materials purchased from College W's bookstore. The expenses paid for the first-year books and materials purchased at College W's bookstore are not qualified tuition and related expenses because under § 1.25A–2(d)(2)(ii) the books and materials are not required to be purchased from College W for enrollment or attendance at the institution. In addition, expenses paid for the first-year books and materials borrowed from other students or purchased from vendors other than College W's bookstore are also not qualified tuition and related expenses because under § 1.25A–2(d)(2)(ii) the books and materials are not required to be purchased from College W for enrollment or attendance at the institution.

Example 3. Assume the same facts as *Example 2,* except that the books and materials are required for first-year students attending College W during 2009. Because the expenses are paid with respect to enrollment or attendance after 2008, § 1.25A–1(d)(3) applies rather than § 1.25A–1(d)(2)(ii), if the taxpayer claims the American

Opportunity Tax Credit under section 25A(i). Under § 1.25A–1(d)(3), expenses for books and other course materials are qualified tuition and related expenses for purposes of the American Opportunity Tax Credit if they are needed for meaningful attendance in the student's course of study at College W. Accordingly, if the taxpayer claims the American Opportunity Tax Credit for 2009, the expenses paid for the first-year books and materials are qualified tuition and related expenses. However, if the taxpayer claims the Lifetime Learning Credit for 2009 under section 25A(c), § 1.25A–2(d)(2)(ii) applies rather than § 1.25A–1(d)(3). Accordingly, if the taxpayer claims the Lifetime Learning Credit, the expenses paid for the first-year books and materials purchased at College W's bookstore are not qualified tuition and related expenses because under § 1.25A–2(d)(2)(ii) the books and materials are not required to be purchased from College W for enrollment or attendance at the institution.

* * * * *

(e) *Applicability date.* (1) Except as provided in paragraph (e)(2) of this section, this section applies on or after December 26, 2002.

(2) Paragraphs (d)(2)(i), (d)(2)(ii), (d)(3), and *Examples 2* and *3* of paragraph (d)(7) of this section apply to qualified tuition and related expenses paid, and education furnished in academic periods beginning, on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. However, taxpayers may apply paragraphs (d)(2)(i), (d)(2)(ii), (d)(3), and *Examples 2* and *3* of paragraph (d)(7) of this section for taxable years beginning after December 31, 2008, for which the period of limitations on filing a claim for credit or refund under section 6511 has not expired.

■ **Par. 5.** Section 1.25A–5 is amended by:

■ 1. In paragraph (e)(2)(ii), revising the *Example.*

■ 2. Redesignating paragraph (f)(6) as paragraph (f)(7).

■ 3. Adding a new paragraph (f)(6).

■ 4. In newly redesignated paragraph (f)(7), adding *Example 4.*

■ 5. Adding paragraph (g).

The revisions and additions read as follows:

§ 1.25A–5 Special rules relating to characterization and timing of payments.

* * * * *

(e) * * *

(2) * * *

(ii) * * *

Example. In December 2016, Taxpayer A, a calendar year taxpayer who is not a dependent of another taxpayer under section 151, receives a bill from College Z for $5,000 for qualified tuition and related expenses to attend College Z for the 2017 spring semester, which begins in January 2017. This is the first semester that Taxpayer A will attend College Z. On December 15, 2016, Taxpayer A pays College Z $1,000 in qualified tuition and related expenses for the 2017 spring semester. On February 15, 2017, Taxpayer A pays College Z the remaining $4,000 due for qualified tuition and related expenses for the 2017 spring semester. In August 2017, Taxpayer A receives a bill from College Z for $7,000 for qualified tuition and related expenses to attend College Z for the 2017 fall semester, which begins in September 2017. Taxpayer A pays the entire $7,000 on September 1, 2017. In December 2017, Taxpayer A receives a bill from College Z for $7,000 for qualified tuition and related expenses to attend for the 2018 spring semester. Taxpayer A pays $1,000 of the 2018 spring semester bill on December 15, 2017 and $6,000 of that bill in February 15, 2018. Taxpayer A does not enroll in an eligible educational institution for the 2018 fall semester or the 2019 spring semester. Taxpayer A may claim an education tax credit on Taxpayer A's 2016 Form 1040 with respect to the $1,000 taxpayer paid to College Z on December 15, 2016 for the 2017 spring semester. On Taxpayer A's 2017 Form 1040, Taxpayer A may claim an education credit with respect to the $12,000 Taxpayer A paid to College Z during 2017 ($4,000 paid on February 15, 2017 for the 2017 spring semester, $7,000 paid on September 1, 2017, for the 2017 fall semester, and $1,000 paid on December 15, 2017, for the 2018 spring semester). On Taxpayer A's 2018 Form 1040, Taxpayer A may claim an education credit with respect to the $6,000 taxpayer paid to College Z on February 15, 2018.

* * * * *

(f) * * *

(6) *Treatment of refunds where qualified tuition and related expenses paid in two taxable years for the same academic period.* If a taxpayer or someone other than the taxpayer—

(i) Pays qualified tuition and related expenses in one taxable year (prior taxable year) for a student's enrollment or attendance at an eligible educational institution during an academic period beginning in the first three months of the taxpayer's next taxable year (subsequent taxable year);

(ii) Pays qualified tuition and related expenses in the subsequent taxable year for the academic period beginning in the first three months of the subsequent taxable year; and

(iii) Receives a refund of qualified tuition and related expenses during the subsequent taxable year for the academic period beginning in the first three months of the subsequent taxable year (including an amount treated as a refund under paragraph (f)(4) or (5) of this section), the taxpayer may allocate the refund in any proportion to qualified tuition and related expenses paid in the prior taxable year under paragraph (f)(2) or (3) of this section or the subsequent taxable year under paragraph (f)(1) of this section, except that the amount of the refund allocated to a taxable year may not exceed the qualified tuition and related expenses paid during the taxable year with respect to the academic period beginning in the subsequent taxable year. The sum of the amounts allocated to each taxable year cannot exceed the amount of the refund.

(7) * * *

Example 4. In December 2016, Taxpayer D, a calendar year taxpayer who is not a dependent of another taxpayer under section 151, receives a bill from University X for $2,000 for qualified tuition and related expenses to attend University X as a full-time student for the 2017 spring semester, which begins in January 2017. In December 2016, D pays $500 of qualified tuition and related expenses for the 2017 spring semester. In January 2017, D pays an additional $1,500 of qualified tuition and related expenses for the 2017 spring semester. Early in the 2017 spring semester, D withdraws from several courses and no longer qualifies as a full-time student. As a result of D's change in status from a full-time student to a part-time student, D receives a $750 refund from University X on February 16, 2017. D has no other qualified tuition and related expenses for 2017. Under paragraph (f)(6) of this section, D may allocate all, or a portion, of the $750 refund to reduce the $1,500 of qualified tuition and related expenses paid in 2017 or D may also allocate a portion of the $750 refund, up to $500, to reduce the qualified tuition and related expenses paid in 2016 and allocate the remainder of the refund to reduce the qualified tuition and related expenses paid in 2017.

(g) *Applicability date.* (1) Except as provided in paragraph (g)(2) of this section, this section applies on or after December 26, 2002.

(2) Paragraphs (e)(2)(ii), (f)(6), and *Example 4* in paragraph (f)(7) of this section apply to qualified tuition and related expenses paid and education furnished in academic periods beginning on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. However, taxpayers may apply paragraphs (e)(2)(ii), (f)(6), and *Example 4* in paragraph (f)(7) of this section in taxable years for which the limitation on filing a claim for credit or refund under section 6511 has not expired.

■ **Par. 6.** Section 1.6050S–0 is amended by:

■ 1. Revising the entry for § 1.6050S–1(a)(2)(i).

■ 2. Removing the entries for § 1.6050S–1(a)(2)(iii) and (iv).

■ 3. Revising the entries for § 1.6050S–1(b)(2) introductory text and (b)(2)(ii).

■ 4. Revising the entry for § 1.6050S–1(b)(3) introductory text.

■ 5. Removing the entries for § 1.6050S–1(b)(3)(iii), (iv) and (v).

■ 6. Revising the entry for § 1.6050S–1(b)(4).
■ 7. Removing the entry for § 1.6050S–1(b)(5).
■ 8. Redesignating the entry for § 1.6050S–1(b)(6) as § 1.6050S–1(b)(5).
■ 9. Adding entries for § 1.6050S–1(c)(1)(i), (ii) and (iii).
■ 10. Removing the entry for § 1.6050S–1(c)(2)(ii).
■ 11. Redesignating the entry for § 1.6050S–1(c)(2)(iii) as § 1.6050S–1(c)(2)(ii).
■ 12. Redesignating the entries for § 1.6050S–1(e) and § 1.6050S–1(f) as § 1.6050S–1(f) and § 1.6050S–1(g), respectively.
■ 13. Adding a new entry for § 1.6050S–1(e).
■ 14. Revising the newly redesignated entry for § 1.6050S–1(f)(4).
■ 15. Adding a new entry for § 1.6050S–1(f)(5).

The revisions and additions to read as follows:

§ 1.6050S–0 Table of contents.

* * * * *

§ 1.6050S–1 Information reporting for qualified tuition and related expenses.

(a) * * *
(2) * * *
(i) No reporting of amounts for books, supplies and equipment unless the amount is a fee required to be paid to the institution.
(A) In general.
(B) Examples.

* * * * *

(b) * * *
(2) Information reporting requirements for educational institutions for qualified tuition and related expenses.

* * * * *

(ii) Information included on return.
(A) Name, address and TIN of institution
(B) Name address and TIN of individual enrolled at institution
(C) Amount of payments of qualified tuition and related expenses
(D) Indication of whether payments pertain to academic period commencing in first three months of following calendar year
(E) Amount of scholarships or grants
(F) Amount of reimbursements or refunds pertaining to expenses reported in prior year
(G) Amount of reductions of scholarships or grants
(H) Statement of whether individual enrolled for at least half of normal full-time work load
(I) Number of months during which individual enrolled for normal full-time workload
(J) Statement of individual's enrollment in graduate-level program
(K) Any additional information required by Form 1098–T or instructions

* * * * *

(3) Requirements for insurers.

* * * * *

(4) Time and place for filing return.
(i) In general.
(ii) Extensions of time.

* * * * *

(c) * * *
(1) * * *
(i) Required information.
(ii) Legend identifying statement as important tax information.
(iii) Instructions.
(A) Statement of payments made or reimbursements or refunds made.
(B) Statement regarding extent of individual's eligibility for credit under section 25A.
(C) Statement regarding reduction in tax credit due to grant or scholarship.
(D) Statement notifying individual of ability to allocate scholarship or grant.
(E) Statement notifying individual of consequences of refunds, reimbursements. reductions in tuition charges or grants or scholarships for prior taxable year.
(F) Statement informing individual of consequences of reimbursement or refund by institution or insurer.
(G) Statement notifying individual to consult forms and publications of IRS.
(H) Name, address and phone number of educational institution or insurer.

* * * * *

(e) Definitions.
(1) Administered and processed.
(i) In general.
(ii) Examples.
(2) Cost of attendance.
(f) * * *
(4) No penalty imposed on eligible educational institutions that certify compliance with paragraph (f)(3) of this section at the time of filing the return.
(5) Failure to furnish TIN.

* * * * *

■ **Par. 7.** Section 1.6050S–1 is amended by:
■ 1. Revising paragraph (a)(2)(i) and removing paragraphs (a)(2)(iii) and (iv).
■ 2. Revising paragraphs (b)(1), (b)(2)(i), and (b)(2)(ii)(D), (E), (G) and (H).
■ 3. Redesignating paragraphs (b)(2)(ii)(I) and (J) as paragraphs (b)(2)(ii)(J) and (K), respectively, and adding a new paragraph (b)(2)(ii)(I).
■ 4. Revising newly redesignated paragraph (b)(2)(ii)(J).
■ 5. Revising paragraphs (b)(2)(iv), (v), (vi) and *Example 1, 2, 3,* and *4* in paragraph (b)(2)(vii).
■ 6. In paragraph (b)(2)(vii), adding *Example 5* and *6.*
■ 7. Removing paragraph (b)(3) and redesignating paragraphs (b)(4), (5) and (6) as paragraphs (b)(3), (4) and (5), respectively.
■ 8. Revising newly redesignated paragraph (b)(4)(i).
■ 9. Removing newly redesignated paragraph (b)(4)(ii) and further redesignating paragraph (b)(4)(iii) as paragraph (b)(4)(ii).
■ 10. Revising paragraphs (c)(1)(iii)(A), (B) and (C).
■ 11. Redesignating paragraphs (c)(1)(iii)(D), (E), (F), and (G) as paragraphs (c)(1)(iii)(E), (F), (G), and (H), respectively.
■ 12. Revising newly re-designated paragraphs (c)(1)(iii)(E), (F), (G), and (H).
■ 13. Adding a new paragraph (c)(1)(iii)(D).
■ 14. Revising paragraph (c)(2)(i).
■ 15. Removing paragraph (c)(2)(ii) and redesignating paragraph (c)(2)(iii) as paragraph (c)(2)(ii).
■ 16. Redesignating paragraphs (e) and (f) as paragraphs (f) and (g), respectively.
■ 17. Adding a new paragraph (e).
■ 18. In newly redesignated paragraph (f):
i. Revising paragraph (f)(3)(ii).
ii. In paragraph (f)(3)(iii), removing the language ''(e)(3)(iii)'' and adding ''(f)(3)(iii)'' in its place.
iii. Further redesignating paragraph (f)(4) as paragraph (f)(5).
iv. Adding new paragraph (f)(4).
■ 19. Revising newly redesignated paragraph (g).

The revisions and additions read as follows:

§ 1.6050S–1 Information reporting for qualified tuition and related expenses.

(a) * * *
(2) * * *
(i) *No reporting of amounts for books, supplies and equipment unless the amount is a fee required to be paid to the institution*—(A) *In general.* The information reporting requirements of this section do not apply to amounts paid for books, supplies, and equipment unless the amount is a fee that must be paid to the eligible educational institution as a condition of enrollment or attendance under § 1.25A–2(d)(2)(ii).

(B) *Examples.* The following examples illustrates the rules of this paragraph (a)(2):

Example 1. First-year students at College W are required to obtain books and other materials used in its mandatory first-year curriculum. The books and other materials are not required to be purchased from College W and may be borrowed from other students or purchased from off-campus bookstores, as well as from College W's bookstore. College W bills students for any books and materials purchased from College W's bookstore. Because the first-year books and materials may be purchased from any vendor, the amount is not a fee that must be paid to the eligible educational institution as a condition of enrollment or attendance and, therefore, is not subject to reporting under paragraph (a)(2)(i) of this section. No amount is reportable even if a first-year student pays College W for the required books and other materials purchased from College W's bookstore.

Example 2. Assume the same facts as *Example 1* of this paragraph (a)(2), except College W furnishes the books and other materials to each first-year student and the

books may not be borrowed or purchased from other sources. College W charges a separate fee for books and materials to all first-year students for these items as part of the bill required to be paid to attend the institution. Under paragraph (a)(2)(i) of this section, because the amount is a fee that must be paid to the eligible educational institution as a condition of enrollment or attendance, the fee, if paid by or on behalf of the student, must be reported on the Form 1098–T as part of the qualified tuition and related expenses.

* * * * *

(b) *Requirement to file return*—(1) *In general.* Eligible educational institutions must report the information described in paragraph (b)(2) of this section, which requires institutions to report, among other information, the amount of payments received during the calendar year for qualified tuition and related expenses. Institutions must report separately adjustments made during the calendar year that relate to payments received for qualified tuition and related expenses that were reported for a prior calendar year. For purposes of paragraph (b)(2) of this section, an adjustment made to payments received means a reimbursement or refund. Insurers must report the information described in paragraph (b)(3) of this section.

(2) *Information reporting requirements*—(i) *In general.* Except as provided in paragraph (a)(2) of this section (regarding exceptions where no information reporting is required), an eligible educational institution must file an information return with the IRS on Form 1098–T, ''Tuition Statement,'' with respect to each individual enrolled (as determined in paragraph (d)(1) of this section) for an academic period beginning during the calendar year (including an academic period beginning during the first three months of the next calendar year) or during a prior calendar year and for whom a transaction described in paragraph (b)(2)(ii)(C), (E), (F), or (G) of this section is made during the calendar year. An eligible educational institution may use a substitute Form 1098–T if the substitute form complies with applicable revenue procedures relating to substitute forms (see § 601.601(d)(2) of this chapter).

(ii) * * *

(D) An indication by the institution whether any payments received for qualified tuition and related expenses reported for the calendar year relate to an academic period that begins during the first three months of the next calendar year and the amount of such payments;

(E) The amount of any scholarships or grants for the payment of the individual's cost of attendance (as defined in paragraph (e)(2) of this section) that the institution administered and processed (as defined in paragraph (e)(1) of this section) during the calendar year;

* * * * *

(G) The amount of any reductions to the amount of scholarships or grants for the payment of the individual's cost of attendance (as defined in paragraph (e)(2) of this section) that were reported by the eligible educational institution with respect to the individual for a prior calendar year;

(H) A statement or other indication showing whether the individual was enrolled for at least half of the normal full-time work load for the course of study the individual is pursuing for at least one academic period that begins during the calendar year (see section 25A and the regulations thereunder for more information regarding workload requirements);

(I) A statement or other indication showing the number of months (for this purpose, one day in a month is treated as an entire month) during the calendar year that the individual was enrolled for the normal full-time workload for the course of study the individual is pursuing at the institution;

(J) A statement or other indication showing whether the individual was enrolled in a program leading to a graduate-level degree, graduate-level certificate, or other recognized graduate-level educational credential, unless the student is enrolled in both a graduate-level program and an undergraduate level program during the same calendar year at the same institution in which case no statement or indication is required; and

* * * * *

(iv) *Separate reporting of reimbursements or refunds of payments of qualified tuition and related expenses that were reported for a prior calendar year.* An institution must separately report on Form 1098–T any reimbursements or refunds (as defined in paragraph (b)(2)(vi) of this section) made during the current calendar year that relate to payments of qualified tuition and related expenses that were reported by the institution for a prior calendar year. Such reimbursements or refunds are not netted against the payments received for qualified tuition and related expenses during the current calendar year.

(v) *Payments received for qualified tuition and related expenses determined.* For purposes of determining the amount of payments received for qualified tuition and related expenses during a calendar year, payments received with respect to an individual during the calendar year from any source (except for any scholarship or grant that, by its terms, must be applied to expenses other than qualified tuition and related expenses, such as room and board) are treated first as payments of qualified tuition and related expenses up to the total amount billed by the institution for qualified tuition and related expenses for enrollment during the calendar year, and then as payments of expenses other than qualified tuition and related expenses for enrollment during the calendar year. Payments received with respect to an amount billed for enrollment during an academic period beginning in the first 3 months of the following calendar year in which the payment is made are treated as payment of qualified tuition and related expenses in the calendar year during which the payment is received by the institution. For purposes of this section, a payment includes any positive account balance (such as any reimbursement or refund credited to an individual's account) that an institution applies toward current charges.

(vi) *Reimbursements or refunds of payments for qualified tuition and related expenses determined.* For purposes of determining the amount of reimbursements or refunds made of payments received for qualified tuition and related expenses, any reimbursement or refund made with respect to an individual during a calendar year (except for any refund of a scholarship or grant that, by its terms, was required to be applied to expenses other than qualified tuition and related expenses, such as room and board) is treated as a reimbursement or refund of payments for qualified tuition and related expenses up to the amount of any reduction in charges for qualified tuition and related expenses. For purposes of this section, a reimbursement or refund includes amounts that an institution credits to an individual's account, as well as amounts disbursed to, or on behalf of, the individual.

(vii) * * *

Example 1. (i) Student A enrolls in University X as a full-time student for the 2016 fall semester. In early August 2016, University X sends a bill to Student A for $16,000 for the 2016 fall semester breaking out the current charges as follows: $10,000 for qualified tuition and related expenses and $6,000 for room and board. In late August 2016, Student A pays $11,000 to University X, leaving a remaining balance to be paid of $5,000. In early September 2016, Student A drops to half-time enrollment for the 2016 fall semester but remains in on-campus housing. In late September 2016, University

X credits $5,000 to Student A's account, reflecting a $5,000 reduction in the $10,000 charge for qualified tuition and related expenses as a result of dropping from full-time to half-time status. No other transactions occur with respect to Student A's account with University X. In late September 2016, University X applies the $5,000 credit toward Student A's current charges, eliminating any outstanding balance on Student A's account with University X.

(ii) Under paragraph (b)(2)(v) of this section, the $11,000 payment is treated as a payment of qualified tuition and related expenses up to the $10,000 billed for qualified tuition and related expenses. Under paragraph (b)(2)(vi) of this section, the $5,000 credited to the student's account is treated as a reimbursement or refund of payments for qualified tuition and related expenses because there is a reduction in charges for qualified tuition and related expenses equal to the $5,000 credit due to Student A dropping to half-time for the 2016 fall semester. Under paragraph (b)(2)(iii) of this section, the $10,000 payment received for qualified tuition and related expenses during 2016 is reduced by the $5,000 reimbursement or refund of payments received for qualified tuition and related expenses during 2016. Therefore, University X is required to report $5,000 of payments received for qualified tuition and related expenses during 2016 on a 2016 Form 1098–T.

Example 2. (i) The facts are the same as in *Example 1* of this paragraph (b)(2)(vii), except that Student A pays the full $16,000 in late August 2016. In late September 2016, University X reduces the tuition charges by $5,000 and issues a $5,000 refund to Student A.

(ii) Under paragraph (b)(2)(v) of this section, the $16,000 payment is treated as a payment of qualified tuition and related expenses up to the $10,000 billed for qualified tuition and related expenses. Under paragraph (b)(2)(vi) of this section, the $5,000 refund is treated as reimbursement or refund of payments for qualified tuition and related expenses because University X reduced the charges for qualified tuition and related expenses equal to the $5,000 refund disbursed to the student due to dropping to half-time for the 2016 fall semester. Under paragraph (b)(2)(iii) of this section, the $10,000 payment received for qualified tuition and related expenses during 2016 is reduced by the $5,000 reimbursement or refund of payments received for qualified tuition and related expenses during 2016. Therefore, University X is required to report $5,000 of payments received for qualified tuition and related expenses during 2016 on a 2016 Form 1098–T.

Example 3. (i) The facts are the same as in *Example 1* of this paragraph (b)(2)(vii), except that Student A is enrolled full-time, and, in early September 2016, Student A decides to live at home with her parents. In late September 2016, University X adjusts Student A's account to eliminate room and board charges and issues a $1,000 refund to Student A.

(ii) Under paragraph (b)(2)(v) of this section, the $11,000 payment is treated as a payment of qualified tuition and related expenses up to the $10,000 billed for qualified tuition and related expenses. Under paragraph (b)(2)(vi) of this section, the $1,000 refund is not treated as reimbursement or refund of payments for qualified tuition and related expenses because University X has reduced room and board charges for the 2016 fall semester, rather than reducing charges for qualified tuition and related expenses for the 2016 fall semester. Therefore, under paragraph (b)(2)(iii) of this section, University X is required to report $10,000 of payments received for qualified tuition and related expenses during 2016 on a 2016 Form 1098–T.

Example 4. (i) Student B enrolls in College Y as a full-time student for the 2017 spring semester. In early December 2016, College Y sends a bill to Student B for $16,000 for the 2017 spring semester breaking out current charges as follows: $10,000 for qualified tuition and related expenses and $6,000 for room and board. In late December 2016, College Y receives a payment of $16,000 from Student B. In mid-January 2017, after the 2017 spring semester classes begin, Student B drops to half-time enrollment. In mid-January 2017, College Y credits Student B's account with $5,000, reflecting a $5,000 reduction in charges for qualified tuition and related expenses, but does not issue a refund to Student B. Thereafter, Student B's account reflects a positive balance of $5,000 due to the credit and there is no other activity on Student B's account until early August when College Y sends a bill for $16,000 for the 2017 fall semester breaking out the current charges as follows: $10,000 for qualified tuition and related expenses and $6,000 for room and board. In early September 2017, College Y applies the $5,000 positive account balance (credit) toward Student B's $16,000 bill for the 2017 fall semester. In late September 2017, Student B pays $6,000 towards the charges for the 2017 fall semester.

(ii) For calendar year 2016, under paragraph (b)(2)(v) of this section, $10,000 of the $16,000 payment received by College Y in December 2016 is treated as a payment of qualified tuition and related expenses. Therefore, College Y is required to report $10,000 of payments received for qualified tuition and related expenses during 2016 on a 2016 Form 1098–T. In addition, College Y is required to indicate that $10,000 of the payments reported on the 2016 Form 1098–T relate to an academic period that begins during the first three months of the next calendar year.

(iii) Under paragraph (b)(2)(vi) of this section, the $5,000 credited to Student B's account in January 2017 is treated as a reimbursement or refund of qualified tuition and related expenses because there is a reduction in charges for qualified tuition and related expenses of $5,000 for the 2017 spring semester. Under paragraph (b)(2)(iv) of this section, however, this reduction is a reimbursement or refund of qualified tuition and related expenses made during 2017 and, therefore, must be separately reported on the 2017 Form 1098–T. The 2016 Form 1098–T reporting $10,000 of qualified tuition and related expenses for 2016 is unchanged.

(iv) Under paragraph (b)(2)(v) of this section, the $5,000 positive account balance that is applied toward charges for the 2017 fall semester is treated as a payment made in 2017. Therefore, College Y received total payments of $11,000 during 2017 (the $5,000 credit plus the $6,000 payment). Under paragraph (b)(2)(v) of this section, the $11,000 of total payments made during 2017 are treated as a payment of qualified tuition and related expenses up to the $10,000 billed for qualified tuition and related expenses for the 2017 fall semester. Therefore, for 2017, College Y is required to report $10,000 of payments received for qualified tuition and related expenses during 2017 and a $5,000 refund of payments of qualified tuition and related expenses reported for 2016 on the 2017 Form 1098–T.

Example 5. (i) Student C enrolls in College Z as a full-time student the 2016 fall semester and the 2017 spring semester. Student C was not enrolled in, and did not attend, any institution of higher education prior to the 2016 fall semester. In August 2016, College Z sends a bill to Student C for $11,000 for the 2016 fall semester. In December 2016, College Z sends a bill to Student C for $11,000 for the 2017 spring semesters. Qualified tuition and related expenses billed for each semester is $6,000 and room and board billed for each semester is $5,000. In September 2016, College Z receives a payment of $11,000 which is applied toward the amount billed for Student C's attendance during the 2016 fall semester. In December 2016, College Z receives a payment of $4,500 which is applied toward the amount billed for Student C's attendance during the 2017 spring semester. In February 2017, College Z receives a payment of $6,500, the remainder of the amount billed for enrollment during the 2017 spring semester.

(ii) On the 2016 Form 1098–T, College Z reports the payment of $10,500 of qualified tuition and related expenses determined as follows: $6,000 for the payment received in September 2016 with respect to the amount billed for qualified tuition and related expenses for the 2016 fall semester and $4,500 for the payment received in December 2016 with respect to the amount billed for qualified tuition and related expenses for the 2017 spring semester. On the 2017 Form 1098–T, College Z reports the payment of $1,500 of qualified tuition and related expenses received in February 2017 with respect to the amount billed for qualified tuition and related expenses for the 2017 spring semester.

Example 6. The facts are the same as *Example 5* of this paragraph (b)(2)(vii) except in January 2017 College Z receives payment of $11,000 for the entire amount billed for the 2017 spring semester. On the 2016 Form 1098–T, College Z reports the payment of $6,000 for the payment received in September 2016 with respect to the amount billed for qualified tuition and related expenses for the 2016 fall semester. On the 2017 Form 1098–T, College Z reports the payment of $6,000 of qualified tuition and related expenses received in January 2017 with respect to the amount billed for qualified tuition and related expenses for the 2017 spring semester.

* * * * *

(4) *Time and place for filing return*—(i) *In general.* Except as provided in paragraph (b)(4)(ii) of this section, Form 1098–T must be filed on or before February 28 (March 31 if filed electronically) of the year following the calendar year in which payments were received for qualified tuition or related expenses, or reimbursements, refunds, or reductions of such amounts were made. An institution or insurer must file Form 1098–T with the IRS according to the instructions for Form 1098–T.

* * * * *

(c) * * *

(1) * * *

(iii) * * *

(A) State that the statement reports total payments received by the institution for qualified tuition and related expenses during the calendar year, or the total reimbursements or refunds made by the insurer;

(B) State that, under section 25A and the regulations thereunder, the taxpayer may claim an education tax credit only with respect to qualified tuition and related expenses actually paid during the calendar year; and that the taxpayer may not be able to claim an education tax credit with respect to the entire amount of payments received for qualified tuition and related expenses reported on the Form 1098–T for the calendar year;

(C) State that the amount of any scholarships or grants reported on the Form 1098–T for the calendar year and other similar amounts not reported on the Form 1098–T (because they are not administered and processed by the eligible educational institution as defined in paragraph (e)(1) of this section) that are allocated by the student to pay qualified tuition and related expenses may reduce the amount of any allowable education tax credit for the taxable year;

(D) State that even if the eligible educational institution applies scholarships or grants reported on the Form 1098–T for the calendar year to qualified tuition and related expenses, the student may, for tax purposes, be able to allocate all or a portion of the scholarships or grants to expenses other than qualified tuition and related expenses (and, therefore, forego having to reduce the amount of the education tax credit the student may claim) if the terms of the scholarship or grant permit it to be used for expenses other than qualified tuition and related expenses and the student includes the amount in income on his federal income tax return.

* * * * *

(E) State that the amount of any reimbursements or refunds of payments received, or reductions in charges, for qualified tuition and related expenses, or any reductions to the amount of scholarships or grants, reported by the eligible educational institution with respect to the individual for a prior calendar year on Form 1098–T may affect the amount of any allowable education tax credit for the prior calendar year (and may result in an increase in tax liability for the year of the refund);

(F) State that the amount of any reimbursements or refunds of qualified tuition and related expenses reported on a Form 1098–T by an eligible educational institution or insurer may reduce the amount of an allowable education tax credit for a taxable year (and may result in an increase in tax liability for the year of the refund);

(G) State that the taxpayer should refer to relevant IRS forms and publications, such as Publication 970, ''Tax Benefits for Education,'' and should not refer to the institution or the insurer, for explanations relating to the eligibility requirements for, and calculation of, any allowable education tax credit; and

(H) Include the name, address, and phone number of the information contact of the eligible educational institution or insurer that filed the Form 1098–T.

(2) *Time and manner for furnishing statement*—(i) *In general.* Except as provided in paragraphs (c)(2)(ii) of this section, an institution or insurer must furnish the statement described in paragraph (c)(1) of this section to each individual for whom it is required to file a return, on or before January 31 of the year following the calendar year in which payments were received for qualified tuition and related expenses, or reimbursements, refunds or reductions of such amounts were made. If mailed, the statement must be sent to the individual's permanent address or the individual's temporary address if the institution or insurer does not know the individual's permanent address. If furnished electronically, the statement must be furnished in accordance with applicable regulations.

* * * * *

(e) *Definitions.* The following definitions apply with respect to this section:

(1) *Administered and processed*—(i) *In general.* A scholarship or grant is ''administered and processed'' by an eligible educational institution if the institution receives payment of an amount (whether by cash, check, or other means of payment) that the institution knows or reasonably should know, is a scholarship or grant, regardless of whether the institution is named payee or co-payee of such amount and regardless of whether, in the case of a payment other than in cash, the student endorses the check or other means of payment for the benefit of the institution. For instance, Pell Grants, described in the Higher Education Act of 1965 (20 U.S.C. 1070), as amended, are administered and processed by an institution in all cases.

(ii) *Examples.* The following examples illustrate the definition in this paragraph (e)(1):

Example 1. University M received a Pell Grant on behalf of Student B, a student enrolled in a degree program at University M. University M provides all required notifications to and obtains all the necessary paperwork from Student B and applies the Pell Grant to Student B's account. Because University M received the Pell Grant and University M knows or should know that the Pell Grant is a scholarship or grant, under paragraph (e)(1)(i) of this section, the Pell Grant is administered and processed by University M.

Example 2. University N receives a check from Organization Y made out to Student C. University N is not named as a payee on the check. The cover letter accompanying the check provides University N with sufficient information to reasonably know that the check represents payment of a scholarship that may be used to pay Student C's qualified tuition and related expenses. Under paragraph (e)(1)(i) of this section, the scholarship from Organization Y is administered and processed by University N. This is the case even though University N is not named on the check as a payee and regardless of whether Student C endorses the check over to University N.

(2) *Cost of attendance.* The term ''cost of attendance'' has the same meaning as section 472 of the Higher Education Act of 1965, 20 U.S.C. 1087ll.

(f) * * *

(3) * * *

(ii) *Acting in a responsible manner.* An institution or insurer must request the TIN of each individual for whom it is required to file a return if it does not already have a record of the individual's correct TIN. If the institution or insurer does not have a record of the individual's correct TIN, then it must solicit the TIN in the manner described in paragraph (f)(3)(iii) of this section on or before December 31 of each year during which it receives payments of qualified tuition and related expenses or makes reimbursements, refunds, or reductions of such amounts with respect to the individual. If an individual refuses to provide his or her TIN upon request, the institution or insurer must file the return and furnish the statement required by this section without the individual's TIN, but with all other

required information. The specific solicitation requirements of paragraph (f)(3)(iii) of this section apply in lieu of the solicitation requirements of § 301.6724–1(e) and (f) of this chapter for the purpose of determining whether an institution or insurer acted in a responsible manner in attempting to obtain a correct TIN. An institution or insurer that complies with the requirements of this paragraph (f)(3) will be considered to have acted in a responsible manner within the meaning of § 301.6724–1(d) of this chapter with respect to any failure to include the correct TIN of an individual on a return or statement required by section 6050S and this section.

* * * * *

(4) *No penalty imposed on eligible educational institutions that certify compliance with paragraph (f)(3) of this section at the time of filing the return.* In the case of returns required to be filed and statements required to be furnished after December 31, 2015, the IRS will not impose a penalty against an eligible educational institution under section 6721 or 6722 for failure to include the individual's correct TIN on the return or statement if the institution makes a true and accurate certification to the IRS under penalties of perjury (in the form and manner prescribed by the Secretary in publications, forms and instructions, or other published guidance) at the time of filing of the return that the institution complied with the requirements in paragraphs (f)(3)(ii) and (iii) of this section. Nothing in this paragraph (f)(4) prevents the IRS from imposing a penalty under section 6721or 6722 if after the IRS receives the certification described in this paragraph (f)(4) the IRS determines that the requirements of paragraph (f)(3) of this section are not satisfied or the failure is unrelated to an incorrect or missing TIN for the individual for whom the institution is required to file a return or statement.

* * * * *

(g) *Applicability date.* The rules in this section apply to information returns required to be filed, and statements required to be furnished, after December 31, 2003, except that paragraphs (a)(2) (b)(1), (b)(2)(i), (b)(2)(ii)(D), (E), and (G) through (K), (b)(2)(iv) through (vii), (b)(4)(i) and (ii), (c)(1)(iii)(B) through (H), (e), and (f)(4) apply to information returns required to be filed, and statements required to be furnished, after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. For information returns required to be filed, and statements required to be furnished, on or before the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**, § 1.6050S–1 (as contained in 26 CFR part 1, revised April 2014) applies.

PART 301—PROCEDURE AND ADMINISTRATION

■ **Par. 8.** The authority citation for part 301 continues to read in part as follows:

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

■ **Par. 9.** Section 301.6724–1 is amended by adding a sentence at the end of paragraph (a)(1) to read as follows:

§ 301.6724–1 Reasonable cause.

(a) * * *

(1) * * * For waiver in the case of eligible educational institutions required to report information under section 6050S with respect to qualified tuition and related expenses, see § 1.6050S–1(f) of this chapter.

* * * * *

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2016–18032 Filed 7–29–16; 11:15 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[REG–103058–16]

RIN 1545–BN23

Information Reporting of Catastrophic Health Coverage and Other Issues Under Section 6055

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to information reporting of minimum essential coverage under section 6055 of the Internal Revenue Code (Code). Health insurance issuers, certain employers, and others that provide minimum essential coverage to individuals must report to the IRS information about the type and period of coverage and furnish related statements to covered individuals. These proposed regulations affect health insurance issuers, employers, governments, and other persons that provide minimum essential coverage to individuals.

DATES: Written or electronic comments and requests for a public hearing must be received by October 3, 2016.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–103058–16), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–103058–16), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224, or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–103058–16).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations under section 6055, John B. Lovelace, (202) 317–7006; concerning the proposed regulations under section 6724, Hollie Marx, (202) 317–6844; concerning the submission of comments, Regina Johnson, (202) 317–6901 (not toll-free calls).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by October 3, 2016. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in these proposed regulations is in § 1.6055–1. The collection of information will be used to determine whether an individual has minimum essential coverage under section 1501(b) of the Patient Protection and Affordable Care Act (26 U.S.C. 5000A(f)). The collection of information is required to comply with the provisions of section 6055. The likely respondents are health insurers, self-insured employers or other sponsors of self-insured health plans, and governments that provide minimum essential coverage.

The burden for the collection of information contained in these proposed regulations will be reflected in the burden on Form 1095–B, Health Coverage, or another form that the IRS designates, which will request the information in the proposed regulation.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Background

Under section 5000A, individuals must for each month have minimum essential coverage, qualify for a health coverage exemption, or make an individual shared responsibility payment with their income tax returns. Section 6055 provides that all persons who provide minimum essential coverage to an individual must report certain information to the IRS that identifies covered individuals and the period of coverage, and must furnish a statement to the covered individuals containing the same information. The information reported under section 6055 allows individuals to establish, and the IRS to verify, that the individuals were covered by minimum essential coverage for months during the year.

Information returns under section 6055 generally are filed using Form 1095–B. A separate and distinct health coverage-related reporting requirement under section 6056 requires that certain large employers report information on Form 1095–C, Employer-Provided Health Insurance Offer and Coverage. Self-insured employers required to file Form 1095–C use Part III of that form, rather than Form 1095–B, to report information required under section 6055 for individuals enrolled in the self-insured employer-sponsored coverage. These proposed regulations provide guidance under section 6055 only, which relates to Form 1095–B and Form 1095–C, Part III. These proposed regulations do not affect information reporting under section 6056 on Form 1095–C, Parts I and II.

Under section 5000A(f)(1), various types of health plans and programs are minimum essential coverage, including: (1) Specified government-sponsored programs such as Medicare Part A, the Medicaid program under Title XIX of the Social Security Act (42 U.S.C. 1936 and following sections), the Children's Health Insurance Program under Title XXI of the Social Security Act (42 U.S.C. 1397aa and following sections) (CHIP), the TRICARE program under chapter 55 of Title 10, U.S.C., health care programs for veterans and other individuals under chapter 17 or 18 of Title 38 U.S.C., coverage for Peace Corps volunteers under 22 U.S.C. 2504(e), and coverage under the Nonappropriated Fund Health Benefits Program under section 349 of Public Law 103–337, (2) coverage under an eligible employer-sponsored plan, (3) coverage under a plan in the individual market (such as a qualified health plan offered through an Affordable Insurance Exchange (Exchange, also known as a Marketplace)), (4) coverage under a grandfathered health plan, and (5) other coverage recognized as minimum essential coverage by the Secretary of Health and Human Services, in coordination with the Secretary of the Treasury.

Under section 5000A(f)(3) and § 1.5000A–2(g) of the Income Tax Regulations, coverage that consists solely of excepted benefits described in section 2791(c)(1), (c)(2), (c)(3), or (c)(4) of the Public Health Service Act (42 U.S.C. 300gg–91(c)), and the regulations under that section, is not minimum essential coverage. Section 1.5000A–2(b)(2) lists government-sponsored programs that provide limited benefits and which are not minimum essential coverage.

Under section 5000A(f)(4), an individual who is a bona fide resident of a United States possession for a month is treated as having minimum essential coverage for that month.

Notice 2015–68, 2015–41 I.R.B. 547, provides guidance on various issues under section 6055. In Notice 2015–68, the Treasury Department and the IRS stated that they intend to propose regulations under section 6055 addressing certain of these issues and requested comments. Comments were requested about the application of the reasonable cause rules under section 6724 to section 6055 reporting, in particular as applied to taxpayer identification number (TIN) solicitation and reporting.

Persons Required To Report

Under § 1.6055–1(c)(1)(iii), the executive department or agency of the governmental unit that provides coverage under a government-sponsored program is the reporting entity for government-sponsored minimum essential coverage. Section 1.6055–1(c)(3)(i) specifically provides that the State agency that administers the Medicaid or CHIP program, respectively, must report government-sponsored coverage under section 6055. Notice 2015–68 provides that Medicaid and CHIP agencies in U.S. possessions or territories are not required to report Medicaid and CHIP coverage because an individual eligible for that coverage is generally a bona fide resident of the possession or territory who is deemed to have minimum essential coverage under section 5000A(f)(4) and, therefore, does not require reporting under section 6055 to verify compliance with section 5000A.

In general, under § 1.6055–1(c)(1)(ii) the reporting entity for coverage under a self-insured group health plan is the plan sponsor. Section 1.6055–1(c)(2) provides rules for identifying which entity is the plan sponsor of a self-insured group health plan for purposes of section 6055. For this purpose, the employer is the plan sponsor of a self-insured group health plan established by a single employer (determined without aggregating related entities under section 414). If the plan or arrangement is established or maintained by more than one employer (including a Multiple Employer Welfare Arrangement (as defined in section 3(40) of the Employee Retirement Income Security Act of 1974 (ERISA)), and the plan is not a multiemployer plan (as defined in section 3(37) of ERISA), each participating employer is a plan sponsor with respect to that employer's employees. For a self-insured group health plan or arrangement that is a multiemployer plan, the plan sponsor is the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan. For a self-insured group health plan or arrangement maintained solely by an employee organization, the plan sponsor is the employee organization.

The existing regulations at § 1.6055–1(d)(2) provide that no reporting is required for minimum essential coverage that provides benefits in addition or as a supplement to other coverage that is minimum essential coverage if the primary and supplemental coverage have the same

plan sponsor or the coverage supplements government-sponsored minimum essential coverage. Notice 2015–68 explained that this rule had proven to be confusing, and, accordingly, the Treasury Department and the IRS intended to propose regulations providing that (1) if an individual is covered by multiple minimum essential coverage plans or programs provided by the same provider, reporting is only required for one of the plans or programs; and (2) reporting generally is not required for an individual's minimum essential coverage to the extent that the individual is eligible for that coverage only if the individual is also covered by other minimum essential coverage for which section 6055 reporting is required.

Information Required To Be Reported

Under section 6055(b) and § 1.6055–1(e)(1), providers of minimum essential coverage must report to the IRS (1) the name, address, and employer identification number (EIN) of the reporting entity required to file the return; (2) the name, address, and TIN, or date of birth if a TIN is not available, of the responsible individual (except that a reporting entity may, but is not required to, report the TIN of a responsible individual not enrolled in the coverage); (3) the name and TIN, or date of birth if a TIN is not available, of each individual who is covered under the policy or program; and (4) the months of coverage for each covered individual.[1] Section 1.6055–1(b)(11) provides that the responsible individual includes a primary insured, employee, former employee, uniformed services sponsor, parent, or other related person named on an application who enrolls one or more individuals, including him or herself, in minimum essential coverage.

In addition, under § 1.6055–1(e)(2), for coverage provided by a health insurance issuer through a group health plan, information returns must report (1) the name, address, and EIN of the employer maintaining the plan, and (2) any other information that the Secretary requires for administering the credit under section 45R (relating to the tax credit for employee health insurance expenses of small employers).

A reporting entity that fails to comply with the filing and statement furnishing requirements of section 6055 may be subject to penalties for failure to file timely a correct information return (section 6721) or failure to furnish timely a correct statement (section 6722). See section 6724(d); see also § 1.6055–1(h)(1). These penalties may be waived if the failure is due to reasonable cause and is not due to willful neglect. See section 6724(a). In particular, under § 301.6724–1(a)(2) of the Procedure and Administration Regulations penalties are waived if a reporting entity demonstrates that it acted in a responsible manner and that the failure is due to significant mitigating factors or events beyond the reporting entity's control. For purposes of section 6055 reporting, if the information reported on a return is incomplete or incorrect as a result of a change in circumstances (such as a retroactive change in coverage), a failure to timely file or furnish a corrected document is a failure to file a correct return or furnish a correct statement under sections 6721 and 6722. See § 1.6055–1(h)(2).

In general, under § 301.6724–1(e) a person will be treated as acting in a responsible manner if the person properly solicits a TIN but does not receive it. For this purpose, proper solicitation of a TIN involves an initial solicitation and two subsequent annual solicitations. In general, an initial solicitation is made when the relationship between the reporting entity and the taxpayer is established. If the reporting entity does not receive the TIN, the first annual solicitation is generally required by December 31 of the year in which the relationship with the taxpayer begins (January 31 of the following year if the relationship begins in December). Generally, if the TIN is still not provided, a second annual solicitation is required by December 31 of the following year. Similar rules applying to filers who file or furnish information reports with incorrect TINs are in § 301.6724–1(f).

The preamble to the section 6055 regulations (T.D. 9660, 79 FR 13220) provides short-term relief from reporting penalties for 2015 coverage. Specifically, the IRS will not impose penalties under sections 6721 and 6722 on reporting entities that can show that they have made good faith efforts to comply with the information reporting requirements. This relief applies to incorrect or incomplete information, including TINs or dates of birth, reported on a return or statement.

Explanation of Provisions and Summary of Comments

1. Reporting of Catastrophic Plans

Under § 1.36B–5(a), Exchanges must report to the IRS information relating to qualified health plans in which individuals enroll through the Exchange. Under section 36B(c)(3)(A), the term qualified health plan has the same meaning as defined in section 1301 of the Affordable Care Act except that it does not include a catastrophic plan described in section 1302 of the Affordable Care Act. Thus, Exchanges are not required to report on catastrophic coverage. Section 1.6055–1(d) provides that health insurance issuers need not report on coverage in a qualified health plan in the individual market enrolled in through an Exchange, because that information is generally reported by Exchanges pursuant to § 1.36B–5. Thus, currently neither the Exchanges nor health insurance issuers are responsible for reporting coverage under a catastrophic plan.

Effective administration of section 5000A generally requires reporting of all minimum essential coverage, including catastrophic plans in which individuals enroll through an Exchange. Accordingly, Notice 2015–68 indicated that the Treasury Department and the IRS intended to propose regulations under section 6055 to narrow the relief provided to issuers in § 1.6055–1(d) by requiring issuers of catastrophic plans to report catastrophic plan coverage on Form 1095–B, effective for coverage in 2016 and returns and statements filed and furnished in 2017. Consistent with Notice 2015–68, the proposed regulations include this requirement but, to allow reporting entities sufficient time to implement these reporting requirements, are proposed to be effective for coverage in 2017 and returns and statements filed and furnished in 2018.

Notice 2015–68 indicated that health insurance issuers could voluntarily report on 2015 catastrophic coverage (on returns and statements filed and furnished in 2016) and were encouraged to do so. Notice 2015–68 further provided that an issuer that reports on 2015 catastrophic coverage will not be subject to penalties for these returns. Given the 2017 effective date for reporting of catastrophic coverage provided in these proposed regulations, health insurance issuers similarly may

[1] The Affordable Care Act also added section 6056, which requires that applicable large employers file and furnish statements containing information related to offers of coverage, if any, made to each full-time employee. To complete these statements properly, employers must have each employee's TIN. In accordance with the requirements of a different Code section (section 3402(f)(2)(A)), employers should have already sought each employee's TIN in advance of the deadline for filing and furnishing statements required under section 6056. Therefore, the TIN solicitation rules in these proposed regulations *only apply* to information reporting under section 6055 (which in the case of an applicable large employer providing coverage under a self-insured plan, includes information reporting on Form 1095–C, Part III).

voluntarily report on 2016 catastrophic coverage (on returns and statements filed and furnished in 2017) and are encouraged to do so. An issuer that reports on 2016 catastrophic coverage will not be subject to penalties for these returns.

2. Reporting of Coverage Under Basic Health Programs

Section 1331 of the Affordable Care Act allows states to establish a Basic Health Program to provide an additional healthcare coverage option to certain individuals not eligible for Medicaid. See 42 CFR part 600. The Basic Health Program is designated as minimum essential coverage under 42 CFR 600.5.

Section 5000A(f) does not identify the Basic Health Program as a government-sponsored program, but it closely resembles government-sponsored coverage such as Medicaid and CHIP. Accordingly, Notice 2015–68 indicated that the state agency that administers the Basic Health Program is the entity that must report that coverage under section 6055. Consistent with Notice 2015–68, these proposed regulations provide that the State agency administering coverage under the Basic Health Program is required to report that coverage under section 6055.

3. Truncated TINs

Section 6055(b) and § 1.6055–1(e) require that health insurance issuers and carriers reporting coverage under insured group health plans report information about the employer sponsoring the plan, including the employer's EIN, to the IRS. Section 6055(c) and § 1.6055–1(g) require that health insurance issuers and carriers reporting information to the IRS furnish a statement to a taxpayer providing information about the filer and the covered individuals. Section 301.6109–4(b)(1) provides that the TIN of a person other than the filer, including an EIN, may be truncated on statements furnished to recipients unless, among other reasons, such truncation is otherwise prohibited by statute or regulations. Thus, under § 1.6055–1(g)(3) of the existing regulations, a recipient's TIN may appear in the form of an IRS truncated taxpayer identification number (TTIN) on a statement furnished to the recipient. These proposed regulations amend the existing regulations to clarify that a TTIN is not an alternative identifying number; rather, it is one of the ways that a TIN may appear, subject to the rules in § 301.6109–4(b)(1).

Existing regulations do not address whether health insurance issuers and carriers are permitted to truncate a sponsoring employer's EIN on statements furnished to taxpayers. Notice 2015–68 advised that the Treasury Department and the IRS intended to propose regulations to clarify that the EIN of the employer sponsoring the plan may be truncated to appear as an IRS TTIN on statements health insurance issuers and carriers furnish to taxpayers. Consistent with Notice 2015–68, the proposed regulations clarify that the EIN of the employer sponsoring the plan may be truncated to appear as an IRS TTIN on statements health insurance issuers and carriers furnish to taxpayers. Section 301.6109–4(b)(2)(ii) prohibits using TTINs if, among other things, a statute specifically requires the use of an EIN. While section 6055(b)(2)(A) requires that the information return filed with the IRS includes the employer's EIN, and section 6055(c)(1)(B) requires that the statement furnished to a taxpayer includes the information required to be shown on the information return with respect to such individual, the statute does not require that the full EIN appear on the statement furnished to taxpayers and the employer's EIN may be truncated to appear in the form of an IRS TTIN.

4. Plans for Which Reporting Is Not Required

Information reporting under section 6055(a) is generally required of every person who provides minimum essential coverage to an individual during the year. In certain instances where the reporting would be duplicative, the existing regulations allow the person who provides supplemental coverage to forgo information reporting. This supplemental coverage rule in § 1.6055–1(d)(2) was intended to eliminate duplicate reporting of an individual's minimum essential coverage under circumstances when there is reasonable certainty that the provider of the ''primary'' coverage will report. This rule has proven to be confusing.

The Treasury Department and the IRS indicated in Notice 2015–68 that regulations would be proposed to replace the existing rules. Accordingly, the proposed regulations provide that (1) if an individual is covered by more than one minimum essential coverage plan or program provided by the same reporting entity, reporting is required for only one of the plans or programs; and (2) reporting is not required for an individual's minimum essential coverage to the extent that the individual is eligible for that coverage only if the individual is also covered by other minimum essential coverage for which section 6055 reporting is required. As in Notice 2015–68, the proposed regulations provide that the second rule applies to eligible employer-sponsored coverage only if the supplemental coverage is offered by the same employer that offered the eligible employer-sponsored coverage for which section 6055 reporting is required. These rules apply month by month and individual by individual.

Thus, under the proposed regulations, applying the first rule, if for a month an individual is enrolled in a self-insured group health plan provided by an employer and also is enrolled in a self-insured health reimbursement arrangement (HRA) provided by the same employer, the reporting entity (the employer) is required to report only one type of coverage for that individual. If an employee is covered under both self-insured arrangements for some months of the year but retires or otherwise drops coverage under the non-HRA group health plan and is covered only under the HRA for other months, the employer must report coverage under the HRA for the months after the employee retires or drops the non-HRA coverage.

Applying the second rule, reporting is not required for minimum essential coverage for a month if that coverage is offered only to individuals who are also covered by other minimum essential coverage, including Medicare, TRICARE, Medicaid, or certain employer-sponsored coverage, for which reporting is required. In these arrangements, the program for which reporting is required represents the primary coverage while the other minimum essential coverage is supplemental to the primary plan.

Under the application of the second rule to eligible employer-sponsored coverage, if an employer offers both an insured group health plan and an HRA for which an employee is eligible if enrolled in the insured group health plan, and an employee enrolls in both, the employer is not required to report the employee's coverage under the HRA. However, if an employee is enrolled in his or her employer's HRA and in a spouse's non-HRA group health plan, the employee's employer is required to report for the HRA, and the employee's spouse's employer (or the health insurance issuer or carrier, if the plan is insured) is required to report for the non-HRA group health plan coverage. The proposed regulations clarify that, for purposes of this rule, an employer is treated as offering minimum essential coverage that is offered by another employer with whom the employer is treated as a single employer under section 414(b), (c), (m), or (o).

Separately, Notice 2015–68 also stated that, because Medicaid and CHIP coverage provided by the governments of American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands is generally made available only to individuals who are treated as having minimum essential coverage under section 5000A(f)(4) (and, therefore, do not need section 6055 reporting to verify minimum essential coverage), the Medicaid and CHIP agencies in those U.S. possessions or territories are not required to report that coverage under section 6055. Consistent with that rule, the proposed regulations provide that reporting under section 6055 is not required with respect to Medicaid and CHIP agencies in U.S. possessions or territories.

5. TIN Solicitation

Information reporting under section 6055 is subject to the penalty provisions of sections 6721 and 6722 for failure to file timely a correct information return or failure to furnish timely a correct statement to the individual. See § 1.6055–1(h). The penalties may be waived under section 6724(a) if the failure is due to reasonable cause and not due to willful neglect; that is, if a reporting entity demonstrates that it acted in a responsible manner and that the failure is due to significant mitigating factors or events beyond the reporting entity's control. See § 301.6724–1(a)(2). Under § 301.6724–1(e), in cases of a missing TIN, the reporting entity is treated as acting in a responsible manner in soliciting a TIN if the reporting entity makes (1) an initial solicitation when an account is opened or a relationship is established, (2) a first annual solicitation by December 31 of the year the account is opened (or January 31 of the following year if the account is opened in December), and (3) a second annual solicitation by December 31 of the year following the year in which the account is opened. Similar rules apply regarding incorrect TINs under § 301.6724–1(f). The rules in § 301.6724–1(e) and (f) were issued prior to the enactment of section 6055 and apply to most forms of information reporting.

Comments received in response to the first notice of proposed rulemaking (REG–132455–11) under section 6055, published in the **Federal Register** (78 FR 54986) on September 9, 2013, raised concerns about the application of the TIN solicitation rules to section 6055 reporting. Accordingly, Notice 2015–68 provided that, pending the issuance of additional guidance, reporting entities will not be subject to penalties for failure to report a TIN if they comply with the requirements of § 301.6724–1(e) with the following modifications: (1) The initial solicitation is made at an individual's first enrollment or, if already enrolled on September 17, 2015, the next open season, (2) the second solicitation (the first annual solicitation) is made at a reasonable time thereafter, and (3) the third solicitation (the second annual solicitation) is made by December 31 of the year following the initial solicitation. Notice 2015–68 also requested comments on the application of the reasonable cause rules under section 6724 to section 6055 reporting.

In response to the request for comments in Notice 2015–68, one commenter requested that the proposed regulations include detailed rules tailored to TIN solicitation for information returns required by section 6055. This commenter expressed concern that, because the current rules were designed primarily to apply to financial relationships, they are difficult to apply to section 6055 reporting, particularly the rules for demonstrating that the filer acted in a responsible manner as described in § 301.6724–1(e) and (f). The Treasury Department and the IRS agree with the commenter that some modification to the rules in § 301.6724–1(e) is warranted to account for the differences between information reporting under section 6055 and information reporting under other provisions of the Code. Accordingly, the Treasury Department and the IRS propose regulations to provide specific TIN solicitation rules for section 6055 reporting. Until final regulations are released, reporting entities may rely on these proposed rules and Notice 2015–68. The preamble below also includes some additional transition rules that apply to reporting entities in certain situations.

Section 301.6724–1(e)(1)(i) provides that an initial TIN solicitation must occur when an account (which includes accounts, relationships, and other transactions) is opened. Section 301.6724–1(e) does not define the term ''opened'' for this purpose. Commenters requested clarification as to how the term ''opened'' should be interpreted for purposes of reporting under section 6055. In the context of financial accounts, an account is generally considered opened on the first day it is available for use by its owner. In most cases, this would be shortly after the application to open that account is received, and this day would be no earlier than the day the application was received. Health coverage does not work in the same way. In some cases, the first effective date of health coverage is before the day the application was received, making it impractical to solicit TINs before the coverage takes effect. In other cases, the effective date of coverage may be months after the day the application was received. To account for this different timing, the proposed regulations provide that, for purposes of section 6055 reporting, an account is considered ''opened'' on the date the filer receives a substantially complete application for new coverage or to add an individual to existing coverage. Accordingly, health coverage providers may generally satisfy the requirement for the initial solicitation by requesting enrollees' TINs as part of the application for coverage.

To address differences in the way financial accounts and health coverage are opened, the proposed regulations also change the timing of the first annual solicitation (the second solicitation overall) with respect to missing TINs. Under § 301.6724–1(e)(1)(ii), a first annual solicitation must be made by December 31 of the year the account is opened (or by January 31 of the following calendar year if the account is opened in December). The timing of the first annual solicitation is dictated by the need to have accurate reporting of information to taxpayers and the IRS in preparation for the filing of an income tax return. Accounts, relationships, and other transactions may be opened or begun throughout the year, and may remain active indefinitely. It is beneficial to the IRS, filers, and taxpayers in the context of accounts, relationships, and other transactions to have a single deadline for the first annual solicitation at the end of the calendar year (or January if the account is opened in December).

By contrast, health coverage is generally offered on an annual basis. While individuals may, depending on their circumstances, enroll in coverage at any point during the year, many covered individuals enroll in coverage during the open enrollment period, which is in advance of the beginning of the coverage year. The most common coverage year is the calendar year and many individuals enroll late each year for coverage the following year. For such individuals, requiring the first annual solicitation (the second solicitation overall) by December 31 of the year in which the application is received is earlier than is necessary (because reporting is not due until more than a year later) and coincides with the end of a plan year, which is already the busiest time of year for coverage providers. To address these considerations, the proposed regulations

require that the first annual solicitation be made no later than seventy-five days after the date on which the account was ''opened'' (*i.e.,* the day the filer received the substantially complete application for coverage), or, if the coverage is retroactive, no later than the seventy-fifth day after the determination of retroactive coverage is made. The deadline for the second annual solicitation (third solicitation overall) remains December 31 of the year following the year the account is opened as required by § 301.6724–1(e)(1)(iii).

As noted above, taxpayers may rely on these proposed regulations and on Notice 2015–68 until final regulations are published. To provide additional relief and ensure that the requirements for the first annual and second annual solicitations may be satisfied with respect to individuals already enrolled in coverage, an additional rule is provided. Under this rule, if an individual was enrolled in coverage on any day before July 29, 2016, the account is considered opened on July 29, 2016. Accordingly, reporting entities have satisfied the requirement for the initial solicitation with respect to already enrolled individuals so long as they requested enrollee TINs either as part of the application for coverage or at any other point before July 29, 2016. The deadlines for the first and second annual solicitations are set by reference to the date the account is opened. Thus, the rule above that treats all accounts for individuals currently enrolled in coverage for which a TIN has not been provided as opened on July 29, 2016, provides additional time for the annual solicitations as well. Specifically, consistent with Notice 2015–68, the first annual solicitation should be made at a reasonable time after July 29, 2016. For this purpose, a reporting entity that makes the first annual solicitation within 75 days of the initial solicitation will be treated as having made the second solicitation within a reasonable time. Reporting entities that have not made the initial solicitation before July 29, 2016 should comply with the first annual solicitation requirement by making a solicitation within a reasonable time of July 29, 2016. Notice 2015–68 also provided that a reporting entity is deemed to have satisfied the initial, first annual, and second annual solicitations for an individual whose coverage was terminated prior to September 17, 2015, and taxpayers may continue to rely on this rule as well.

Section 301.6724–1(e)(1)(v) provides that the initial and first annual solicitations relate to failures on returns filed for the year in which the account is opened (meaning that showing reasonable cause with respect to the year the account is opened generally requires making the initial and first annual solicitations in the year the account is opened). Because these proposed regulations provide that an account is considered opened for section 6055 purposes when a substantially complete application for that account is received, an account would, in some cases, be considered open in a year prior to the year for which coverage is actually effective and for which reporting is required. This would occur, for example, when a reporting entity receives an application during open enrollment for coverage effective as of the first day of the next coverage year. To ensure that reporting entities that make the initial solicitation and first annual solicitation are eligible for relief for the first year for which reporting is required, the proposed regulations provide that, for purposes of reporting under section 6055, the initial and first annual solicitations relate to failures on returns required to be filed for the year that includes the day that is the first effective date of coverage for a covered individual. Similarly, § 301.6724–1(e)(1)(v) provides that the second annual solicitation relates to failures on returns filed for the year immediately following the year in which the account is opened and succeeding calendar years (meaning that showing reasonable cause with respect to years after the account is opened generally requires making the second annual solicitation during the year following the year the account is opened). As with the initial and first annual solicitations, the existing rule under § 301.6724–1(e)(1)(v) could provide relief for the wrong year when combined with the proposed definition of account opening under section 6055. Accordingly, the proposed regulations provide that the second annual solicitation relates to failures on returns filed for the year immediately following the year to which the first annual solicitation relates, and succeeding calendar years.

In contrast to missing TINs, the Treasury Department and the IRS do not recognize a similar need to modify the existing first annual solicitation rules for incorrect TINs in § 301.6724–1(f)(1)(ii). As with many other types of information reports, information reports of health coverage are generally filed after the end of the tax year, and thus, it is only after the tax year that a filer would generally receive notice of an incorrect TIN. Because the end of the tax year typically corresponds with the end of the coverage year, there is no reason to distinguish the timing of the correction of incorrect TINs for health coverage from all other types of accounts for which information reporting is required. Consequently, the proposed regulations do not alter the rules for incorrect TINs in § 301.6724–1(f)(1)(ii) and (iii) as applied to information reporting under section 6055. However, as with the rules regarding missing TINs under § 301.6724–1(e)(1)(ii), the rules regarding incorrect TINs in § 301.6724–1(f)(1)(i) make reference to the time an account is ''opened.'' Accordingly, the proposed regulations, which provides that for purposes of section 6055 reporting an account is considered ''opened'' at the time the filer receives an application for new coverage or to add an individual to existing coverage, also applies for purposes of the initial solicitation for incorrect TINs in § 301.6724–1(f)(1)(i).[2]

a. Application of the TIN Solicitation Rules to ''Responsible Individuals'' and ''Covered Individuals''

A commenter requested clarification that the initial and annual solicitations of § 301.6724–1(e)(1)(i) and (ii) need be made only to the responsible individual for all individuals covered under a single policy. The commenter further suggested that TIN solicitations made to a responsible individual be treated as TIN solicitations made to all individuals named on the responsible individual's policy.

Under § 1.6055–1(e)(1)(ii) and (iii), filers must report the TIN of each covered individual (who, under § 301.6721–1(g)(5), are also ''payees''), and § 1.6055–1(g)(1) requires that the TIN of each covered individual be shown on statements furnished to the responsible individual. Current § 1.6055–1(g)(1) provides that, for purposes of the penalties under section 6722, the furnishing of a statement to the responsible individual is treated as the furnishing of a statement to a covered individual. This rule is intended to allow reporting entities to satisfy the section 6722 requirements for all covered individuals by furnishing the required statement only to the responsible individual. The Treasury Department and the IRS also intend for a similar rule to apply to the TIN solicitation rules under the section 6724 regulations. To clarify that this is how

[2] A filer of the information return required under § 1.6055–1 may receive an error message from the IRS indicating that a TIN and name provided on the return do not match IRS records. An error message is neither a Notice 972CG, Notice of Proposed Civil Penalty, nor a requirement that the filer must solicit a TIN in response to the error message.

these rules apply, the proposed regulations expressly provide that TIN solicitations (both initial and annual) made to the responsible individual for a policy or plan are treated as TIN solicitations of every covered individual on the policy or plan for purposes of § 301.6724–1(e)(1) and (f)(1). The filer does not need to make separate solicitations from the responsible individual for each covered individual nor does it need to separately solicit the TINs of each covered individual by contacting each covered individual directly. However, we decline to adopt the commenter's suggestion that a TIN solicitation made to a responsible individual be treated as a TIN solicitation made to all individuals named on that responsible individual's policy at any time, including those individuals added to a policy after the TIN solicitations. When a new individual is added to a policy, the coverage provider establishes a relationship with that individual. The individual is new to the filer, and it is the filer's responsibility to solicit that individual's TIN. Accordingly, to qualify for the penalty waiver, filers must solicit TINs for each individual added to a policy under the procedures outlined in § 301.6724–1(e)(1)(i) and (f)(1)(i); however, any other individual for whom the filer already has a TIN or already has solicited a TIN the prescribed amount of times need not be solicited again regardless of what changes take place during the filer's coverage of that individual.

b. Different Forms of TIN Solicitations

A commenter to Notice 2015–68 requested that the provision of renewal applications to enrollees be permitted to satisfy the annual solicitation requirement for purposes of § 301.6724–1(e)(1)(ii) and (iii) and (f)(1)(ii) and (iii) if those renewal applications request TINs from covered individuals. Under current law, TIN requests may be made in a number of different formats. The provision of a renewal application that requests TINs for all covered individuals satisfies the annual solicitation provisions of § 301.6724–1(e)(1)(ii) and (iii) and (f)(1)(ii) and (iii) if it is sent by the deadline for those annual solicitations. Thus, no changes to the regulations are necessary for renewal applications to satisfy the annual solicitation requirement.

The same commenter requested that the requirement in § 301.6724–1(e)(2)(i)(B) to provide the responsible individual with a Form W–9 should be eliminated. The commenter was concerned that this requirement imposes burdens on responsible individuals that make it less likely that they will respond to a TIN solicitation. Section 301.6724–1(e)(2)(i)(B) requires that an annual solicitation include a ''Form W–9 or an acceptable substitute . . .'' Thus, the existing regulations do not require that Form W–9 be sent. Filers are allowed to request TINs on an acceptable substitute for Form W–9, which includes a renewal application or other request for a TIN. Thus, this comment is not adopted.

This commenter also requested that the requirement in § 301.6724–1(e)(2)(i)(C) that annual solicitations include a return envelope be eliminated, and, if not eliminated, that clarification be provided as to how this requirement applies to multiple TINs. Existing regulations include this requirement because individuals are more likely to comply with a TIN solicitation if that solicitation includes a return envelope. We see no reason that the requirement to include a return envelope, which exists for other information reporting provisions, should be removed for reporting under section 6055. Thus, the proposed regulations do not adopt this comment. However, filers may request more than one TIN at the same time and do not need to send separate envelopes with each request. For example, on a renewal application requesting the TINs for all covered individuals, filers need only provide one return envelope for that application or request.

c. Solicitations by Employers

A commenter requested that employers be permitted to make TIN solicitations on behalf of filers. The commenter offered that employers are frequently in a better position than coverage providers to request TINs from the employers' employees and the employees' dependents, and, for practical reasons, it would make sense to allow employers to step in the shoes of the coverage provider for purposes of making the solicitations under § 301.6724–1(e)(1) and (f)(1).

Under existing regulations, actions taken by employers may satisfy the requirement for making an initial or annual TIN solicitation. Employers may, for example, provide their employees with applications for health coverage. If these applications request that the applicants provide TINs for all individuals to be covered, the coverage provider has made an initial solicitation for these individuals' TINs.

The commenter further requested that a filer that arranges to have an employer take on responsibility for the TIN solicitations be treated as having met the penalty waiver requirements of § 301.6724–1(e)(1) and (f)(1). Under existing regulations, qualifying for a penalty waiver requires that the solicitations actually be made. To avoid creating a less stringent standard in cases where an employer is acting on the filer's behalf, the proposed regulations do not adopt the commenter's proposal.

d. Electronic TIN Solicitations

A commenter requested that filers be permitted to make annual TIN solicitations by electronic means if the responsible individual has consented to the receipt of information concerning his or her coverage in the same electronic format in which the annual solicitation is made. IRS Publication 1586, Reasonable Cause Regulations and Requirements for Missing and Incorrect Name/TINs (including instructions for reading CD/DVDs), provides that filers may establish an electronic system for payees (including covered individuals) to receive and respond to TIN solicitations, provided certain listed requirements are met. IRS Publication 1586 can be found at *www.irs.gov/forms-pubs.* Because filers are already able to solicit TINs electronically, it is unnecessary to address the commenter's recommendation for electronic TIN solicitations with these proposed regulations.

Proposed Effective/Applicability Date

These regulations are generally proposed to apply for taxable years ending after December 31, 2015, and may be relied on for calendar years ending after December 31, 2013.

The only exception is the rules in section 1 of this preamble relating to reporting of coverage under catastrophic plans. Those rules are proposed to apply for calendar years beginning after December 31, 2016. Health insurance issuers may voluntarily report on 2015 and 2016 catastrophic coverage (on returns and statements filed and furnished in 2016 and 2017 respectively). An issuer that reports on 2015 and/or 2016 catastrophic coverage will not be subject to penalties for these returns.

In addition, until these the proposed regulations are finalized, taxpayers may continue to rely on the rules provided in Notice 2015–68.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required.

It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations.

It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the information collection required under these regulations is imposed under section 6055. Consistent with the statute, the proposed regulations require a person that provides minimum essential coverage to an individual to file a return with the IRS reporting certain information and to furnish a statement to the responsible individual who enrolled an individual or family in the coverage. These regulations primarily provide the method of filing and furnishing returns and statements under section 6055. Moreover, the proposed regulations attempt to minimize the burden associated with this collection of information by limiting reporting to the information that the IRS will use to verify minimum essential coverage and administer tax credits.

Based on these facts, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required.

Pursuant to section 7805(f), this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Statement of Availability of IRS Documents

IRS Revenue Procedures, Revenue Rulings notices, notices and other guidance cited in this preamble are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, or by visiting the IRS Web site at *http://www.irs.gov.*

Comments and Requests for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the ''**ADDRESSES**'' heading. The Treasury Department and the IRS request comments on all aspects of the proposed rules. All comments will be available for public inspection at *www.regulations.gov* or upon request. A public hearing will be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these proposed regulations is John B. Lovelace of the Office of Associate Chief Counsel (Income Tax and Accounting). However, other personnel from the IRS and the Treasury Department participated in the development of the regulations.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 301 are proposed to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

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

■ **Par. 2.** Section 1.6055–1 is amended by:
■ 1. Adding paragraphs (b)(13) and (14).
■ 2. Redesignating paragraph (c)(1)(iv) as (c)(1)(v) and adding a new paragraph (c)(1)(iv).
■ 3. Revising paragraphs (d)(1) and (2).
■ 4. Redesignating paragraph (d)(3) as (d)(5) and adding a new paragraph (d)(3).
■ 5. Adding paragraphs (d)(4) and (6).
■ 6. Revising paragraph (g)(3).
■ 7. Revising paragraph (h)(1).
■ 8. Adding paragraph (h)(3).
■ 9. Revising paragraph (j).

The revisions and additions read as follows:

§ 1.6055–1 Information reporting for minimum essential coverage.

* * * * *

(b) * * *

(13) *Catastrophic plan.* The term catastrophic plan has the same meaning as in section 1302(e) of the Affordable Care Act (42 U.S.C. 18022(e)).

(14) *Basic health program.* The term basic health program means a basic health program established under section 1331 of the Affordable Care Act (42 U.S.C. 18051).

(c) * * *

(1) * * *

(iv) The state agency that administers a Basic Health Program;

* * * * *

(d) *Reporting not required*—(1) *Qualified health plans.* Except for coverage under a catastrophic plan, a health insurance issuer is not required to file a return or furnish a report under this section for coverage in a qualified health plan in the individual market enrolled in through an Exchange.

(2) *Duplicative coverage.* If an individual is covered for a month by more than one minimum essential coverage plan or program provided by the same reporting entity, reporting is required for only one of the plans or programs for that month.

(3) *Supplemental coverage.* Reporting is not required for minimum essential coverage of an individual for a month if that individual is eligible for that coverage only if enrolled in other minimum essential coverage for which section 6055 reporting is required and is not waived under this paragraph (d)(3). This paragraph (d)(3) applies with respect to eligible employer-sponsored coverage only if the supplemental coverage is offered by the same employer that offered the eligible employer-sponsored coverage for which reporting is required. For this purpose, an employer is treated as offering minimum essential coverage offered by any other person that is a member of a controlled group of entities under section 414(b) or (c), an affiliated service group under section 414(m), or an entity in an arrangement described under section 414(o) of which the employer is also a member.

(4) *Certain coverage provided by Territories and Possessions.* The agencies that administer Medicaid and the Children's Health Insurance Program in American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the United States Virgin Islands are not required to report that coverage under section 6055.

* * * * *

(6) *Examples.* The following examples illustrate the rules of this paragraph (d).

Example 1. Upon being hired, Taxpayer A enrolls in a self-insured major medical group health plan and a health reimbursement arrangement (HRA), both offered by A's employer, V. Both the group health plan and the HRA are minimum essential coverage, and V is the reporting entity for both. Because V is the reporting entity for both the self-insured major medical group health plan and the HRA, under paragraph (d)(2) of this section V must report under paragraph (a) of this section for either its self-insured major medical group health plan or its HRA for A

for the months in which A is enrolled in both plans.

Example 2. Taxpayer B is enrolled in an insured employer-sponsored group health plan offered by B's employer, W. B is also covered by an HRA offered by W. Under the terms of the HRA, B is eligible for the HRA because B is enrolled in W's insured employer-sponsored group health plan. W's insured employer-sponsored group health plan is minimum essential coverage and, under paragraphs (a) and (c)(1)(i) of this section, the issuer of the insured employer-sponsored group health plan must report coverage under the plan. Therefore, for the months in which B is enrolled in both plans, under paragraph (d)(3) of this section, W does not need to report the HRA for B because the issuer is required to report on coverage for B in the insured employer-sponsored group health plan offered by W for those months.

Example 3. Taxpayer C enrolls in a Medicare Savings Program administered by X, a state Medicaid agency, which provides financial assistance with Medicare Part A premiums. Only individuals enrolled in Medicare Part A are offered coverage in this Medicare Savings Program. Medicare Part A is government-sponsored minimum essential coverage and, under paragraphs (a) and (c)(1)(iii) of this section, Medicare must report coverage under the program. Therefore, under paragraph (d)(3) of this section, X does not need to report under paragraph (a) of this section for C's coverage under the Medicare Savings Program.

Example 4. Taxpayer E obtains a Medicare supplemental insurance (Medigap) policy that provides financial assistance with costs not covered by Medicare Part A from Z, a health insurance issuer. Only individuals enrolled in Medicare Part A are offered coverage under this Medigap policy. Medicare Part A is minimum essential coverage and, under paragraphs (a) and (c)(1)(iii) of this section, Medicare is required to report E's coverage under Medicare Part A. Therefore, under paragraph (d)(3) of this section, Z does not need to report E's coverage under the Medigap policy.

Example 5. Taxpayer F is covered by an HRA offered by F's employer, P. F is also enrolled in a non-HRA group health plan that is self-insured and sponsored by F's spouse's employer, Q. P and Q are not treated as one employer under section 414(b), (c), (m), or (o). Under the terms of the HRA, F is eligible for the HRA only because F is enrolled in a non-HRA group health plan, which in this case is the group health plan offered by Q. However, because the HRA and the non-HRA group health plan are offered by different employers, paragraph (d)(3) of this section does not apply. Accordingly, under paragraphs (a) and (c)(2)(i)(A) of this section, P must report F's enrollment in the HRA, and Q must report F's (and F's spouse's) enrollment in the non-HRA group health plan.

* * * * *

(g) * * *

(3) *Form of the statement.* A statement required under this paragraph (g) may be made either by furnishing to the responsible individual a copy of the return filed with the Internal Revenue Service or on a substitute statement. A substitute statement must include the information required to be shown on the return filed with the Internal Revenue Service and must comply with requirements in published guidance (see § 601.601(d)(2) of this chapter) relating to substitute statements. An individual's identifying number may be truncated to appear in the form of an IRS truncated taxpayer identification number (TTIN) on the statement furnished to the responsible individual. The identifying number of the employer may also be truncated to appear in the form of a TTIN on the statement furnished to the responsible individual. For provisions relating to the use of TTINs, see § 301.6109–4 of this chapter (Procedure and Administration Regulations).

* * * * *

(h) * * * (1) *In general.* For provisions relating to the penalty for failure to file timely a correct information return required under section 6055, see section 6721 and the regulations under that section. For provisions relating to the penalty for failure to furnish timely a correct statement to responsible individuals required under section 6055, see section 6722 and the regulations under that section. See section 6724, and the regulations thereunder, and paragraph (h)(3) of this section for provisions relating to the waiver of penalties if a failure to file or furnish timely or accurately is due to reasonable cause and not due to willful neglect.

* * * * *

(3) *Application of section 6724 waiver of penalties to section 6055 reporting*—(i) *In general.* Paragraphs (e) and (f) of § 301.6724–1 of this chapter, as modified by this paragraph (h)(3), apply to reasonable cause waivers of penalties under sections 6721 and 6722 for failure to file timely or accurate information returns or to furnish individual statements required to be filed or furnished under section 6055.

(ii) *Account opened.* For purposes of section 6055 reporting and the solicitation rules contained in paragraphs (i), (ii), (iii), and (v) of § 301.6724–1(e)(1) of this chapter and paragraph (i) of § 301.6724–1(f)(1) of this chapter, an account is considered opened at the time the reporting entity receives a substantially complete application for coverage (including an application to add an individual to existing coverage) from or on behalf of an individual for whom the reporting entity does not already provide coverage.

(iii) *First annual solicitation deadline for missing TINs.* In lieu of the deadline for the first annual solicitation contained in paragraph (ii) of § 301.6724–1(e)(1) of this chapter, the first annual solicitation must be made on or before the seventy-fifth day after the date on which an account is opened (or, in the case of retroactive coverage, the seventy-fifth day after the determination of retroactive coverage is made). The period from the date on which the reporting entity receives an application for coverage to the last day on which the first annual solicitation may be made is the first annual solicitation period.

(iv) *Failures to which a solicitation relates*—(A) *Missing TIN.* For purposes of reporting under section 6055 and the solicitation rules contained in paragraph (1) of § 301.6724–1(e) of this chapter, the initial and first annual solicitations relate to failures on returns required to be filed for the year which includes the first effective date of coverage for a covered individual. The second annual solicitation relates to failures on returns filed for the year immediately following the year to which the first annual solicitation relates and for succeeding calendar years.

(B) *Incorrect TIN.* For purposes of reporting under section 6055 and the solicitation rules contained in paragraph (i) of § 301.6724–1(f)(1) of this chapter, the initial solicitation relates to failures on returns required to be filed for the year which includes the first effective date of coverage for a covered individual.

(v) *Solicitations made to responsible individual.* For purposes of reporting under section 6055 and the solicitation rules contained in § 301.6724–1(e) and (f) of this chapter, an initial or annual solicitation made to the responsible individual is treated as a solicitation made to a covered individual.

* * * * *

(j) *Applicability date*—(1) Except as provided in paragraphs (j)(2) and (3) of this section, this section applies for calendar years ending after December 31, 2014.

(2) Paragraphs (b)(14), (c)(1)(v), (d)(2) through (6), and (g)(3) of this section apply to calendar years ending after December 31, 2015. Paragraphs (d)(2), (d)(3), and (g)(3) of § 1.6055–1 as contained in 26 CFR part 1 edition revision as of April 1, 2016, apply to calendar years ending after December 31, 2014 and beginning before January 1, 2016.

(3) Paragraphs (b)(13) and (d)(1) of this section apply to calendar years beginning after December 31, 2016.

Paragraph (d)(1) of § 1.6055–1 as contained in 26 CFR part 1 edition revised as of April 1, 2016, applies to calendar years ending after December 31, 2015 and beginning before January 1, 2017.

PART 301—PROCEDURE AND ADMINISTRATION

■ **Par. 3.** The authority for part 301 continues to read in part as follows:

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

■ **Par. 4.** Section 301.6724–1 is amended by adding a sentence to the end of paragraph (e)(1)(vi)(A) to read as follows:

§ 301.6724–1 Reasonable cause.

* * * * *

(e) * * *

(1) * * *

(vi) *Exceptions and limitations.* (A) * * * See § 1.6055–1(h)(3) of this chapter, which provides rules on the time, form, and manner in which a TIN must be provided for information returns required to be filed and individual statements required to be furnished under section 6055.

* * * * *

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2016–18100 Filed 7–29–16; 11:15 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 246, and 252

[Docket DARS–2016–0014]

RIN 0750–AI92

Defense Federal Acquisition Regulation Supplement: Amendments Related to Sources of Electronic Parts (DFARS Case 2016–D013)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2016 that makes contractors and subcontractors subject to approval (as well as review and audit) by appropriate DoD officials when identifying a contractor-approved supplier of electronic parts.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before October 3, 2016, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2016–D013, using any of the following methods:

○ *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering ''DFARS Case 2016–D013'' under the heading ''Enter keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''DFARS Case 2016–D013.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''DFARS Case 2016–D013'' on your attached document.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2016–D013 in the subject line of the message.

○ *Fax:* 571–372–6094.

o *Mail:* Defense Acquisition Regulations System, Attn: Ms. Amy G. Williams, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal 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: Ms. Amy G. Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to revise the DFARS to implement section 885(b) of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2016 (Pub. L. 114–92), which amends section 818(c)(3)(D)(iii) of the NDAA for FY 2012 (Pub. L. 112–81). Section 885(b) provides that contractors and subcontractors are subject to approval (as well as review and audit) by appropriate DoD officials when identifying a contractor-approved supplier of electronic parts.

II. Discussion and Analysis

This rule proposes to amend DFARS 212.301(f)(xix)(C), 246.870–0(a), and 252.246–7008(b) to cite to section 885(b) of the NDAA for FY 2016. In addition, the rule proposes to amend DFARS 246.870–2(a)(1)(ii)(C) and 252.246–7008(b)(2) to provide that contractor and subcontractor identification of contractor-approved suppliers of electronic parts is subject to review, audit, and approval by the contracting officer or a designee.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule does not add any new provisions or clauses to implement section 885(b) of the NDAA for FY 2016, which amends section 818 of the NDAA for FY 2012. It revises an existing clause 252.246–7008, which applies to acquisitions at or below the simplified acquisition threshold (SAT) and to contracts and subcontracts for the acquisition of commercial items (including commercially available off-the-shelf (COTS) items. A determination and findings was signed under DFARS Case 2014–D005 on May 26, 2016, by the Director, Defense Procurement and Acquisition Policy, to justify the application of section 818 of the NDAA for FY 2012 to acquisitions at or below the SAT and to contracts and subcontracts for the acquisition of commercial items (including COTS items).

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Regulatory Flexibility Act

DoD does not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

This proposed rule implements section 885(b) of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2016 (Pub. L. 114–92), which

amended section 818 of the NDAA for FY 2012.

The objective of this proposed rule is to provide to DoD the authority to approve contractor-approved suppliers of electronic parts, in accordance with section 885(b) of the NDAA for FY 2016.

Based on data available in the Federal Procurement Data System for FY 2013 and 2014, DoD estimates that this rule will apply to approximately 65,357 small entities that have DoD prime contracts or subcontracts for: Electronic parts; end items, components, parts, or assemblies containing electronic parts; or services, if the contractor will supply electronic parts or components, parts, or assemblies containing electronic parts as part of the service.

This proposed rule does not impose any reporting, recordkeeping, or other compliance requirements other than being subject to approval by DoD if the contractor or subcontractor identifies a contractor-approved supplier of electronic parts. However, the contractor may proceed with the acquisition of electronic parts from a contractor-approved supplier unless otherwise notified by DoD.

The proposed rule does not duplicate, overlap, or conflict with any other Federal rules.

DoD was unable to identify any significant alternatives that would reduce the economic impact on small entities and still fulfill the requirements of the statute.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2016–D013), in correspondence.

VI. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 212, 246, and 252

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 212, 246, and 252 are proposed to be amended as follows:

■ 1. The authority citation for parts 212, 246, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

212.301 [Amended]

■ 2. In section 212.301, amend paragraph (f)(xix)(C) by removing ''(Pub. L. 113–291)'' and adding ''(Pub. L. 113–291) and section 885 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92)'' in its place.

PART 246—QUALITY ASSURANCE

246.870–0 [Amended]

■ 3. Amend section 246.870–0, by removing ''(Pub. L. 113–291)'' and adding ''(Pub. L. 113–291) and section 885 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92)'' in its place.

■ 4. In section 246.870–2, revise paragraph (a)(1)(ii)(C) to read as follows:

246.870–2 Policy.

(a) * * *

(1) * * *

(ii) * * *

(C) The selection of such contractor-approved suppliers is subject to review, audit, and approval by the contracting officer. The contractor may proceed with the acquisition of electronic parts from a contractor-approved supplier unless otherwise notified by DoD.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 5. Amend section 252.246–7008 by—

■ a. Removing the clause date ''(AUG 2016)'' and adding ''(DATE)'' in its place;

■ b. In paragraph (b) introductory text, by removing '''(Pub. L. 113–291)'' and adding ''(Pub. L. 113–291) and section 885 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92)'' in its place; and

■ c. Revising paragraph (b)(2)(iii).

The revision reads as follows:

252.246–7008 Sources of Electronic Parts.

* * * * *

(b) * * *

(2) * * *

(iii) The Contractor's selection of such contractor-approved suppliers is subject to review, audit, and approval by the Contracting Officer. The Contractor may proceed with the acquisition of electronic parts from a contractor-approved supplier unless otherwise notified by DoD.

* * * * *

[FR Doc. 2016–18194 Filed 8–1–16; 8:45 am]

BILLING CODE 6820–ep–P

Notices

Federal Register
Vol. 81, No. 148
Tuesday, August 2, 2016

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

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Delaware Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that an orientation and planning meeting of the Delaware State Advisory Committee to the Commission (DE SAC) will convene at 1:00 p.m. (EDT) on Wednesday, August 31, 2016, by conference call. The purpose of the orientation meeting is to inform the newly appointed members about the rules of operation for the advisory committee. The purpose of the planning meeting is to discuss project planning, the selection of additional committee officers and plans for future meetings.

Interested members of the public may listen to the discussion by calling the following toll-free conference call number: 1–877–874–1571 and conference call ID code: 4239535#. Please be advised that before placing them into the conference call, the conference call operator will ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–888–364–3109 and provide the operator with the conference call number: 1–877–874–1571 and conference call ID code: 4239535#.

Members of the public are invited to submit written comments; the comments must be received in the regional office by September 30, 2016. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376–7548, or emailed to Evelyn Bohor at *ero@usccr.gov.* Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at: *http://database.faca.gov/committee/committee.aspx?cid=240&aid=17FACA* and clicking on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone number, email or street address.

Agenda

Rollcall

Ivy L. Davis, Director, Director, Eastern Regional Office and Designated Federal Official (DFO)

Welcome and Introductions

Lisa B. Goodman, Chair, Delaware State Advisory Committee (DE SAC)

Orientation Meeting

Ivy L. Davis, DFO

Planning Meeting

Lisa B. Goodman, Chair, DE SAC

DATES: Wednesday, August 31, 2016 at 1:00 p.m. (EDT).

ADDRESSES: The meeting will be held via teleconference.

PUBLIC CALL INFORMATION: Conference call number: 1–877–874–1571; Conference Call ID code: 4239535#. TDD: Dial Federal Relay Service 1–800–977–8339 and give the operator the above conference call number and conference call ID Code.

FOR FURTHER INFORMATION CONTACT: Ivy L. Davis, at *ero@usccr.gov* or by phone at 202–376–7533

Dated: July 28, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016–18263 Filed 8–1–16; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Connecticut Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA) that an orientation and planning meeting of the Connecticut Advisory Committee to the Commission will convene at 12:00 p.m. (EDT) on Wednesday, August 10, 2016, at the ACLU, 330 Main Street, Hartford, CT 06106. The purpose of the orientation meeting is to inform the newly appointed Committee members about the rules of operation of federal advisory committees and to select additional officers, as determined by the Committee. The purpose of the planning meeting is to discuss potential topics that the Committee may wish to study.

Persons who plan to attend the meeting and who require other accommodations, please contact Evelyn Bohor at *ebohor@usccr.gov* at the Rocky Mountain Regional Office at least ten (10) working days before the scheduled date of the meeting.

Members of the public are invited to submit written comments; the comments must be received in the regional office by Monday, September 12, 2016. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376–7548, or emailed to Evelyn Bohor at *ero@usccr.gov.* Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

The activities of this advisory committee, including records and documents discussed during the meeting, will be available for public viewing, as they become available at:

https://database.faca.gov/committee/meetings.aspx?cid=239. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone number, email or street address.

AGENDA:

Orientation and Administrative Matters
Barbara de La Viez, Deputy Director, Eastern Regional Office and Designated Federal Official
Discussion of Potential Civil Rights topics
David J. McGuire, Chair
Discussion of Potential Topics of Study
CT State Advisory Committee

DATES: Wednesday, August 10, 2016, at 12:00 p.m. (EDT).

ADDRESSES: 330 Main Street, Hartford, CT 06106.

FOR FURTHER INFORMATION CONTACT: Ivy L. Davis at *ero@usccr.gov,* or 202–376–7533.

EXCEPTIONAL CIRCUMSTANCE: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstances of an administrative exceptional circumstance. Given the exceptional urgency of the events, the agency and advisory committee deem it important for the advisory committee to meet on the date given.

Dated: July 27, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016–18160 Filed 8–1–16; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–49–2016]

Foreign-Trade Zone (FTZ) 279—Terrebonne Parish, Louisiana; Notification of Proposed Production Activity; Thoma-Sea Marine Constructors, LLC, Subzone 279A (Shipbuilding), Houma and Lockport, Louisiana

The Houma-Terrebonne Airport Commission, grantee of FTZ 279, submitted a notification of proposed production activity to the FTZ Board on behalf of Thoma-Sea Marine Constructors, LLC (Thoma-Sea), located in Houma and Lockport, Louisiana. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on July 27, 2016.

Thoma-Sea already has authority for the construction and repair of oceangoing vessels within Subzone 279A. The current request would add a foreign status material/component to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status material/component and specific finished product described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Thoma-Sea from customs duty payments on the foreign-status materials/components used in export production. On its domestic sales, Thoma-Sea would be able to choose the duty rate during customs entry procedures that applies to offshore supply ships and vessels (duty-free) for the foreign-status materials/components noted below and in the existing scope of authority. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The additional material/component sourced from abroad is: Tunnel thrusters (duty-free).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is September 12, 2016.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: July 27, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–18350 Filed 8–1–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–921]

Lightweight Thermal Paper From the People's Republic of China: Notice of Rescission of Countervailing Duty Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department is rescinding the administrative review of the countervailing duty order on lightweight thermal paper from the People's Republic of China. The period of review is January 1, 2014, through December 31, 2014.

DATES: Effective August 2, 2016.

FOR FURTHER INFORMATION CONTACT: Sergio Balbontin at (202) 482–6478, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On November 3, 2015, the Department of Commerce (Department) published a notice of opportunity to request an administrative review of the countervailing duty order on lightweight thermal paper (LWTP) from the People's Republic of China (PRC) for the period of review (POR) of January 1, 2014, through December 31, 2014.[1] The Department received a timely-filed request from Appvion, Inc. (Appvion), in accordance with 19 CFR 351.213(b), for an administrative review.[2] On February 9, 2016, the Department published a notice of initiation.[3] On March 10, 2016, Jaan Huey Co., Ltd. (Jaan Huey), a company for which the Department initiated an administrative review, informed the Department that it would not participate in this administrative review.[4] Subsequent to the *Initiation Notice,* the Department requested from U.S. Customs and

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 80 FR 67706 (November 3, 2015).

[2] *See* letter from Appvion, ''Lightweight Thermal Paper From The People's Republic Of China: Request For Administrative Review,'' date November 30, 2015.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 81 FR 6832 (February 9, 2016) (*Initiation Notice*).

[4] *See* letter from Jaan Huey, ''Notice of Non-Participation in CVD Review: Annual Countervailing Duty Administrative Review of Lightweight Thermal Paper From the People's Republic of China,'' dated March 10, 2016.

Border Protection (CBP) data for U.S. imports of subject merchandise during the POR for the companies for which an administrative review was requested.[5] The CBP data demonstrated that there were no entries of subject merchandise exported by these companies during the POR.[6] The Department solicited interested party comments,[7] and we received no comments.

Rescission of Review

It is the Department's practice to rescind an administrative review of a countervailing duty order, pursuant to 19 CFR 351.213(d)(3), when there are no reviewable entries of subject merchandise during the POR for which liquidation is suspended.[8] Normally, upon completion of an administrative review, the suspended entries are liquidated at the countervailing duty assessment rate calculated for the review period. *See* 19 CFR 351.212(b)(l). Therefore, for an administrative review to be conducted, there must be a reviewable, suspended entry that the Department can order CBP to liquidate at the newly calculated countervailing duty assessment rate. Accordingly, in the absence of suspended entries of subject merchandise during the period of this administrative review (January 1, 2014, through December 31, 2014), we are now rescinding this administrative review of the countervailing duty order on LWTP from the PRC, pursuant to 19 CFR 351.213(d)(3).

This notice is issued and published pursuant to section 751 of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: July 25, 2016.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2016–18302 Filed 8–1–16; 8:45 am]

BILLING CODE 3510–DS–P

[5] *See* Memorandum, ''Administrative Review of Certain Lightweight Thermal Paper from the People's Republic of China: Request for U.S. Customs and Border Protection Data,'' dated April 19, 2016.

[6] *Id.*

[7] *Id.*

[8] *See, e.g., Certain Welded Carbon Steel Standard Pipe and Tube From Turkey: Notice of Final Rescission of Countervailing Duty Administrative Review, In Part,* 77 FR 6542 (February 8, 2012).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–824]

Polyethylene Terephthalate Film, Sheet, and Strip from India: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review; 2014–2015

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

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty (AD) order on polyethylene terephthalate film, sheet, and strip (PET Film) from India. The period of review (POR) is July 1, 2014, through June 30, 2015. The Department selected two respondents for individual review, Jindal Poly Films Limited of India (Jindal) and SRF Limited (SRF). The Department preliminarily determines that both Jindal and SRF made sales of subject merchandise at prices below normal value (NV) during the POR. The preliminary results are listed below in the section titled ''Preliminary Results of Review.'' If these preliminary results are adopted in the final results, the Department will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on all appropriate entries of subject merchandise during the POR. Interested parties are invited to comment on these preliminary results.

DATES: Effective August 2, 2016.

FOR FURTHER INFORMATION CONTACT: Alex Cipolla at (202) 482–4956; AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The merchandise subject to the order is polyethylene terephthalate film, sheet, and strip. The PET Film subject to the order is currently classifiable under subheading 3920.62.00.90 of the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS subheading is provided for convenience and customs purposes. The written description is dispositive. A full description of the scope of the order is contained in the memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, ''Decision Memorandum for Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review: Polyethylene Terephthalate Film, Sheet, and Strip from India; 2014–2015'' (Preliminary Decision Memorandum), which is dated concurrently with these preliminary results and hereby adopted by this notice.

Partial Rescission of Administrative Review

On April 1, 2015, the Department published in the **Federal Register** a notice of opportunity to request an administrative review of the AD order on PET Film from India.[1] The Department received multiple timely requests for an administrative review of the AD order on PET Film from India and on September 2, 2015, in accordance with section 751(a) of the Tariff Act of 1930, as amended (''the Act''), the Department initiated a review of nine companies in this proceeding.[2] In response to timely filed withdrawal requests, we are rescinding this administrative review with respect to Ester, MTZ, Polyplex, Vacmet, and Uflex pursuant to 19 CFR 351.213(d)(1).[3] Accordingly, the companies subject to the instant review are: Jindal, SRF, Gaware, and Vacmet India, of which the Department has selected Jindal and SRF as the mandatory respondents.[4]

Methodology

The Department is conducting this review in accordance with section 751(a)(2) of the Act. Export price is calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Decision Memorandum is attached as an Appendix to this notice.

The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To RequestAdministrative Review,* 80 FR 37583 (July 1, 2015).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 80 FR 53106 (September 2, 2015) (*Initiation Notice*). The nine companies were Ester Industries Limited (Ester), Garware Polyester Ltd. (Garware), Jindal, MTZ Polyesters Ltd. (MTZ), Polyplex Corporation Ltd. (Polyplex), SRF, Uflex Ltd. (Uflex), Vacmet, and Vacmet India.

[3] For Additional Information *see* The Preliminary Decision Memorandum at ''Partial Rescission.''

[4] *See* Respondent Selection Memorandum.

and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS''). ACCESS is available to registered users at *https://access.trade.gov/login.aspx* and it is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/*. The signed Preliminary Decision Memorandum and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Companies Not Selected for Individual Review

We preliminarily assign to those companies not selected for individual review the average of the rates calculated for Jindal and SRF in this review, in accordance with section 735(c)(5) of the Act. *See* the Preliminary Decision Memorandum.

Preliminary Results of Review

As a result of this review, we preliminarily determine the following weighted-average dumping margins for the period July 1, 2014, through June 30, 2015.

Manufacturer/exporter	Weighted-average margin (percent)
Jindal Poly Films Limited [5]	0.82
SRF Limited	0.56
Garware Polyester Ltd.	0.77
Vacmet India	0.77

Disclosure and Public Comment

The Department will disclose to interested parties the calculations performed in connection with these preliminary results within five days of the date of publication of this notice.[6] Pursuant to 19 CFR 351.309(c), interested parties may submit cases briefs no later than 30 days after the date of publication of this notice.[7] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[8] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[9] Case and rebuttal briefs should be filed using ACCESS.[10] In order to be properly filed, ACCESS must successfully receive an electronically-filed document in its entirety by 5:00 p.m. Eastern Time.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS, within 30 days after the date of publication of this notice.[11] Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs.

The Department will issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act, unless that time is extended.

Assessment Rates

Upon completion of the administrative review, the Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries in accordance with 19 CFR 351.212(b)(1). We will instruct CBP to liquidate entries of merchandise produced and/or exported by respondent companies. We intend to issue instructions to CBP 15 days after the date of publication of the final results of this review.

For the individually examined respondents Jindal and SRF, if the weighted-average dumping margins are not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, we will calculate importer-specific (or customer-specific) *ad valorem* assessment rates on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales and the total entered value of the sales in accordance with 19 CFR 351.212(b)(1).

However, where the respondent did not report the entered value for its sales, we will calculate importer-specific (or customer-specific) per-unit duty assessment rates. Where the respondents' weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For companies Ester, MTZ, Polyplex, Uflex, and Vacmet for which this review is rescinded, we will instruct CBP to assess antidumping duties at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse for consumption, in accordance with 19 CFR 351.212(c)(1)(i).

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of PET Film from India entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the company under review will be the rate established in the final results of this review (except, if the rate is zero or *de minimis, i.e.,* less than 0.5 percent, no cash deposit will be required); (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this or any previous review, the cash deposit rate will be the all others rate for this proceeding, 5.71 percent. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Interested Parties

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties and/or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties and/or countervailing duties occurred and the subsequent assessment of doubled antidumping duties.

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h)(1) and 351.221(b)(4).

[5] The Initiation Notice lists the company as Jindal Poly Films Limited of India.

[6] *See* 19 CFR 351.224(b).

[7] *See* 19 CFR 351.309(c)(ii).

[8] *See* 19 CFR 351.309(d).

[9] *See* 19 CFR 351.309(c)(2) and (d)(2).

[10] *See* 19 CFR 351.303.

[11] *See* 19 CFR 351.310(c).

Dated: July 27, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

1. Summary.
2. Background.
3. Partial Rescission.
4. Scope of the Order.
5. Comparisons to Normal Value.
6. Product Comparisons.
7. Date of Sale.
8. Export Price.
9. Normal Value.
10. Currency Conversion.
11. Companies Not Selected for Individual Review.
12. Recommendation.

[FR Doc. 2016–18333 Filed 8–1–16; 8:45 am]

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DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No. 160606494–6494–01]

Request for Comments on Post-Quantum Cryptography Requirements and Evaluation Criteria

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice; request for comments

SUMMARY: The National Institute of Standards and Technology (NIST) is requesting comments on a proposed process to solicit, evaluate, and standardize one or more quantum-resistant public-key cryptographic algorithms. Current algorithms are vulnerable to attacks from large-scale quantum computers. The purpose of this notice is to solicit comments on the draft minimum acceptability requirements, submission requirements, evaluation criteria, and evaluation process of candidate algorithms from the public, the cryptographic community, academic/research communities, manufacturers, voluntary standards organizations, and Federal, state, and local government organizations so that their needs can be considered in the process of developing new public-key cryptography standards. The draft requirements and evaluation criteria are available on the NIST Computer Security Resource Center Web site: *http://www.nist.gov/pqcrypto.*

DATES: Comments must be received on or before September 16, 2016.

ADDRESSES: Comments may be sent electronically to *pqc-comments@nist.gov* with ''Comment on Post-Quantum Cryptography Requirements and Evaluation Criteria'' in the subject line. Written comments may also be submitted by mail to Information Technology Laboratory, ATTN: Post-Quantum Cryptography Comments, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8930, Gaithersburg, MD 20899–8930.

Comments received in response to this notice will be published electronically at *http://www.nist.gov/pqcrypto,* so commenters should not include information they do not wish to be posted (*e.g.,* personal or confidential business information).

FOR FURTHER INFORMATION CONTACT: Dr. Lily Chen, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8930, Gaithersburg, MD 20899–8930, email: *Lily.Chen@nist.gov,* by telephone (301) 975–6974.

Technical inquiries regarding the proposed draft acceptability requirements, submission requirements, or the evaluation criteria should be sent electronically to *pqc-comments@nist.gov.*

A public email list-serve has been set up for announcements, as well as a forum to discuss the standardization effort being initiated by NIST. For directions on how to subscribe, please visit *http://www.nist.gov/pqcrypto.*

SUPPLEMENTARY INFORMATION: In recent years, there has been a substantial amount of research on quantum computers—machines that exploit quantum mechanical phenomena to solve mathematical problems that are difficult or intractable for conventional computers. If large-scale quantum computers are ever built, they will compromise the security of many commonly used cryptographic algorithms. In particular, quantum computers would completely break many public-key cryptosystems, including those standardized in FIPS 186–4, Digital Signature Standard (*http://dx.doi.org/10.6028/NIST.FIPS.186-4*), SP 800–56A Revision 2, Recommendation for Pair-Wise Key Establishment Schemes Using Discrete Logarithm Cryptography (*http://dx.doi.org/10.6028/NIST.SP.800-56Ar2*), and SP 800–56B Revision 1, Recommendation for Pair-Wise Key-Establishment Schemes Using Integer Factorization Cryptography (*http://dx.doi.org/10.6028/NIST.SP.800-56Br1*).

Due to this concern, many researchers have begun to investigate post-quantum cryptography (PQC) (also called quantum-resistant cryptography). The goal of this research is to develop cryptographic algorithms that would be secure against both quantum and classical computers. A significant effort will be required in order to develop, standardize, and deploy new post-quantum algorithms. In addition, this transition needs to take place well before any large-scale quantum computers are built, so that any information that is later compromised by quantum cryptanalysis is no longer sensitive when that compromise occurs.

NIST has taken a number of steps in response to this potential threat. On April 2–3, 2015, NIST held a public workshop on Cybersecurity in a Post-Quantum World to solicit input on public-key cryptographic policy in the time of quantum computers. NIST also published NISTIR 8105, Report on Post-Quantum Cryptography (*http://dx.doi.org/10.6028/NIST.IR.8105*), in April 2016 which shares NIST's understanding of the status of quantum computing and post-quantum cryptography.

As a result of study and public feedback, NIST has decided to develop additional public-key cryptographic algorithms through a public standardization process, similar to the development processes for the hash function SHA–3 and the Advanced Encryption Standard (AES). To begin the process, NIST has drafted a set of minimum acceptability requirements, submission requirements, and evaluation criteria for candidate algorithms. The draft document containing these requirements and criteria is available at the Web site: *http://www.nist.gov/pqcrypto.* NIST seeks comments on these draft minimum acceptability requirements, submission requirements, evaluation criteria, and the evaluation process, as well as suggestions for other criteria and for the relative importance of each individual criterion in the evaluation process. Since neither the submission requirements nor the evaluation criteria have been finalized, and may evolve over time as a result of the public comments that NIST receives, candidate algorithms should NOT be submitted at this time.

Authority: In accordance with the Information Technology Management Reform Act of 1996 (Pub. L. 104–106) and the Federal Information Security Management Act of 2002 (Pub. L. 107–347), the Secretary of Commerce is authorized to approve FIPS. NIST activities to develop computer security standards to protect federal sensitive (unclassified) information systems are undertaken pursuant to specific responsibilities assigned to NIST by Section 20 of the National Institute of Standards and Technology Act (15 U.S.C. 278g–3), as amended.

Dated: July 27, 2016.

Kent Rochford,

Associate Director for Laboratory Programs.

[FR Doc. 2016–18150 Filed 8–1–16; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE769

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold a Webinar-based meeting of its River *Herring* and *Shad* (RH/S) Committee.

DATES: The meeting will be held Monday, August 15, 2016, from 1 p.m. to 4:30 p.m.

ADDRESSES: The meeting will be held via Webinar (*http://mafmc.adobeconnect.com/rh-s-com-aug15-2016/*) with a telephone audio connection (provided when connecting).

Council address: Mid-Atlantic Fishery Management Council, 800 N. State St., Suite 201, Dover, DE 19901; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D. Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 526–5255. The Council's Web site, *www.mafmc.org,* also has details on the proposed agenda, Webinar access, and briefing materials.

SUPPLEMENTARY INFORMATION:

Agenda

In October 2016, the Council will consider whether to develop an Amendment that could add several species of river *Herrings* and *Shads* as Council-managed species. This RH/S Committee meeting will review a white paper and draft decision document related to the need for Council management of blueback *Herring, Lewife,* American *Shad,* and hickory *Shad.* Public comments will also be taken.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

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

Dated: July 28, 2016.

Tracey L. Thompson,

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

[FR Doc. 2016–18217 Filed 8–1–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE761

Atlantic Highly Migratory Species; Meeting of the Atlantic Highly Migratory Species Advisory Panel

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

ACTION: Notice of public meeting and webinar/conference call.

SUMMARY: NMFS will hold a 2-day Atlantic Highly Migratory Species (HMS) Advisory Panel (AP) meeting in September 2016. The intent of the meeting is to consider options for the conservation and management of Atlantic HMS. The meeting is open to the public.

DATES: The AP meeting and webinar will be held from 9 a.m. to 6 p.m. on both Wednesday and Thursday, September 7 and September 8, 2016.

ADDRESSES: The meeting will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Avenue, Silver Spring, MD 20910. The meeting presentations will also be available via WebEx webinar/conference call.

On Wednesday, September 7, 2016, the conference call information is phone number 1–888–469–2188; Participant Code: 7954019; and the webinar event address is: *https://noaaevents2.webex.com/noaaevents2/onstage/g.php?MTID=eec1bb32466dd8905125c5db01b539623*; event password: NOAA.

On Thursday, September 8, 2016, the conference call information is phone number 1–888–469–2188; Participant Code: 7954019; and the webinar event address is: *https://noaaevents2.webex.com/noaaevents2/onstage/g.php?MTID=e9fcef19f3c43ce6255dfad07807a71f4*; event password: NOAA.

Participants are strongly encouraged to log/dial in 15 minutes prior to the meeting. NMFS will show the presentations via webinar and allow public comment during identified times on the agenda.

FOR FURTHER INFORMATION CONTACT: Peter Cooper or Margo Schulze-Haugen at (301) 427–8503.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.,* as amended by the Sustainable Fisheries Act, Public Law 104–297, provided for the establishment of an AP to assist in the collection and evaluation of information relevant to the development of any Fishery Management Plan (FMP) or FMP amendment for Atlantic HMS. NMFS consults with and considers the comments and views of AP members when preparing and implementing FMPs or FMP amendments for Atlantic tunas, swordfish, billfish, and sharks.

The AP has previously consulted with NMFS on: Amendment 1 to the Billfish FMP (April 1999); the HMS FMP (April 1999); Amendment 1 to the HMS FMP (December 2003); the Consolidated HMS FMP (October 2006); and Amendments 1, 2, 3, 4, 5a, 5b, 6, 7, 8, 9 and 10 to the 2006 Consolidated HMS FMP (April and October 2008, February and September 2009, May and September 2010, April and September 2011, March and September 2012, January and September 2013, April and September 2014, March and September 2015, March 2016), among other things.

The intent of this meeting is to consider alternatives for the conservation and management of all Atlantic tunas, swordfish, billfish, and shark fisheries. We anticipate discussing the results of the 2016 dusky shark stock assessment and the Amendment 5b timeline; Draft Amendment 10 on Essential Fish Habitat, including potential Habitat Areas of Particular Concern; implementation updates for Final Amendment 7 on bluefin tuna management; and progress updates on various other rulemakings, including archival tag requirements, blacknose and small coastal shark management; domestic implementation of recommendations from the 2015 meeting of the International Commission for the Conservation of Atlantic Tunas; and potential changes to limited access vessel upgrading requirements and Individual Bluefin Quota program inseason transfer criteria. We also anticipate discussing recreational topics regarding data collection and economic surveys, as well as progress updates regarding the exempted fishing permit request to conduct research in pelagic longline closed areas. Finally, we also intend to

invite other NMFS offices to provide updates on their activities relevant to HMS fisheries.

Additional information on the meeting and a copy of the draft agenda will be posted prior to the meeting at: *http://www.nmfs.noaa.gov/sfa/hms/advisory_panels/hms_ap/meetings/ap_meetings.html.*

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Peter Cooper at (301) 427–8503 at least 7 days prior to the meeting.

Dated: July 27, 2016.

Emily H. Menashes,

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

[FR Doc. 2016–18248 Filed 8–1–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE768

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will hold a four-day meeting to consider actions affecting the Gulf of Mexico fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will begin at 8:30 a.m. on Monday, August 15, 2016, and end at 4:15 p.m. on Thursday, August 18, 2016.

ADDRESSES: The meeting will be held at the Astor Crowne Plaza hotel, located at 739 Canal Street, New Orleans, LA; telephone: (504) 962–0500.

Council address: Gulf of Mexico Fishery Management Council, 2203 N. Lois Avenue, Suite 1100, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Douglas Gregory, Executive Director, Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION:

Agenda

Monday, August 15, 2016; 8:30 a.m. to 5:30 p.m.

The Gulf Council will begin with updates and presentations from administrative and management committees. The Administrative/Budget Committee will discuss the Final 2014 No-cost Extension Expenditures; review the Revised Budgets for 2017–2019; review and approve the Updated Regional Operating Agreement with National Marine Fisheries Service (NMFS); hold a discussion regarding Scientific and Statistical Committee (SSC) members also being State Designees; discuss Council Committee Assignments; and review Administrative Handbook revisions. The Data Collection Management Committee will receive a presentation on National Fish and Wildlife Foundation's (NFWF) For-Hire Pilot Program; review modifications to the Generic Charter Vessel and Headboat Reporting Requirements, cost analysis of Commercial Electronic Reporting Program and Atlantic States' Coastal Cooperative Statistics Program Meeting Summary. The Joint Coral/Habitat Protection Management Committees will review a draft of the 5-year Essential Fish Habitat (EFH) review; receive a summary of the Joint *Shrimp* Advisory Panel (AP)/Coral SSC/AP meeting; review a letter regarding the Flower Garden Banks National Marine Sanctuary Draft Environmental Impact Statement; and hold a discussion on fishing regulations for the Flower Garden National Marine Sanctuary.

There will be a CLOSED SESSION to discuss appointments for the Ad Hoc Private Recreational Advisory Panel from 4 p.m. to 5:30 p.m.

Tuesday, August 16, 2016; 8:30 a.m. to 5:30 p.m.

The *Reef Fish* Management Committee will review draft Amendment 36A—Commercial Individual Fishing Quota (IFQ) Modifications; Headboat Collaborative Project; draft Amendment 46—Modify Gray *Triggerfish* Rebuilding Plan; draft Amendment 42—*Reef Fish* Recreational Management for Headboat Survey Vessels; and, draft Amendment 41—*Red Snapper* Management for Federally Permitted Charter Vessels.

Wednesday, August 17, 2016; 8:30 a.m. to 5 p.m.

The *Reef Fish* Management Committee will review an options paper for Amendment 44—Minimum Stock Size Threshold (MSST) for *Reef Fish* Stocks; discuss the carryover of unharvested *Red Snapper* allocations; and receive a summary on the Standing and Special *Reef Fish* SSC Report. The *Mackerel* Management Committee will review an options paper for Coastal Migratory *Pelagics* (CMP) Amendment 29—Allocation Sharing and Accountability Measures for Gulf King *Mackerel.*

The Full Council will convene mid-morning (approximately 11:15 a.m.) with Call to Order, Announcements, presentation of the Law Enforcement Officer of the Year Award and Introductions. Induction of Council Members; Adoption of Agenda and Approval of Minutes; and review of Exempt Fishing Permit (EFPs) Applications, if any. After lunch (12 p.m. to 1:30 p.m.), the Council will receive a summary from the Artificial Reef Summit; Joint Law Enforcement Presentation; and NMFS–SERO Landing Summaries. The Council will receive public testimony from 2:15 p.m. to 5 p.m., on Agenda Testimony item: Flower Garden Banks National Marine Sanctuary Draft Environmental Impact Statement; and, hold an open public testimony period regarding any other fishery issues or concern. Anyone wishing to speak during public comment should sign in at the registration station located at the entrance to the meeting room.

Thursday, August 18, 2016; 8:30 a.m. to 4:15 p.m.

The Council will receive committee reports from the Administrative/Budget, Data Collection, Joint Coral/Habitat Protection, and Mackerel Management Committees. After lunch (11:30 a.m. to 1 p.m.), the Council will receive a committee report from the *Reef Fish* Management Committee; and, vote on Exempted Fishing Permit (EFP) applications, if any. The Council will receive updates from supporting agencies: South Atlantic Fishery Management Council; Gulf States Marine Fisheries Commission; U.S. Coast Guard; U.S. Fish and Wildlife Service; and, the Department of State.

Lastly, the Council will discuss any Other Business items; and, hold an election for Chair and Vice Chair.

Meeting Adjourns

The timing and order in which agenda items are addressed may change as required to effectively address the issue. The latest version will be posted on the Council's file server, which can be accessed by going to the Council's Web site at *http://www.gulfcouncil.org* and clicking on FTP Server under Quick Links. For meeting materials, select the ''Briefing Books/Briefing Book 2016–08''

folder on Gulf Council file server. The username and password are both ''gulfguest.'' The meetings will be webcast over the internet. A link to the webcast will be available on the Council's Web site, at *http://www.gulfcouncil.org.*

Although other non-emergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subjects of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided that the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira (see **ADDRESSES**) at least 5 days prior to the meeting date.

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

Dated: July 28, 2016.

Tracey L. Thompson,

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

[FR Doc. 2016–18218 Filed 8–1–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request: Socioeconomics of Ocean Recreation Operations in the Monterey Bay, Greater Farallones and Cordell Bank National Marine Sanctuaries

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before October 3, 2016.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov).*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Dr. Danielle Schwarzmann 240–533–0705 *danielle.schwarzmann@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for a new information collection to benefit natural resource managers in Greater Farallones National Marine Sanctuary (GFNMS), Cordell Bank National Marine Sanctuary (CBNMS) and the Monterey Bay National Marine Sanctuary (MBNMS). The National Ocean Service (NOS), Office of National Marine Sanctuaries (ONMS) proposes to collect information from wildlife watching operations to ascertain the market value of marine wildlife via the ocean recreational industry in the region that serves passengers aboard their vessels that take people out for non-consumptive recreation in and around the three sanctuaries.

Up-to-date socioeconomic data is needed to support the conservation and management goals of GFNMS, CBNMS and MBNMS to strengthen and improve conservation of marine wildlife, including whales, pinnipeds, sea otters, and seabirds within the jurisdiction of the sanctuary and to satisfy legal mandates under the National Marine Sanctuaries Act (16 U.S.C. 1431 et seq), Endangered Species Act (16 U.S.C. 1531 et seq), Marine Mammal Protection Act (16 U.S.C. 1361 et seq), National Environmental Policy Act (42 U.S.C. 4321), Executive Order 12866 (EO 12866), and other pertinent statutes.

GFNMS, CBNMS and MBNMS have identified a lack of baseline socioeconomic information on ocean recreation businesses. The information is not available to assess the possible economic benefits of marine wildlife protection to the local economy, or the potential impact on ocean recreation businesses. The type of data targeted for this collection; that is, information on costs and earnings from the marine wildlife watching industry, are only currently available for recreational and commercial fishing. Thus, current economic information on the importance of marine wildlife to the local tourism industry is required. We already have approval for the survey of for hire operations in MBNMS under OMB Control No. 0648–0726. The primary focus for this survey will be to gather data on the non-consumptive, market value of marine wildlife. Specifically, researchers will collect data to determine the contribution of marine wildlife watching operations to the economy in the regions.

A second component of the proposed research is the survey of passengers of the for hire operations. The primary focus of this survey is to obtain demographic profiles of users, spending on wildlife viewing trips to estimate the economic impact/contribution to the local economy and the non-market economic value of the use and how those values change with changes in user and natural resource attributes. This information will be required for all three sanctuaries.

II. Method of Collection

For the for hire operations, a research team goes into the business to fill-out forms using records provided by the businesses and answers to questions in a face-to-face interview.

For passengers aboard the operations vessels, respondents have a choice of either electronic or paper forms. Methods of submittal include email of electronic forms, and mail and facsimile transmission of paper forms.

III. Data

OMB Control Number: 0648–XXXX.

Form Number: None.

Type of Review: Regular submission (request for a new information collection).

Affected Public: For profit organizations; individuals or households.

For-Hire Operation Survey:

Estimated Number of Respondents: 30.

Estimated Time per Response: 2.5 hours per survey

Estimated Total Annual Burden Hours: 75 hours.

Passenger Survey:

Estimated Number of Respondents Survey: 3,000.

Total Annual Burden Hours All Surveys: 2,120 hours.

Estimated Total Annual Cost to Public: Other than burden hours there will be no cost to the public.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c)

ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: July 27, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–18195 Filed 8–1–16; 8:45 am]

BILLING CODE 3510–NK–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities Under OMB Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, (PRA), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected costs and burden.

DATES: Comments must be submitted on or before September 1, 2016.

ADDRESSES: Comments regarding the burden estimated or any other aspect of the information collection, including suggestions on reducing the burden, may be submitted directly to the Office of Information and Regulatory Affairs (OIRA) in OMB, within 30 days of the notice's publication, by email at *OIRAsubmissions@omb.eop.gov.* Please identify the comments by OMB Control No. 3038–0111. Please provide the Commission with a copy of all submitted comments at the address listed below. Please refer to OMB Reference No. 3038–0111, found on *http://reginfo.gov.* Comments may also be mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Commodity Futures Trading Commission, 725 17th Street NW., Washington, DC 20503; or through the Agency's Web site at *http://comments.cftc.gov.* Follow the instructions for submitting comments through the Web site.

Comments may also be mailed to: Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581 or by Hand Delivery/Courier at the same address.

A copy of the supporting statements for the collection of information discussed above may be obtained by visiting *http://RegInfo.gov.* All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.*

For Further Information or a Copy Contact: Laura B. Badian, Assistant General Counsel, 202–418–5969, *lbadian@cftc.gov;* Paul Schlichting, Assistant General Counsel, 202–418–5884, *pschlichting@cftc.gov;* or Herminio Castro, Counsel, (202) 418–6705, *hcastro@cftc.gov;* Office of the General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581. Please refer to OMB Control No. 3038–0111 in any correspondence.

SUPPLEMENTARY INFORMATION:

Title: Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants; Comparability Determinations with Margin Requirements, (OMB Control No. 3038–0111). This is a request for a revision of an information collection.

Abstract: Section 731 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act''),[1] amended the Commodity Exchange Act (''CEA''), to add, as section 4s(e) thereof, provisions concerning the establishment of initial and variation margin requirements for swap dealers and major swap participants.[2] Each swap dealer and major swap participant for which there is a Prudential Regulator, as defined in section 1a(39) of the CEA,[3] must meet margin requirements established by the applicable Prudential Regulator, and each swap dealer and major swap participant for which there is no Prudential Regulator (collectively, ''Covered Swap Entities'' or ''CSEs'') must comply with the Commission's margin requirements. With regard to the cross-border application of the swap provisions enacted by Title VII of the Dodd-Frank Act, section 2(i) of the CEA provides the Commission with express authority over activities outside the United States relating to swaps when certain conditions are met. Specifically, section 2(i) of the CEA provides that the provisions of the CEA relating to swaps enacted by Title VII of the Dodd-Frank Act (including Commission rules and regulations promulgated thereunder) shall not apply to activities outside the United States unless those activities (1) have a direct and significant connection with activities in, or effect on, commerce of the United States or (2) contravene such rules or regulations as the Commission may prescribe or promulgate as are necessary or appropriate to prevent the evasion of any provision of Title VII.[4] Because margin requirements are critical to ensuring the safety and soundness of a CSE and the stability of the U.S. financial markets, the Commission believes that its margin rules should apply on a cross-border basis in a manner that effectively addresses risks to a CSE and the U.S. financial system.

On May 31, 2016, the Commission published a Final Rule addressing the cross-border application of its margin requirements for uncleared swaps of CSEs (with substituted compliance available in certain circumstances), except as to a narrow class of uncleared swaps between a non-U.S. CSE and a non-U.S. counterparty that fall within a limited exclusion (the ''Exclusion'').[5] As described below, the adopting release for the Final Rule contained a collection of information regarding requests for comparability determinations, which was previously included in the proposing release, and for which the Office of Management and Budget (''OMB'') assigned OMB control number 3038–0111, titled ''Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants; Comparability Determinations with Margin Requirements.'' In addition, the adopting release included two additional information collections regarding non-segregation jurisdictions[6] and non-netting jurisdictions[7] that were

[1] Pub. L. 111–203, 124 Stat. 1376 (2010).

[2] 7 U.S.C. 6s(e).

[3] 7 U.S.C. 1a(39).

[4] 7 U.S.C. 2(i).

[5] 81 FR 34818 (May 31, 2016).

[6] As used in the adopting release, a ''non-segregation jurisdiction'' is a jurisdiction where inherent limitations in the legal or operational infrastructure of the foreign jurisdiction make it impracticable for the CSE and its counterparty to post initial margin pursuant to custodial arrangements that comply with the Commission's margin rules, as further described in section II.B.4.b of the adopting release.

[7] As used in the adopting release, a ''non-netting jurisdiction'' is a jurisdiction in which a CSE cannot conclude, with a well-founded basis, that the netting agreement with a counterparty in that foreign jurisdiction meets the definition of an ''eligible master netting agreement'' set forth in the

not previously proposed. Accordingly, the Commission is requesting approval by OMB of the revised information collection under OMB Control Number 3038–0111.

Section 23.160(d) of the Final Rule includes a special provision for non-netting jurisdictions. This provision allows CSEs that cannot conclude after sufficient legal review with a well-founded basis that the netting agreement with a counterparty in a foreign jurisdiction meets the definition of an ''eligible master netting agreement'' set forth in the Commission's final margin rule (''Final Margin Rule'') [8] to nevertheless net uncleared swaps in determining the amount of margin that they post, provided that certain conditions are met.[9] In order to avail itself of this special provision, the CSE must treat the uncleared swaps covered by the agreement on a gross basis in determining the amount of initial and variation margin that it must collect, but may net those uncleared swaps in determining the amount of initial and variation margin it must post to the counterparty, in accordance with the netting provisions of the Final Margin Rule.[10] A CSE that enters into uncleared swaps in ''non-netting'' jurisdictions in reliance on this provision must have policies and procedures ensuring that it is in compliance with the special provision's requirements, and maintain books and records properly documenting that all of the requirements of this exception are satisfied.[11]

Section 23.160(e) of the Final Rule includes a special provision for non-segregation jurisdictions that allows non-U.S. CSEs that are Foreign Consolidated Subsidiaries (as defined in the Final Rule) and foreign branches of U.S. CSEs to engage in swaps in foreign jurisdictions where inherent limitations in the legal or operational infrastructure make it impracticable for the CSE and its counterparty to post collateral in compliance with the custodial arrangement requirements of the Commission's margin rules, subject to certain conditions. In order to rely on this special provision, a Foreign Consolidated Subsidiary or foreign branch of a U.S. CSE is required to satisfy all of the conditions of the rule, including that (1) inherent limitations in the legal or operational infrastructure of the foreign jurisdiction make it impracticable for the CSE and its counterparty to post any form of eligible initial margin collateral for the uncleared swap pursuant to custodial arrangements that comply with the Commission's margin rules; (2) foreign regulatory restrictions require the CSE to transact in uncleared swaps with the counterparty through an establishment within the foreign jurisdiction and do not permit the posting of collateral for the swap in compliance with the custodial arrangements of section 23.157 of the Final Margin Rule in the United States or a jurisdiction for which the Commission has issued a comparability determination under the Final Rule with respect to section 23.157; (3) the CSE's counterparty is not a U.S. person and is not a CSE, and the counterparty's obligations under the uncleared swap are not guaranteed by a U.S. person; [12] (4) the CSE collects initial margin in cash on a gross basis, and posts and collects variation margin in cash, for the uncleared swap in accordance with the Final Margin Rule; (5) for each broad risk category, as set out in section 23.154(b)(2)(v) of the Final Margin Rule, the total outstanding notional value of all uncleared swaps in that broad risk category, as to which the CSE is relying on section 23.160 (e), may not exceed 5 percent of the CSE's total outstanding notional value for all uncleared swaps in the same broad risk category; (6) the CSE has policies and procedures ensuring that it is in compliance with the requirements of this provision; and (7) the CSE maintains books and records properly documenting that all of the requirements of this provision are satisfied.[13]

The new information collections covered by this notice require CSEs to have policies and procedures ensuring that they are in compliance with all of the requirements of the special provisions for non-netting jurisdictions and non-segregation provisions, respectively, and to maintain books and records properly documenting that all of the requirements of the special provisions for non-netting jurisdictions and non-segregation jurisdictions, respectively, are satisfied. Both information collections are necessary as a means for the Commission to be able to determine that CSEs relying on these special provisions are entitled to do so and are complying with the special provisions' requirements. Both information collections are also necessary to implement sections 4s(e) of the CEA, which mandates that the Commission adopt rules establishing minimum initial and variation margin requirements for CSEs on all swaps that are not cleared by a registered derivatives clearing organization, and section 2(i) of the CEA, which provides that the provisions of the CEA relating to swaps that were enacted by Title VII of the Dodd-Frank Act (including any rule prescribed or regulation promulgated thereunder) apply to activities outside the United States that have a direct and significant connection with activities in, or effect on, commerce of the United States.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The Commission did not receive any comments on the 60-day **Federal Register** notice, 81 FR 34855, dated May 31, 2016.

• *Burden Statement—Information Collection for Non-Netting Jurisdictions:* The Commission estimates that approximately 54 CSEs may rely on section 23.160(d) of the Final Rule.[14] Furthermore, the Commission estimates that these CSEs would incur an average of 10 annual burden hours to maintain books and records properly documenting that all of the

Final Margin Rule, as described in section II.B.5.b of the adopting release.

[8] *See* Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants, 81 FR 636 (Jan. 6, 2016). The Final Margin Rule, which became effective April 1, 2016, is codified in part 23 of the Commission's regulations. *See* 17 CFR 23.150–159, 161.

[9] The Final Margin Rule permits offsets in relation to either initial margin or variation margin calculation when (among other things), the offsets related to swaps are subject to the same eligible master netting agreement. This ensures that CSEs can effectively foreclose on the margin in the event of a counterparty default, and avoids the risk that the administrator of an insolvent counterparty will ''cherry-pick'' from posted collateral to be returned.

[10] In the event that the special provision for non-segregation jurisdictions applies to a CSE, then the special provision for non-netting jurisdictions would not apply to the CSE even if the relevant jurisdiction is also a ''non-netting jurisdiction.'' In this circumstance, the CSE must collect the gross amount of initial margin in cash (but would not be required to post initial margin), and post and collect variation margin in cash in accordance with the requirements of the special provision for non-segregation jurisdictions, as discussed in section II.B.4.b.

[11] *See* § 23.160(d) of the Final Rule.

[12] The Commission would expect the CSE's counterparty to be a local financial end user that is required to comply with the foreign jurisdiction's laws and that is prevented by regulatory restrictions in the foreign jurisdiction from posting collateral for the uncleared swap in the United States or a jurisdiction for which the Commission has issued a comparability determination under the Final Rule, even using an affiliate.

[13] *See* 17 CFR 23.160(e).

[14] Currently, there are approximately 106 swap entities provisionally registered with the Commission. The Commission estimates that of the approximately 106 swap entities that are provisionally registered, approximately 54 are CSEs that are subject to the Commission's margin rules as they are not subject to a Prudential Regulator. Because all of these CSEs are eligible to use the special provision for non-netting jurisdictions, the Commission estimates that 54 CSEs may rely on section 23.160(d) of the Final Rule.

requirements of this exception are satisfied (including policies and procedures ensuring that they are in compliance). Based upon the above, the estimated hour burden for collection is calculated as follows:

Estimated Number of Respondents per Year: 54.

Estimated Burden Hours per Registrant: 10.

Estimated Total Annual Burden Hours: 540.

Frequency of Collection: Once; As needed.

• *Burden Statement—Information Collection for Non-Segregation Jurisdictions:* The Commission currently estimates that there are between five and ten jurisdictions for which the first two conditions specified above for non-segregation jurisdictions are satisfied and where Foreign Consolidated Subsidiaries and foreign branches of U.S. CSEs that are subject to the Commission's margin rules may engage in swaps, or for purposes of the PRA estimate, an average of 7.5 non-segregation jurisdictions. The Commission estimates that approximately 12 Foreign Consolidated Subsidiaries and foreign branches of U.S. CSEs may rely on section 23.160(e) of the Final Rule in some or all of these jurisdiction(s). The Commission estimates that each Foreign Consolidated Subsidiary or foreign branch of a U.S. CSE relying on this provision would incur an average of 20 annual burden hours to maintain books and records properly documenting that all of the requirements of this provision are satisfied (including policies and procedures ensuring that they are in compliance) with respect to each jurisdiction as to which they rely on the special provision. Thus, based on the average of 7.5 non-segregation jurisdictions, the Commission estimates that each of the approximately 12 Foreign Consolidated Subsidiaries and foreign branches of U.S. CSEs that may rely on this provision will incur an estimated 150 average burden hours per year (*i.e.,* 20 average burden hours per jurisdiction multiplied by 7.5). Based upon the above, the estimated hour burden for collection is calculated as follows:

Estimated Number of Respondents per Year: 12.

Estimated Burden Hours per Registrant: 150.

Estimated Total Annual Burden Hours: 1,800 hours.

Frequency of Collection: Once; As needed.

There are no capital costs or operating and maintenance costs associated with this collection.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: July 27, 2016.

Christopher J. Kirkpatrick,

Secretary of the Commission.

[FR Doc. 2016–18213 Filed 8–1–16; 8:45 am]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities Under OMB Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected costs and burden.

DATES: Comments must be submitted on or before September 1, 2016.

ADDRESSES: Comments regarding the burden estimated or any other aspect of the information collection, including suggestions for reducing the burden, may be submitted directly to the Office of Information and Regulatory Affairs (OIRA) in OMB, within 30 days of the notice's publication, by email at *OIRAsubmissions@omb.eop.gov.* Please identify the comments by OMB Control No. 3038–0067. Please provide the Commission with a copy of all submitted comments at the address listed below. Please refer to OMB Reference No. 3038–0067, found on *http://reginfo.gov.* Comments may also be mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Commodity Futures Trading Commission, 725 17th Street NW., Washington, DC 20503 or through the Agency's Web site at *http://comments.cftc.gov.* Follow the instructions for submitting comments through the Web site.

Comments may also be mailed to: Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581 or by Hand Delivery/Courier at the same address.

A copy of the supporting statements for the collection of information discussed above may be obtained by visiting *http://RegInfo.gov.* All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.*

For Further Information or a Copy Contact: Sue McDonough, Counsel, Office of General Counsel, Commodity Futures Trading Commission, (202) 418–5132; email: *smcdonough@cftc.gov,* and refer to OMB Control No. 3038–0067.

SUPPLEMENTARY INFORMATION:

Title: Part 162 Subpart C—Identity Theft Rule (OMB Control No. 3038–0067). This is a request for extension of a currently approved information collection.

Abstract: This collection of information is needed because under part 162 subpart C—Identify Theft, CFTC-regulated entities are required to develop and implement reasonable policies and procedures to identify, detect, and respond to relevant red flags (the Identity Theft Red Flags Rules) and, in the case of entities that issue credit or debit cards, to assess the validity of, and communicate with cardholders regarding, address changes. Section 162.30 includes the following information collection requirements for each CFTC-regulated entity that qualifies as a ''financial institution'' or ''creditor'' under part 162 subpart C and that offers or maintains covered accounts: (i) Creation and periodic updating of an identity theft prevention program (''Program'') that is approved by the board of directors, an appropriate committee thereof, or a designated senior management employee; (ii) periodic staff reporting to the board of directors on compliance with the Identity Theft Red Flags Rules and related guidelines; and (iii) training of staff to implement the Program. Section 162.32 includes the following information collection requirements for each CFTC-regulated entity that is a credit or debit card issuer: (i) Establishment of policies and procedures that assess the validity of a change of address notification if a request for an additional or replacement card on the account follows soon after the address change; and (ii) notification of a cardholder, before issuance of an additional or replacement card, at the previous address or through some other previously agreed-upon form of communication, or alternatively, assessment of the validity of the address change request through the entity's established policies and procedures. The Commission uses the collection of information to discharge its regulatory responsibilities to protect investors from the risks of identity theft.

CFTC staff estimates of the hour burdens associated with section 162.30 include the one-time burden of complying with this section for newly-formed CFTC-regulated entities, as well as the ongoing costs of compliance for all CFTC-regulated entities. With respect to the one-time burden hours, staff estimates that each newly-formed financial institution or creditor would incur a burden of 2 hours to conduct an initial assessment of covered accounts. Staff estimates that approximately 572 CFTC-regulated financial institutions and creditors are newly formed each year, and the total estimated one-time burden to initially assess covered accounts is therefore 1,144 hours. Staff also estimates that each financial institution or creditor that maintains covered accounts would incur an additional initial burden of 29 hours to develop and obtain board approval of a Program and hours to train the staff of the financial institution or creditor. Staff estimates that approximately 47 [1] CFTC-regulated financial institutions and creditors that maintain covered accounts are newly formed each year, and thus the total estimated one-time burden to develop and obtain board approval of a Program and train staff is 1,363 hours. Thus, the total initial estimated burden for all newly-formed CFTC-regulated entities is 2,507 hours (1,144 hours + 1,363 hours).

With respect to ongoing annual burden hours, CFTC staff estimates that each financial institution or creditor would incur a burden of 2 hours to periodically assess whether it offers or maintains covered accounts. Staff estimates that there are approximately 3,956 CFTC-regulated entities that are either financial institutions or creditors, and the total estimated annual burden to periodically assess covered accounts is therefore 7,912 hours. Staff also estimates that each financial institution or creditor that maintains covered accounts would incur an additional annual burden of 4 hours to prepare and present an annual report to the board and 2 hours to periodically review and update the Program. Staff estimates that there are approximately 47 CFTC-regulated entities that are financial institutions or creditors that offer or maintain covered accounts, and thus the total estimated additional annual burden for these entities is 282 hours. Thus, the total ongoing annual estimated burden for all CFTC-regulated entities is 8,194 hours (7912 hours + 282 hours).

The collections of information required by section 162.32 will apply only to CFTC-regulated entities that issue credit or debit cards. CFTC staff understands that CFTC-regulated entities generally do not issue credit or debit cards, but instead may partner with other entities, such as banks, that issue cards on their behalf. These other entities, which are not regulated by the CFTC, are already subject to substantially similar change of address obligations pursuant to other federal regulators' identity theft red flags rules. Therefore, staff does not expect that any CFTC-regulated entities will be subject to the information collection requirements of section 163.32, and accordingly, staff estimates that there is no hour burden related to section 162.32 for CFTC-regulated entities.

In total, CFTC staff estimates that the aggregate annual information collection burden of part 162 subpart C is 10,701 hours (2,507 hours + 8,194 hours). This estimate of burden hours is made solely for the purposes of the Paperwork Reduction Act and is not derived from a quantitative, comprehensive, or even representative survey or study of the burdens associated with Commission rules and forms. Compliance with part 162 subpart C, including compliance with the information collection requirements thereunder, is mandatory for each CFTC regulated entity that qualifies as a ''financial institution'' or ''creditor'' under part 162 subpart C (as discussed above, certain collections of information under part 162 subpart C are mandatory only for financial institutions or creditors that offer or maintain covered accounts).

The Commission did not receive any comments on the 60-day **Federal Register** notice, 81 FR 35001, dated June 1, 2016.

Estimated Number of Respondents: 4,622.

Estimated Average Burden Hours per Respondent: 2.32.

Estimated Total Annual Burden Hours: 10,723.[2]

Frequency of Collection: Once.

There are no capital costs or operating and maintenance costs associated with this collection.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: July 27, 2016.

Christopher J. Kirkpatrick,

Secretary of the Commission.

[FR Doc. 2016–18212 Filed 8–1–16; 8:45 am]

BILLING CODE 6351–01–P

[1] Based on a review of new registrations typically filed with the CFTC each year, CFTC staff estimates that approximately 6 futures commission merchants (''FCMs''), 83 introducing brokers (''IBs''), 282 commodity trading advisors (''CTAs), and 198 commodity pool operators (''CPOs'') are newly formed each year, for a total of 572 entities. CFTC staff also has observed that approximately 50 percent of all CPOs are dually registered as CTAs. With respect to RFEDs, CFTC staff has observed that all entities registering as RFEDs also register as FCMs. Based on these observation, CFTC has determined that the total number of newly-formed financial institutions and creditors is 470 (569–99 CPOs that are also registered as CTAs). There were no newly registered RFEDs, SDs, or MSPs. Each of these 470 financial institutions or creditors would bear the initial one-time burden of compliance. Of the total 470 newly-formed entities, staff estimates that all of the FCMs are likely to carry covered accounts, 10 percent of CTAs and CPOs are likely to carry covered accounts, and none of the IBs are likely to carry covered accounts, for a total of 47 newly-formed financial institutions or creditors carrying covered accounts that would be required to conduct an initial one-time burden of compliance with subpart C of part 162.

[2] This total annual burden hour reflects a slight increase in the estimated total annual burden hours to account for the average burden hours per respondent of 2.32 hours.

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Paducah

AGENCY: Department of Energy (DOE).

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Paducah. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, August 18, 2016, 6:00 p.m.

ADDRESSES: Barkley Centre, 111 Memorial Drive, Paducah, Kentucky 42001.

FOR FURTHER INFORMATION CONTACT: Jennifer Woodard, Deputy Designated Federal Officer, Department of Energy Paducah Site Office, Post Office Box 1410, MS–103, Paducah, Kentucky 42001, (270) 441–6825.

SUPPLEMENTARY INFORMATION: *Purpose of the Board:* The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management and related activities.

Tentative Agenda:

- Call to Order, Introductions, Review of Agenda
- Administrative Issues
- Public Comments (15 minutes)
- Adjourn

Breaks taken as appropriate.

Public Participation: The EM SSAB, Paducah, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to

a disability, please contact Jennifer Woodard as soon as possible in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Jennifer Woodard at the telephone number listed above. Requests must be received as soon as possible prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments. The EM SSAB, Paducah, will hear public comments pertaining to its scope (clean-up standards and environmental restoration; waste management and disposition; stabilization and disposition of non-stockpile nuclear materials; excess facilities; future land use and long-term stewardship; risk assessment and management; and clean-up science and technology activities). Comments outside of the scope may be submitted via written statement as directed above.

Minutes: Minutes will be available by writing or calling Jennifer Woodard at the address and phone number listed above. Minutes will also be available at the following Web site: *http://www.pgdpcab.energy.gov/2016_meetings.htm.*

Issued at Washington, DC, on July 27, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–18186 Filed 8–1–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

President's Council of Advisors on Science and Technology

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open teleconference.

SUMMARY: This notice sets forth the schedule and summary agenda for a conference call of the President's Council of Advisors on Science and Technology (PCAST), and describes the functions of the Council. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: August 15, 2016, 4:00 p.m. to 5:00 p.m.

ADDRESSES: To receive the call-in information, attendees should register for the conference call on the PCAST Web site, *http://www.whitehouse.gov/ostp/pcast* no later than 1:00 p.m. (ET) on Friday, August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Information regarding the meeting agenda, time, location, and how to register for the meeting is available on the PCAST Web site at: *http://whitehouse.gov/ostp/pcast.* Questions about the meeting should be directed to Ms. Jennifer Michael at *Jennifer_L_Michael@ostp.eop.gov,* (202) 456–4444.

SUPPLEMENTARY INFORMATION: The President's Council of Advisors on Science and Technology (PCAST) is an advisory group of the nation's leading scientists and engineers, appointed by the President to augment the science and technology advice available to him from inside the White House, cabinet departments, and other Federal agencies. See the Executive Order at *http://www.whitehouse.gov/ostp/pcast.* PCAST is consulted about and provides analyses and recommendations concerning a wide range of issues where understandings from the domains of science, technology, and innovation may bear on the policy choices before the President. PCAST is co-chaired by Dr. John P. Holdren, Assistant to the President for Science and Technology, and Director, Office of Science and Technology Policy, Executive Office of the President, The White House; and Dr. Eric S. Lander, President, Broad Institute of the Massachusetts Institute of Technology and Harvard.

Type of Meeting: Open.

Proposed Schedule and Agenda: The President's Council of Advisors on Science and Technology (PCAST) is scheduled to hold a public conference call on August 15, 2016 from 4:00 p.m. to 5:00 p.m.

Open Portion of Meeting: During this open meeting, PCAST is scheduled to vote on its biodefense and forensics studies. Additional information and the agenda, including any changes that arise, will be posted at the PCAST Web site at: *http://whitehouse.gov/ostp/pcast.*

Public Comments: It is the policy of the PCAST to accept written public comments of any length, and to accommodate oral public comments whenever possible. The PCAST expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements.

The public comment period for this meeting will take place on August 15, 2016 at a time specified in the meeting agenda posted on the PCAST Web site at *http://whitehouse.gov/ostp/pcast.* This public comment period is designed only for substantive commentary on PCAST's work, not for business marketing purposes.

Oral Comments: To be considered for the public speaker list at the meeting, interested parties should register to speak at *http://whitehouse.gov/ostp/pcast,* no later than 1:00 p.m. Eastern Time on August 12, 2016. Phone or email reservations will not be accepted. To accommodate as many speakers as possible, the time for public comments will be limited to two (2) minutes per person, with a total public comment period of up to 10 minutes. If more speakers register than there is space available on the agenda, PCAST will randomly select speakers from among those who applied. Those not selected to present oral comments may always file written comments with the committee.

Written Comments: Although written comments are accepted continuously, written comments should be submitted to PCAST no later than 1:00 p.m. Eastern Time on August 12, 2016 so that the comments may be made available to the PCAST members prior to this meeting for their consideration. Information regarding how to submit comments and documents to PCAST is available at *http://whitehouse.gov/ostp/pcast* in the section entitled ''Connect with PCAST.''

Please note that because PCAST operates under the provisions of FACA, all public comments and/or presentations will be treated as public documents and will be made available for public inspection, including being posted on the PCAST Web site.

Meeting Accommodations: Individuals requiring special accommodation to access this public meeting should contact Ms. Jennifer Michael at least ten business days prior to the meeting so that appropriate arrangements can be made.

Issued in Washington, DC, on July 27, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–18185 Filed 8–1–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Northern New Mexico

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a combined meeting of the Environmental Monitoring and Remediation Committee and Waste Management Committee of the Environmental Management Site-Specific Advisory Board (EM SSAB), Northern New Mexico (known locally as the Northern New Mexico Citizens' Advisory Board [NNMCAB]). The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, August 24, 2016, 1:00 p.m.–4:00 p.m.

ADDRESSES: NNMCAB Office, 94 Cities of Gold Road, Santa Fe, NM 87506.

FOR FURTHER INFORMATION CONTACT: Menice Santistevan, Northern New Mexico Citizens' Advisory Board, 94 Cities of Gold Road, Santa Fe, NM 87506. Phone (505) 995–0393; Fax (505) 989–1752 or Email: *menice.santistevan@em.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Purpose of the Environmental Monitoring and Remediation Committee (EM&R): The EM&R Committee provides a citizens' perspective to NNMCAB on current and future environmental remediation activities resulting from historical Los Alamos National Laboratory (LANL) operations and, in particular, issues pertaining to groundwater, surface water and work required under the New Mexico Environment Department Order on Consent. The EM&R Committee will keep abreast of DOE–EM and site programs and plans. The committee will work with the NNMCAB to provide assistance in determining priorities and the best use of limited funds and time. Formal recommendations will be proposed when needed and, after consideration and approval by the full NNMCAB, may be sent to DOE–EM for action.

Purpose of the Waste Management (WM) Committee: The WM Committee reviews policies, practices and procedures, existing and proposed, so as to provide recommendations, advice, suggestions and opinions to the NNMCAB regarding waste management operations at the Los Alamos site.

Tentative Agenda:

- Call to Order and Introductions
- Approval of Agenda
- Approval of Minutes from June 15, 2016
- Old Business
  - o Discuss Topics for Future Recommendations
  - o Requests for Future Presentations
- New Business
  - o Election of WM Committee Vice-Chair
- Update from DOE
- Presentation: Climate Change Effects in the Southwest
- Public Comment Period
- Adjourn

Public Participation: The NNMCAB's Committees welcome the attendance of the public at their combined committee meeting and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Menice Santistevan at least seven days in advance of the meeting at the telephone number listed above. Written statements may be filed with the Committees either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Menice Santistevan at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Menice Santistevan at the address or phone number listed above. Minutes and other Board documents are on the Internet at: *http://energy.gov/em/nnmcab/northern-new-mexico-citizens-advisory-board.*

Issued at Washington, DC, on July 27, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–18187 Filed 8–1–16; 8:45 am]

BILLING CODE 6405–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1852–014; ER10–1971–029; ER11–4462–020.

Applicants: Florida Power & Light Company, NextEra Energy Power Marketing, LLC, NEPM II, LLC.

Description: Notification of Change in Status of Florida Power & Light Company, *et al.*

Filed Date: 7/26/16.

Accession Number: 20160726–5173.

Comments Due: 5 p.m. ET 8/16/16.

Docket Numbers: ER16–1479–001.

Applicants: Kentucky Utilities Company.

Description: Compliance filing: Compliance Filing Brown Solar Depriciation Rates to be effective 6/9/2016.

Filed Date: 7/27/16.

Accession Number: 20160727–5058.

Comments Due: 5 p.m. ET 8/17/16.

Docket Numbers: ER16–2019–000.

Applicants: Five Points Solar Park LLC.

Description: Supplement to June 24, 2016 Five Points Solar Park LLC tariff filing.

Filed Date: 7/21/16.

Accession Number: 20160721–5123.

Comments Due: 5 p.m. ET 8/1/16.

Docket Numbers: ER16–2289–000.

Applicants: Golden Fields Solar I, LLC.

Description: Initial rate filing: Market-Based Rate Tariff to be effective 8/1/2016.

Filed Date: 7/26/16.

Accession Number: 20160726–5148.

Comments Due: 5 p.m. ET 8/16/16.

Docket Numbers: ER16–2290–000.

Applicants: Spartan Renewable Energy, Inc.

Description: Baseline eTariff Filing: Spartan Renewable Energy, Inc. Market-Based Rate Tariff to be effective 1/1/2017.

Filed Date: 7/26/16.

Accession Number: 20160726–5151.

Comments Due: 5 p.m. ET 8/16/16.

Docket Numbers: ER16–2291–000.

Applicants: Duke Energy Carolinas, LLC.

Description: § 205(d) Rate Filing: Amendment to NCEMC NITSA SA No. 210 to be effective 7/1/2016.

Filed Date: 7/27/16.

Accession Number: 20160727–5031.

Comments Due: 5 p.m. ET 8/17/16.

Docket Numbers: ER16–2292–000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: PSCo-BkCoU-Trans Intercon Agrmt 0.0.0 Filing to be effective 9/26/2016.

Filed Date: 7/27/16.

Accession Number: 20160727–5060.

Comments Due: 5 p.m. ET 8/17/16.

Docket Numbers: ER16–2293–000.

Applicants: Drift Sand Wind Project, LLC.

Description: Baseline eTariff Filing: MBR Tariff to be effective 9/1/2016.

Filed Date: 7/27/16.
Accession Number: 20160727–5069.
Comments Due: 5 p.m. ET 8/17/16.
Docket Numbers: ER16–2294–000.
Applicants: Interstate Power and Light Company.
Description: § 205(d) Rate Filing: Revised IPL Rate Schedule for Blackstart Resource Services to be effective 9/1/2016.
Filed Date: 7/27/16.
Accession Number: 20160727–5072.
Comments Due: 5 p.m. ET 8/17/16.
Docket Numbers: ER16–2295–000.
Applicants: Duke Energy Carolinas, LLC.
Description: § 205(d) Rate Filing: Affected System Operating Agreement SA No. 481 to be effective 7/1/2016.
Filed Date: 7/27/16.
Accession Number: 20160727–5074.
Comments Due: 5 p.m. ET 8/17/16.
Docket Numbers: ER16–2296–000.
Applicants: Southwest Power Pool, Inc.
Description: Compliance filing: 3127 Montana-Dakota Utilities Co. NITSA and NOA to be effective 10/1/2015.
Filed Date: 7/27/16.
Accession Number: 20160727–5104.
Comments Due: 5 p.m. ET 8/17/16.
Docket Numbers: ER16–2297–000.
Applicants: Osborn Wind Energy, LLC.
Description: Baseline eTariff Filing: Osborn Wind Energy, LLC Application for Market-Based Rates to be effective 10/1/2016.
Filed Date: 7/27/16.
Accession Number: 20160727–5105.
Comments Due: 5 p.m. ET 8/17/16.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES16–45–000.
Applicants: Spring Canyon Interconnection LLC.
Description: Application for Blanket Authorization to Issue Securities and Assume Liabilities of Spring Canyon Interconnection LLC.
Filed Date: 7/20/16.
Accession Number: 20160720–5166.
Comments Due: 5 p.m. ET 8/10/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 27, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–18284 Filed 8–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–2289–000]

Golden Fields Solar I, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding Golden Fields Solar I, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 16, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 27, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–18285 Filed 8–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–157–000.
Applicants: Alcoa Power Generating Inc., Cube Yadkin Generation LLC, Cube Yadkin Transmission LLC.
Description: Joint Application for Authorization for Disposition and Consolidation of Jurisdictional Facilities and Acquisition of Existing Generation Facilities and Request for Expedited Action of Alcoa Power Generating Inc., et al.
Filed Date: 7/26/16.
Accession Number: 20160726–5036.
Comments Due: 5 p.m. ET 8/16/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1513–003.
Applicants: Wolverine Power Supply Cooperative, Inc.
Description: Notice of Change in Status and Request for Waiver of Wolverine Power Supply Cooperative, Inc.
Filed Date: 7/25/16.
Accession Number: 20160725–5244.
Comments Due: 5 p.m. ET 8/15/16.

Docket Numbers: ER14–2751–004.
Applicants: Xcel Energy Southwest Transmission Company, LLC.

Description: Compliance Filing of Xcel Energy Southwest Transmission Company, LLC.
Filed Date: 7/25/16.
Accession Number: 20160725–5235.
Comments Due: 5 p.m. ET 8/15/16.

Docket Numbers: ER14–2752–005.
Applicants: Xcel Energy Transmission Development Company, LLC.
Description: Compliance Filing of Xcel Energy Transmission Development Company, LLC.
Filed Date: 7/25/16.
Accession Number: 20160725–5234.
Comments Due: 5 p.m. ET 8/15/16.

Docket Numbers: ER16–1277–002; ER16–1293–002.
Applicants: White Pine Solar, LLC, White Oak Solar, LLC.
Description: Notice of Non-material Change in Status of White Pine Solar, LLC, et al.
Filed Date: 7/25/16.
Accession Number: 20160725–5245.
Comments Due: 5 p.m. ET 8/15/16.

Docket Numbers: ER16–1286–001.
Applicants: Southwest Power Pool, Inc.
Description: Tariff Amendment: Response to Letter Requesting Additional Information in ER16–1286 and ER16–1314 to be effective 5/29/2016.
Filed Date: 7/25/16.
Accession Number: 20160725–5202.
Comments Due: 5 p.m. ET 8/15/16.

Docket Numbers: ER16–1314–001.
Applicants: Southwest Power Pool, Inc.
Description: Tariff Amendment: Response to Letter Requesting Additional Information in ER16–1286 and ER16–1314 to be effective 3/1/2016.
Filed Date: 7/25/16.
Accession Number: 20160725–5203.
Comments Due: 5 p.m. ET 8/15/16.

Docket Numbers: ER16–2275–000.
Applicants: Kingman Wind Energy I, LLC.
Description: Baseline eTariff Filing: Kingman Wind Energy I, LLC Application for Market-Based Rates to be effective 10/1/2016.
Filed Date: 7/25/16.
Accession Number: 20160725–5197.
Comments Due: 5 p.m. ET 8/15/16.

Docket Numbers: ER16–2276–000.
Applicants: Kingman Wind Energy II, LLC.
Description: Baseline eTariff Filing: Kingman Wind Energy II, LLC Application for Market-Based Rates to be effective 10/1/2016.
Filed Date: 7/25/16.
Accession Number: 20160725–5198.
Comments Due: 5 p.m. ET 8/15/16.

Docket Numbers: ER16–2277–000.
Applicants: Solar Star California XLI, LLC.
Description: Initial rate filing: Market-Based Rate Tariff to be effective 8/1/2016.
Filed Date: 7/25/16.
Accession Number: 20160725–5201.
Comments Due: 5 p.m. ET 8/15/16.

Docket Numbers: ER16–2278–000.
Applicants: Cube Yadkin Generation LLC.
Description: Baseline eTariff Filing: MBR Application to be effective 9/25/2016.
Filed Date: 7/26/16.
Accession Number: 20160726–5001.
Comments Due: 5 p.m. ET 8/16/16.

Docket Numbers: ER16–2279–000.
Applicants: Southern California Edison Company.
Description: Tariff Cancellation: Notices of Cancellation to GIA and Distrib Service Agmt with Ganna Halvorsen to be effective 9/25/2016.
Filed Date: 7/26/16.
Accession Number: 20160726–5004.
Comments Due: 5 p.m. ET 8/16/16.

Docket Numbers: ER16–2280–000.
Applicants: Southern California Edison Company.
Description: Section 205(d) Rate Filing: First Amended LGIA Valentine Solar, LLC for Avalon Hybrid Project to be effective 7/27/2016.
Filed Date: 7/26/16.
Accession Number: 20160726–5005.
Comments Due: 5 p.m. ET 8/16/16.

Docket Numbers: ER16–2281–000.
Applicants: American Transmission Systems, Incorporated, PJM Interconnection, L.L.C.
Description: Section 205(d) Rate Filing: American Transmission Systems, Inc. Filing of Revised Service Agreement No. 4240 to be effective 9/15/2016.
Filed Date: 7/26/16.
Accession Number: 20160726–5052.
Comments Due: 5 p.m. ET 8/16/16.

Docket Numbers: ER16–2282–000.
Applicants: Northern Indiana Public Service Company.
Description: Section 205(d) Rate Filing: Supplement for Coonrod 69 kv Delivery Point to be effective 7/31/2016.
Filed Date: 7/25/16.
Accession Number: 20160725–5246.
Comments Due: 5 p.m. ET 8/15/16.

Docket Numbers: ER16–2283–000.
Applicants: Genbright LLC.
Description: Request for Limited Waiver of Genbright, LLC.
Filed Date: 7/26/16.
Accession Number: 20160726–5062.
Comments Due: 5 p.m. ET 8/16/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 26, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–18288 Filed 8–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–136–000.
Applicants: Patua Acquisition Company, LLC, Patua Project, LLC.
Description: Amendment to June 29, 2016 Application For Prospective Authorization Under Section 203 of the Federal Power Act of Patua Acquisition Company, LLC, et al.
Filed Date: 7/15/16.
Accession Number: 20160715–5156.
Comments Due: 5 p.m. ET 7/25/16.

Docket Numbers: EC16–153–000.
Applicants: Antelope DSR 2, LLC.
Description: Application for Authorization Under Section 203 of the Federal Power Act for the Disposition of Jurisdictional Facilities, Request for Expedited Consideration and Confidential Treatment of Antelope DSR 2, LLC.
Filed Date: 7/20/16.
Accession Number: 20160720–5073.
Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: EC16–154–000.
Applicants: Western Antelope Dry Ranch LLC.
Description: Application for Authorization Under Section 203 of the Federal Power Act for the Disposition of Jurisdictional Facilities, Request for

Expedited Consideration and Confidential Treatment of Western Antelope Dry Ranch LLC.

Filed Date: 7/20/16.

Accession Number: 20160720–5112.

Comments Due: 5 p.m. ET 8/10/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2265–011; ER12–21–020; ER11–2211–009; ER11–2209–009; ER11–2210–009; ER11–2207–009; ER11–2206–009; ER13–1150–007; ER13–1151–007; ER11–2855–020; ER14–1818–011; ER10–2260–007; ER10–2261–007; ER10–2338–013; ER10–2340–013; ER13–1991–008; ER13–1992–008; ER11–3727–015; ER10–2262–006; ER11–2062–020; ER11–2508–019; ER11–4307–020; ER12–1711–015; ER12–261–019; ER10–2264–007; ER10–1581–017; ER10–2354–009; ER11–2107–011; ER11–2108–011; ER10–2888–020; ER13–1803–011; ER13–1790–011; ER13–1746–012; ER12–1525–015; ER12–2019–013; ER10–2266–006; ER12–2398–014; ER11–3459–014; ER11–4308–020; ER11–2805–019; ER11–2856–020; ER13–2107–010; ER13–2020–010; ER13–2050–010; ER11–2857–020; ER10–2359–008; ER10–2381–008.

Applicants: NRG Power Marketing LLC, Agua Caliente Solar, LLC, Alta Wind I, LLC, Alta Wind II, LLC, Alta Wind III, LLC, Alta Wind IV, LLC, Alta Wind V, LLC, Alta Wind X, LLC, Alta Wind XI, LLC, Avenal Park LLC, Boston Energy Trading and Marketing LLC, Cabrillo Power I LLC, Cabrillo Power II LLC, CP Power Sales Nineteen, L.L.C., CP Power Sales Twenty, L.L.C., Desert Sunlight 250, LLC, Desert Sunlight 300, LLC, El Segundo Energy Center LLC, El Segundo Power, LLC, Energy Plus Holdings LLC, GenOn Energy Management, LLC, Green Mountain Energy Company, High Plains Ranch II, LLC, Independence Energy Group LLC, Long Beach Generation LLC, Long Beach Peakers LLC, Midway-Sunset Cogeneration Company, North Community Turbines LLC, North Wind Turbines LLC, Norwalk Power LLC, NRG California South LP, NRG Delta LLC, NRG Marsh Landing LLC, NRG Solar Alpine LLC, NRG Solar Avra Valley LLC, NRG Solar Blythe LLC, NRG Solar Borrego I LLC, NRG Solar Roadrunner LLC, Reliant Energy Northeast LLC, RRI Energy Services, LLC, Sand Drag LLC, Solar Partners I, LLC, Solar Partners II, LLC, Solar Partners VIII, LLC, Sun City Project LLC, Sunrise Power Company, LLC, Walnut Creek Energy, LLC.

Description: Supplement to June 30, 2016 Updated Market Power Analysis of the Southwest Region of NRG Power Marketing LLC, et al.

Filed Date: 7/18/16.

Accession Number: 20160718–5172.

Comments Due: 5 p.m. ET 8/29/16.

Docket Numbers: ER14–2952–005.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Report Filing: 2016–07–20_SSR Cost Allocation Refiling of Refund Report to be effective N/A.

Filed Date: 7/20/16.

Accession Number: 20160720–5080.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–994–002.

Applicants: Pacific Gas and Electric Company.

Description: Compliance filing: Compliance Filing to Revise Appendix A of the Western IA (SA 59) to be effective 4/1/2016.

Filed Date: 7/20/16.

Accession Number: 20160720–5072.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–2238–000.

Applicants: Consolidated Edison Company of New York, Inc., Orange and Rockland Utilities, Inc., New York Independent System Operator, Inc.

Description: § 205(d) Rate Filing: Con Edison and O&R Transco Agreements to be effective 5/27/2016.

Filed Date: 7/19/16.

Accession Number: 20160719–5106.

Comments Due: 5 p.m. ET 8/9/16.

Docket Numbers: ER16–2239–000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: 2019–07–19 WAPA DTBAOA Agreement Amendment 1 to be effective 9/18/2016.

Filed Date: 7/19/16.

Accession Number: 20160719–5107.

Comments Due: 5 p.m. ET 8/9/16.

Docket Numbers: ER16–2240–000.

Applicants: Rush Springs Wind Energy, LLC.

Description: Baseline eTariff Filing: Rush Springs Wind Energy, LLC Application for Market-Based Rates to be effective 10/1/2016.

Filed Date: 7/19/16.

Accession Number: 20160719–5109.

Comments Due: 5 p.m. ET 8/9/16.

Docket Numbers: ER16–2241–000.

Applicants: Ninnescah Wind Energy, LLC.

Description: Baseline eTariff Filing: Ninnescah Wind Energy, LLC Application for Market-Based Rates to be effective 10/1/2016.

Filed Date: 7/19/16.

Accession Number: 20160719–5111.

Comments Due: 5 p.m. ET 8/9/16.

Docket Numbers: ER16–2242–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2016–07–20_SA 2928 ITCTransmission-Tuscola Wind III GIA (J301) to be effective 7/21/2016.

Filed Date: 7/20/16.

Accession Number: 20160720–5039.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–2243–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2016–07–20_SA 2929 ITCTransmission-Huron Wind GIA (J308) to be effective 7/21/2016.

Filed Date: 7/20/16.

Accession Number: 20160720–5045.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–2244–000.

Applicants: Duke Energy Carolinas, LLC.

Description: § 205(d) Rate Filing: Amendment to PMPA NITSA SA No. 355 to be effective 7/1/2016.

Filed Date: 7/20/16.

Accession Number: 20160720–5058.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–2245–000.

Applicants: Wabash Valley Power Association, Inc.

Description: § 205(d) Rate Filing: Amendments to Rate Schedules—Boone REMC to be effective 9/20/2016.

Filed Date: 7/20/16.

Accession Number: 20160720–5082.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–2246–000.

Applicants: Antelope DSR 1, LLC.

Description: Baseline eTariff Filing: Antelope DSR 1, LLC SFA to be effective 8/1/2016.

Filed Date: 7/20/16.

Accession Number: 20160720–5111.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–2247–000.

Applicants: Antelope DSR 2, LLC.

Description: Baseline eTariff Filing: Antelope DSR 2, LLC SFA to be effective 8/1/2016.

Filed Date: 7/20/16.

Accession Number: 20160720–5114.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–2248–000.

Applicants: Antelope DSR 3, LLC.

Description: Baseline eTariff Filing: Antelope DSR 3, LLC SFA to be effective 8/1/2016.

Filed Date: 7/20/16.

Accession Number: 20160720–5115.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–2249–000.

Applicants: Elevation Solar C LLC.

Description: Baseline eTariff Filing: Elevation Solar C LLC SFA to be effective 8/1/2016.

Filed Date: 7/20/16.

Accession Number: 20160720–5116.

Comments Due: 5 p.m. ET 8/10/16.

Docket Numbers: ER16–2250–000.
Applicants: Solverde 1, LLC.
Description: Baseline eTariff Filing: Solverde 1, LLC SFA to be effective 8/1/2016.
Filed Date: 7/20/16.
Accession Number: 20160720–5117.
Comments Due: 5 p.m. ET 8/10/16.
Docket Numbers: ER16–2251–000.
Applicants: Western Antelope Blue Sky Ranch B LLC.
Description: Baseline eTariff Filing: Western Antelope Blue Sky Ranch B LLC SFA to be effective 8/1/2016.
Filed Date: 7/20/16.
Accession Number: 20160720–5118.
Comments Due: 5 p.m. ET 8/10/16.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES16–44–000.
Applicants: ITC Midwest LLC.
Description: Application Under Section 204 of the Federal Power Act of ITC Midwest LLC.
Filed Date: 7/20/16.
Accession Number: 20160720–5107.
Comments Due: 5 p.m. ET 8/10/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 20, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–18287 Filed 8–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG16–130–000.
Applicants: Cimarron Bend Wind Project I, LLC.
Description: Cimarron Bend Wind Project I, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 7/26/16.
Accession Number: 20160726–5120.
Comments Due: 5 p.m. ET 8/16/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15–1682–004.
Applicants: TransCanyon DCR, LLC.
Description: Compliance filing: Formula Rate Implementation Protocols Compliance Filing to be effective 7/6/2015.
Filed Date: 7/26/16.
Accession Number: 20160726–5079.
Comments Due: 5 p.m. ET 8/16/16.
Docket Numbers: ER16–200–003.
Applicants: Duke Energy Indiana, LLC.
Description: Compliance filing: Compliance Filing Reactive Settlement to be effective 1/1/2016.
Filed Date: 7/26/16.
Accession Number: 20160726–5095.
Comments Due: 5 p.m. ET 8/16/16.
Docket Numbers: ER16–2284–000.
Applicants: DTE Electric Company.
Description: § 205(d) Rate Filing: Revised Croswell Interconnection Agreement to be effective 9/1/2016.
Filed Date: 7/26/16.
Accession Number: 20160726–5075.
Comments Due: 5 p.m. ET 8/16/16.
Docket Numbers: ER16–2285–000.
Applicants: Desert Wind Farm LLC.
Description: Baseline eTariff Filing: Baseline new to be effective 9/24/2016.
Filed Date: 7/26/16.
Accession Number: 20160726–5091.
Comments Due: 5 p.m. ET 8/16/16.
Docket Numbers: ER16–2286–000.
Applicants: Public Service Company of Colorado.
Description: § 205(d) Rate Filing: PSCo–WAPA–TSGT–320–NOC Filing to be effective 9/25/2016.
Filed Date: 7/26/16.
Accession Number: 20160726–5101.
Comments Due: 5 p.m. ET 8/16/16.
Docket Numbers: ER16–2287–000.
Applicants: Niagara Mohawk Power Corporation, New York Independent System Operator, Inc.
Description: § 205(d) Rate Filing: SGIA 2293 between National Grid and Innovative/Colonie to be effective 4/29/2016.
Filed Date: 7/26/16.
Accession Number: 20160726–5131.
Comments Due: 5 p.m. ET 8/16/16.
Docket Numbers: ER16–2288–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Service Agreement No. 4503, Queue Position AB1–166 to be effective 6/27/2016.
Filed Date: 7/26/16
Accession Number: 20160726–5145.
Comments Due: 5 p.m. ET 8/16/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 26, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–18282 Filed 8–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–2290–000]

Spartan Renewable Energy, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding Spartan Renewable Energy, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard

to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 16, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 27, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–18286 Filed 8–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for electronic review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket No.	File date	Presenter or requester
Prohibited		
1. CP15–117–000	7–18–2016	Transcontinental Gas Pipeline Company, LLC.
2. P–9690–000	7–18–2016	Private Citizen.
3. CP15–117–000	7–21–2016	Oglethrope Power Corporation.
Exempt		
1. P–2165–067	7–11–2016	U.S. House Representative Robert B. Aderholt.
2. CP15–558–000	7–11–2016	U.S. House Representative Matt Cartwright.
3. CP14–96–000	7–18–2016	State of New York Senator Daniel Squadron.
4. P–10810–000	7–18–2016	U.S. House Representative John Moolenaar.
5. CP15–514–000	7–19–2016	FERC Staff.[1]
6. P–13102–003	7–21–2016	FERC Staff.[2]

[1] Memo dated July 18, 2016 forwarding letter from Teresa Spagna from U.S. Army Corps of Engineers.
[2] Telephone Memo dated July 20, 2016 reporting call with Nick Josten from Birch Power Company.

Dated: July 26, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–18283 Filed 8–1–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9950–14–OAR]

Clean Air Act Advisory Committee (CAAAC): Notice of Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: The Environmental Protection Agency (EPA) announces an upcoming public teleconference of the Clean Air Act Advisory Committee (CAAAC) to discuss draft recommendations from the Ports Initiative Workgroup of the Mobile Sources Technical Review Subcommittee (MSTRS). The EPA established the CAAAC on November 19, 1990, to provide independent advice and counsel to EPA on policy issues associated with implementation of the Clean Air Act of 1990. The Committee advises on economic, environmental, technical, scientific and enforcement policy issues.

DATES: Pursuant to 5 U.S.C. App. 2 Section 10(a) (2), notice is hereby given that the CAAAC will hold a teleconference to discuss draft recommendations from the MSTRS Ports Initiative Workgroup on September 7, 2016 from 2:00 p.m. to 3:30 p.m. (Eastern Time).

Inspection of Committee Documents: The committee agenda and any documents prepared for the meeting will be publicly available on the CAAAC Web site at *http://www.epa.gov/oar/caaac/* prior to the meeting. Thereafter, these documents, together with CAAAC meeting minutes, will be available on the CAAAC Web site or by contacting the Office of Air and Radiation Docket and requesting information under docket EPA–HQ–OAR–2004–0075. The docket office can be reached by email at: *a-and-r-Docket@epa.gov* or FAX: 202–566–9744.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wants further information concerning the CAAAC's public teleconference may contact Tamara Saltman at *saltman.tamara@epa.gov* or Sarah Froman at *froman.sarah@epa.gov* of the Office of Air and Radiation, U.S. EPA. Additional information about this meeting, the CAAAC, and its subcommittees and workgroups can be found on the CAAAC Web site: *http://www.epa.gov/oar/caaac/*. For information on access or services for individuals with disabilities, please contact Lorraine Reddick at *reddick.lorraine@epa.gov,* preferably at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

Dated: July 19, 2016.

Jim DeMocker,

Interim Designated Federal Officer, Clean Air Act Advisory Committee, Office of Air and Radiation.

[FR Doc. 2016–18329 Filed 8–1–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9950–16–OARM]

National Advisory Council for Environmental Policy and Technology

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Federal Advisory Committee teleconference.

SUMMARY: Under the Federal Advisory Committee Act, Public Law 92463, the Environmental Protection Agency (EPA) gives notice of a public meeting of the National Advisory Council for Environmental Policy and Technology (NACEPT). NACEPT provides advice to the EPA Administrator on a broad range of environmental policy, technology, and management issues. NACEPT members represent academia, industry, non-governmental organizations, and state, local and tribal governments. The purpose of this meeting is for NACEPT to discuss draft recommendations regarding actions that EPA should take in response to technological and sociological developments in the area of citizen science. A copy of the meeting agenda will be posted at *http://www2.epa.gov/faca/nacept.*

DATES: NACEPT will hold a public teleconference on August 22, 2016, from 12:00 p.m. to 5:00 p.m. (EDT).

ADDRESS: The meeting will be held at the EPA Headquarters, William Jefferson Clinton Federal Building East, Room 1132, 1201 Constitution Avenue NW., Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Eugene Green, Designated Federal Officer, *green.eugene@epa.gov,* (202) 564–2432, U.S. EPA, Office of Resources, Operations and Management; Federal Advisory Committee Management Division (MC1601M), 1200 Pennsylvania Avenue NW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION: Requests to make oral comments or to provide written comments to NACEPT should be sent to Eugene Green at *green.eugene@epa.gov* by August 15, 2016. The teleconference is open to the public, with limited seating available on a first-come, first-served basis. Members of the public wishing to participate in the teleconference should contact Eugene Green via email or calling (202) 564–2432 no later than August 15, 2016.

MEETING ACCESS: Information regarding accessibility and/or accommodations for individuals with disabilities should be directed to Eugene Green at the email address or phone number listed above. To ensure adequate time for processing, please make requests for accommodations at least 10 days prior to the meeting.

Dated: July 25, 2016.

Eugene Green,

Designated Federal Officer.

[FR Doc. 2016–18342 Filed 8–1–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0192]

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 Communications 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 Office of Management and Budget (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 September 1, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the 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 No.: 3060–0192.

Title: Section 87.103, Posting Station License.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and state, local and tribal government.

Number of Respondents and Responses: 33,622 respondents, 33,622 responses.

Estimated Time per Response: .25 hours.

Frequency of Response: Recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in 47 U.S.C. 303.

Total Annual Burden: 8,406 hours.

Annual Cost Burden: No cost.

Privacy Act Impact Assessment: No impacts.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: Section 87.103 states the following: (a) Stations at fixed locations. The license or a photocopy must be posted or retained in the station's permanent records. (b) Aircraft radio stations. The license must be either posted in the aircraft or kept with the aircraft registration certificate. If a single authorization covers a fleet of aircraft, a copy of the license must be either posted in each aircraft or kept with each aircraft registration certificate. (c) Aeronautical mobile stations. The license must be retained as a permanent part of the station records.

The recordkeeping requirement contained in Section 87.103 is necessary to demonstrate that all transmitters in the Aviation Service are properly licensed in accordance with the requirements of Section 301 of the Communications Act of 1934, as amended, 47 U.S.C. 301, No. 2020 of the International Radio Regulation, and Article 30 of the Convention on International Civil Aviation.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2016–18209 Filed 8–1–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

[NOTICE 2016–06]

Disclosure of Certain Documents in Enforcement and Other Matters

AGENCY: Federal Election Commission.

ACTION: Statement of policy.

SUMMARY: The Commission is adopting a policy with respect to placing certain documents on the public record in enforcement, administrative fines, and alternative dispute resolution cases, as well as administrative matters. The categories of records that will be included in the public record are described below.

DATES: Effective on September 1, 2016.

FOR FURTHER INFORMATION CONTACT: Adav Noti, Acting Associate General Counsel, 999 E Street NW., Washington, DC 20463, 202–694–1650 or 1–800–424–9530.

SUPPLEMENTARY INFORMATION: The ''confidentiality provision'' of the Federal Election Campaign Act, 52 U.S.C. 30101 *et seq.* (FECA), provides that: ''Any notification or investigation under [Section 30109] shall not be made public by the Commission . . . without the written consent of the person receiving such notification or the person with respect to whom such investigation is made.'' 52 U.S.C. 30109(a)(12)(A). For approximately the first 25 years of its existence, the Commission viewed the confidentiality requirement as ending with the termination of a case. The Commission placed on its public record the documents that had been considered by the Commissioners in their determination of a case, minus those materials exempt from disclosure under the FECA or under the Freedom of Information Act, 5 U.S.C. 552 (FOIA). *See* 11 CFR 5.4(a)(4). In *AFL–CIO* v. *FEC,* 177 F. Supp. 2d 48 (D.D.C. 2001), the district court disagreed with the Commission's interpretation of the confidentiality provision and found that the protection of section 30109(a)(12)(A) does not lapse at the time the Commission terminates an investigation. 177 F. Supp. 2d at 56.

Following that district court decision, the Commission placed on the public record only those documents that reflected the agency's ''final determination'' with respect to enforcement matters. Such disclosure is required under 52 U.S.C. 30109(a)(4)(B)(ii) and section (a)(2)(A) of the FOIA. In all cases, the final determination is evidenced by a certification of Commission vote. The Commission also continued to disclose documents that explained the basis for the final determination. Depending upon the nature of the case, those documents consisted of General Counsel's Reports (frequently in redacted form); Probable Cause to Believe Briefs; conciliation agreements; Statements of Reasons issued by one or more of the Commissioners; or, a combination of the foregoing. The district court indicated that the Commission was free to release these categories of documents. *See* 177 F. Supp. 2d at 54 n.11. In administrative fines cases, the Commission began placing on the public record only the Final Determination Recommendation and certification of vote on final determination. In alternative dispute resolution cases, the public record consisted of the certification of vote and the negotiated agreement.

Although it affirmed the judgment of the district court in *AFL–CIO,* the Court of Appeals for the District of Columbia Circuit differed with the lower court's restrictive interpretation of the confidentiality provision of 52 U.S.C. 30109(a)(12)(A). The Court of Appeals stated that: ''the Commission may well be correct that . . . Congress merely intended to prevent disclosure of the fact that an investigation is pending,''

and that: ''deterring future violations and promoting Commission accountability may well justify releasing more information than the minimum disclosures required by section [30109](a).'' *See AFL–CIO* v. *FEC,* 333 F.3d 168, 174, 179 (D.C. Cir. 2003). However, the Court of Appeals warned that, in releasing enforcement information to the public, the Commission must ''attempt to avoid unnecessarily infringing on First Amendment interests where it regularly subpoenas materials of a 'delicate nature . . . represent[ing] the very heart of the organism which the first amendment was intended to nurture and protect.' '' *Id.* at 179 (citation omitted). The decision suggested that, with respect to materials of this nature, a ''balancing'' of competing interests is required—on one hand, consideration of the Commission's interest in promoting its own accountability and in deterring future violations and, on the other, consideration of the respondent's interest in the privacy of association and belief guaranteed by the First Amendment. Noting that the Commission had failed to tailor its disclosure policy to avoid unnecessarily burdening the First Amendment rights of the political organizations it investigates, *id.* at 178, the Court found the agency's disclosure regulation at 11 CFR 5.4(a)(4) to be impermissible, *id.* at 179. In December 2003, the Commission issued an interim disclosure policy. *See* Statement of Policy Regarding Disclosure of Closed Enforcement or Related Files, 68 FR 70423 (Dec. 20, 2003) (''Interim Disclosure Policy'').

The Commission is issuing this policy statement to identify several categories of documents integral to its decisionmaking process that will be disclosed upon termination of an enforcement matter, as well as documents integral to its administrative functions. This policy replaces the Interim Disclosure Policy as the Commission's permanent disclosure policy.

The categories of documents that the Commission intends to disclose as a matter of regular practice either do not implicate the Court's concerns or, because they play a critical role in the resolution of a matter, the balance tilts decidedly in favor of public disclosure, even if the documents reveal some confidential information. In addition, the Commission will make certain other documents available on a case by case basis which will assist the public in understanding the record without intruding upon the associational interests of the respondents.

Enforcement

With respect to enforcement matters, the Commission will place the following categories of documents on the public record:

1. Complaint (including supplements and amendments thereto);
2. Internal agency referral where the Commission opens a Matter Under Review;
3. Response (including supplements and amendments thereto) to complaint;
4. General Counsel's Reports [1] (including supplements [2] thereto) that recommend dismissal, reason to believe, no reason to believe, no action at this time, probable cause to believe, no probable cause to believe, no further action, or acceptance of a conciliation agreement;
5. Notification of reason to believe findings;
6. Factual and Legal Analyses identified as the subject of a vote in a Commission certification;
7. Respondent's response to reason to believe findings;
8. Briefs (General Counsel's Brief and Respondent's Brief);
9. Statements of Reasons issued by one or more Commissioners;
10. Conciliation Agreements;
11. Evidence of payment of civil penalty or of disgorgement;
12. Certifications of Commission votes;
13. Attachments to complaints and attachments to responses to complaints;
14. Memoranda and reports (including supplements [2] thereto) from the Office of the General Counsel prepared for the Commission in connection with a specific pending Matter Under Review circulated through the Office of the Secretary for the consideration and deliberation of the Commission;
15. Complaint notification letters, and correspondence from respondents submitted in response to them;
16. Notifications to respondents that were previously identified as ''Unknown Respondents,'' and correspondence from respondents submitted in response to them;
17. Designations of counsel;
18. Requests for extensions of time;
19. Responses to requests for extensions of time;
20. Tolling agreements; and
21. Closeout letters.

The Commission is placing the foregoing categories of documents on the public record in all matters it closes on or after September 1, 2016, regardless of the outcome. By doing so, the Commission complies with the requirements of 52 U.S.C. 30109(a)(4)(B)(ii) and 5 U.S.C. 552(a)(2)(A). Conciliation Agreements are placed on the public record pursuant to 52 U.S.C. 30109(a)(4)(B)(ii). On a case by case basis, the Commission may place on the public record other documents that edify public understanding of a closed matter.

The Commission will place these documents on the public record as soon as practicable, and will endeavor to do so within 30 days of the date on which notifications are sent to complainant and respondent. *See* 11 CFR 111.20(a). In the event a Statement of Reasons is required, but has not been issued before the date proposed for the release of the remainder of the documents in a matter, those documents will be placed on the public record and the Statement of Reasons will be added to the file when issued.

The Commission is not placing on the public record certain other materials from its investigative files, such as subpoenaed records, deposition transcripts, and other records produced in discovery, even if those evidentiary documents are referenced in, or attached to, documents specifically subject to release under this policy. The Commission also will not place the following categories of documents on the public record:

1. *Sua sponte* submissions and accompanying attachments;
2. External referrals from other agencies and law enforcement sources in which the Commission declines to open a Matter Under Review;
3. Documents (other than notification letters) related to debt settlement plans and proposed administrative terminations in which the Commission does not approve the debt settlement plan or administrative termination.

Administrative Fines

With respect to administrative fines cases, the Commission will place the entire administrative file on the public record, which includes the following:

1. Reason to Believe recommendation;
2. Respondent's response;
3. Reviewing Officer's memoranda to the Commission;

[1] This category of documents does not include General Counsel's Reports that have been withdrawn by the Office of the General Counsel. The Commission may, upon the affirmative vote of four or more Commissioners, place such documents on the public record on a case by case basis.

[2] Supplements are documents that contain new or additional substantive analysis from the Office of the General Counsel prepared for the Commission in connection with a specific pending Matter Under Review circulated through the Office of the Secretary for the consideration and deliberation of the Commission. Supplements do not include documents that solely transmit replacement pages to correct errors in circulated reports or memoranda.

4. Final Determination recommendation;
5. Certifications of Commission votes;
6. Statements of Reasons;
7. Evidence of payment of fine; and
8. Referral to Department of the Treasury.

Alternative Dispute Resolution

With respect to alternative dispute resolution (ADR) cases, the Commission will place the following categories of documents on the public record:

1. Complaint or internal agency referral;
2. Response to complaint;
3. ADR Office's informational memorandum on assignment to the Commission;
4. Notification to respondent that case has been assigned to ADR;
5. Letter or Commitment Form from respondent participating in the ADR program;
6. ADR Office recommendation as to settlement or dismissal;
7. Certifications of Commission votes;
8. Settlement agreement executed by the respondent and Commission; and
9. Evidence of compliance with terms of settlement.

When disclosing documents in administrative fines and alternative dispute resolution cases, the Commission will release publicly available records that are referenced in, or attached to, documents specifically subject to release under this policy.

Administrative Functions

The Commission will also place on the public record the following non-exclusive list of documents integral to its administrative functions:

1. Statistics related to number of EPS dismissals by fiscal year and current quarter;
2. Statistics related to number of cases opened and closed by fiscal year and current quarter, average number of days to close a matter, and total civil penalties assessed;
3. Case closing processing statistics;
4. Monthly reports from the Department of the Treasury of the balance available in the Presidential Election Campaign Fund;
5. Yearly Long Term Budget Estimates for the Presidential Election Campaign Fund;
6. Memoranda from the Office of the General Counsel prepared for the Commission in connection with debt settlement plans and proposed administrative terminations circulated through the Office of the Secretary for the consideration and deliberation of the Commission in which the Commission ultimately approves the debt settlement plan or administrative termination;
7. Certifications of Commission votes in which the Commission approves a debt settlement plan or administrative termination;
8. Service Contract Inventory Reports submitted by the Commission to the Office of Federal Procurement Policy pursuant to section 743 of Division C of the 2010 Consolidated Appropriations Act;
9. Annual reports of activities performed by the agency that in the judgment of the agency head are not inherently governmental submitted by the Commission to the Office of Management and Budget pursuant to the Federal Activities Inventory Reform Act of 1998;
10. Reports of official travel paid for by non-government sources made to the U.S. Office of Government Ethics pursuant to 31 U.S.C. 1353;
11. Annual reports of the receipt and disposition of gifts and decorations tendered by foreign governments to federal employees, spouses, and dependents submitted by the Commission to the State Department pursuant to Public Law 95–105;
12. Annual reports made by the Commission pursuant to Equal Employment Opportunity Commission Management Directive 715; and
13. Annual reports on the agency's privacy management program submitted by the Commission to the Office of Management and Budget.

With this policy, the Commission intends to provide guidance to outside counsel, the news media, and others seeking to understand the Commission's disposition of enforcement, administrative fines, and alternative dispute resolution cases and administrative functions. This will enhance their ability to assess particular matters in light of past decisions. This policy does not alter any existing regulation or policy requiring or permitting the Commission to redact documents, including those covered by this policy, to comply with the FECA, the principles set forth by the court of appeals in *AFL–CIO,* and the FOIA. In appropriate cases implicating the law enforcement privilege, an entire document may be withheld.

Dated: July 25, 2016.

On behalf of the Commission.

Matthew S. Petersen,

Chairman, Federal Election Commission.

[FR Doc. 2016–18190 Filed 8–1–16; 8:45 am]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (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 August 17, 2016.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Richard Michael Howard and Patricia A. Turner Howard,* both of Gulf Shores, Alabama; as members of the Vision Bancshares, Inc. Shareholders Agreement to acquire shares of Vision Bancshares, Inc., parent of Vision Bank, N.A., both in Ada, Oklahoma.

Board of Governors of the Federal Reserve System, July 28, 2016.

Michele T. Fennell,

Assistant Secretary of the Board.

[FR Doc. 2016–18243 Filed 8–1–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be

available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 26, 2016.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Farmers & Merchants Agency, Inc.,* Pierz, Minnesota; to merge with Eden Valley Bancshares, Inc., and thereby indirectly acquire State Bank in Eden Valley, both in Eden Valley, Minnesota.

Board of Governors of the Federal Reserve System, July 28, 2016.

Michele T. Fennell,

Assistant Secretary of the Board.

[FR Doc. 2016–18242 Filed 8–1–16; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–CSE–2016–04; Docket No. 2016–0002; Sequence No. 18]

Notice of the General Services Administration's Labor-Management Relations Council Meeting

AGENCY: Office of Human Resources Management (OHRM), General Services Administration (GSA).

ACTION: Notice of meeting.

SUMMARY: The General Services Administration's Labor-Management Relations Council (GLMRC), a Federal Advisory Committee established in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C., App., and Executive Order 13522, plans to hold a one and one-half day meeting that is open to the public.

DATES: The meeting will be held on Tuesday, August 16, 2016 from 9:30 a.m. to 4:30 p.m., Eastern Standard Time (EST), and reconvene Wednesday, August 17, 2016 from 9:30 a.m. to 12:00 noon, EST.

ADDRESSES: On August 16, the meeting will be held in Room 2143, and the second day, August 17, the meeting will be held in Room 4046 of GSA's Headquarters Building located at 1800 F Street NW., Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Ms. Paula D. Lucak, GLMRC Designated Federal Officer (DFO), OHRM, General Services Administration, at telephone 202–739–1730, or email at *gmlrc@gsa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The GLMRC is a forum for managers and the exclusive national labor Union representatives of GSA employees: the American Federation of Government Employees (AFGE) and the National Federation of Federal Employees (NFFE). In this forum, managers and the Unions discuss Government operations to promote satisfactory labor relations and improve the productivity and effectiveness of GSA. The GLMRC serves as a complement to the existing collective bargaining process and allows managers and the Unions to collaborate in continuing to deliver the highest quality services to the public. The Council discusses workplace challenges and problems and recommends solutions that foster a more productive and cost-effective service to the taxpayer, through improving job satisfaction and employees' working conditions.

Agenda

The purpose of the meeting is for the GLMRC to build its collaborative labor-management relationship, discuss the Council's activities and direction ahead for the year, and to consider Agency initiatives. The topics to be discussed include Council metrics, employee engagement activities, and human resource initiative updates.

Meeting Access

This site is accessible to individuals with disabilities. In order to gain entry into the Federal building where the meeting is being held, public attendees who are Federal employees should bring their Federal employee identification cards. Members of the general public should bring their driver's license or another form of government-issued identification.

Availability of Materials for the Meeting

Please see the GLRMC Web site: *http://www.gsa.gov/portal/content/225831* for any materials available in advance of the meeting, and for meeting minutes that will be made available after the meeting. Detailed meeting minutes will be posted within 90 days of the meeting.

Procedures for Providing Public Comments

The public is invited to submit written comments for the meeting until 5:00 p.m., EST, on the Monday prior to the meeting on August 15, 2016, by either of the following methods: *Electronic or Paper Statements:* Submit electronic statements to Ms. Paula Lucak, Designated Federal Officer, at *paula.lucak@gsa.gov;* or send paper statements in triplicate to Ms. Lucak at 1800 F Street NW., Suite 7003A, Washington, DC 20405. In general, public comments will be posted on the GLMRC Web site. All comments, including attachments and other supporting materials received, are part of the public record and subject to public disclosure.

Any comments submitted in connection with the GLMRC meeting will be made available to the public under the provisions of the Federal Advisory Committee Act.

Dated: July 28, 2016.

Renee Y. Jones,

OHRM Director (Acting), Office of Human Resources Management, Office of HR Strategy and Services, Center for Talent Engagement, General Services Administration.

[FR Doc. 2016–18340 Filed 8–1–16; 8:45 am]

BILLING CODE 6820–34–P

GENERAL SERVICES ADMINISTRATION

[Notice-MA–2016–04; Docket No. 2016–0002, Sequence No. 17]

Federal Travel Regulation (FTR); Reimbursement for Use of Transportation Network Companies While on Official Travel

AGENCY: Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Notice of a bulletin.

SUMMARY: The purpose of this notice is to inform agencies that FTR Bulletin 16–05, pertaining to the authorization of and reimbursement for use of Transportation Network Companies (TNCs) by Federal travelers on temporary duty, is now available online at *www.gsa.gov/ftrbulletin.*

DATES: *Effective:* August 2, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Jill Denning, Program Analyst, Office of Asset and Transportation Management (MA), OGP, GSA, at 202–208–7642 or via email at *jill.denning@gsa.gov.* Please cite FTR Bulletin 16–05.

SUPPLEMENTARY INFORMATION: In recent years, a new kind of transportation service provider, known as Transportation Network Companies (TNCs), have begun operations across the United States and the world. TNCs connect paying passengers with drivers-for-hire via Web sites and mobile apps. TNCs are a form of special conveyance for purposes of the Federal Travel Regulation (FTR), and may be an efficient and cost effective alternative to taxis or rental cars. This bulletin provides guidance to agencies subject to FTR to clarify that they may authorize and reimburse employees for use of TNC for official business away from the employee's official station in accordance with internal agency policy and when permissible under local laws and ordinances. Pursuant to the authority of 5 U.S.C. 5702(a) this bulletin applies only to employees on temporary duty travel. FTR Bulletin 16–05 and all other FTR Bulletins can be found at *www.gsa.gov/ftrbulletin.*

Dated: July 28, 2016.

Troy Cribb,

Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2016–18279 Filed 8–1–16; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Request for Nominations for Individuals and Consumer Organizations for Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Nominees recommended to serve as a voting or nonvoting consumer representative may be self-nominated or may be nominated by a consumer organization. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or email stating that interest to FDA (see **ADDRESSES**) by September 1, 2016, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by September 1, 2016. Nominations will be accepted for current vacancies and for those that will or may occur through January 31, 2017.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process and consumer representative nominations should be submitted electronically to *kimberly.hamilton@fda.hhs.gov,* by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002, or by FAX at: 301–847–8640.

Consumer representative nominations should be submitted electronically by logging into the FDA Advisory Committee Membership Nomination Portal at: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm,* by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002, or by FAX at: 301–847–8640. Additional information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at: *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: *For questions relating to participation in the selection process:* Kimberly Hamilton, Advisory Committee Oversight and Management Staff (ACOMS), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002, 301–796–8220, email: *kimberly.hamilton@fda.hhs.gov.*

For questions relating to specific advisory committees or panels, contact the appropriate Contact Person listed in table 1 in the **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing (see table 1 for Contact Person).

TABLE 1—ADVISORY COMMITTEE CONTACTS

Contact person	Committee/panel
Bryan Emery, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6132, Silver Spring, MD 20993–0002, phone: 240–402–8054, email: *Bryan.Emery@fda.hhs.gov*.	Blood Products Advisory Committee.
Evella Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring, MD 20993–0002, phone: 301–796–6683, email: *Evella.Washington@fda.hhs.gov*.	Ear, Nose and Throat Devices Panel.
Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2430, Silver Spring, MD 20993–0002, phone: 301–796–0889, email: *Cindy.Hong@fda.hhs.gov*.	Gastrointestinal Drugs Advisory Committee.
Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2434, Silver Spring, MD 20993–0002, phone: 301–796–4043, email: *Jennifer.Shepherd@fda.hhs.gov*.	Medical Imaging Advisory Committee.
Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1643, Silver Spring, MD 20993–0002, phone: 301–796–0889, email: *Sara.Anderson@fda.hhs.gov*.	National Mammography Quality Assurance Advisory Committee.

TABLE 1—ADVISORY COMMITTEE CONTACTS—Continued

Contact person	Committee/panel
Moon Hee Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2434, Silver Spring, MD 20993–0002, phone: 301–796–2894, email: *MoonHee.Choi@fda.hhs.gov*.	Peripheral & Central Nervous Systems Advisory Committee.
Sujata Vijh, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6128, Silver Spring, MD 20993–0002, phone: 240–4020–7107, email: *Sujata.Vijh@fda.hhs.gov*.	Vaccine and Related Biologic Products Advisory Committee.

TABLE 2—COMMITTEE DESCRIPTIONS, TYPE OF CONSUMER REPRESENTATIVE VACANCY, AND APPROXIMATE DATE NEEDED

Committee/panel/areas of expertise needed	Type of vacancy	Approximate date needed
Blood Products Advisory Committee—Knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions.	1—Voting	Immediately.
Ear, Nose and Throat Devices Panel—Experts in otology, neurology, and audiology.	1—Nonvoting	Immediately.
Gastrointestinal Drugs Advisory Committee—Knowledgeable in the fields of gastroenterology, endocrinology, surgery, clinical pharmacology, physiology, pathology, liver function, motility, esophagitis, and statistics.	1—Voting	Immediately.
Medical Imaging Advisory Committee—Knowledgeable in the fields of nuclear medicine, radiology, epidemiology, statistics, and related specialties.	1—Voting	Immediately.
National Mammography Quality Assurance Advisory Committee—Physician, practitioner, or other health professional whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography.	1—Nonvoting	January 31, 2017.
Peripheral and Central Nervous System Drugs Advisory Committee—Knowledgeable in the fields of neurology, neuropharmacology, neuropathology, otolaryngology, epidemiology or statistics, and related specialties.	1—Voting	January 31, 2017.
Vaccines and Related Biological Products Advisory Committee—Knowledgeable in the fields of immunology, molecular biology, rDNA, virology, bacteriology, epidemiology or biostatistics, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry.	1—Voting	Immediately.

II. Functions and General Description of the Committee Duties

A. Blood Products Advisory Committee

Reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases as well as the safety, effectiveness, and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological product licenses, and on the quality and relevance of FDA's research program which provides the scientific support for regulating these products.

B. Certain Panels of the Medical Devices Advisory Committee

Reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area: (1) Advises on the classification or reclassification of devices into one of three regulatory categories; (2) advises on any possible risks to health associated with the use of devices; (3) advises on formulation of product development protocols; (4) reviews premarket approval applications for medical devices; (5) reviews guidelines and guidance documents; (6) recommends exemption of certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; (7) advises on the necessity to ban a device; and (8) responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of Food and Drugs (the Commissioner) on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The Panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

C. Gastrointestinal Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human

drug products for use in the treatment of gastrointestinal diseases.

D. Medical Imaging Advisory Committee

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

E. National Mammography Quality Assurance Advisory Committee

Advises the Agency on the following: (1) Development of appropriate quality standards and regulations for mammography facilities; (2) standards and regulations for bodies accrediting mammography facilities under this program; regulations with respect to sanctions; (3) procedures for monitoring compliance with standards; (4) establishing a mechanism to investigate consumer complaints; (5) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities; (6) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (7) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (8) determining the costs and benefits of compliance with these requirements.

F. Peripheral and Central Nervous System Advisory Committee

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases.

G. Vaccines and Related Biological Products Advisory Committee

Reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, as well as considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products.

III. Criteria for Members

Persons nominated for membership as consumer representatives on committees or panels should meet the following criteria: (1) Demonstrate ties to consumer and community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

IV. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see **ADDRESSES**) within 30 days of publication of this document.

Within the subsequent 30 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing at least two qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or resume. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

V. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Agency's advisory committees or panels. Self-nominations are also accepted. Nominations should include a cover letter and current curriculum vitae or resume for each nominee, including a current business and/or home address, telephone number, and email address if available, and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations should also specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations should include confirmation that the nominee is aware of the nomination, unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest. Members will be invited to serve for terms up to 4 years.

FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. Upon selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting or nonvoting consumer representatives will not participate in the selection process.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 27, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016–18216 Filed 8–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2071]

Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use—Compliance Policy; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency or we) is announcing the availability of a document titled ''Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use—Compliance Policy; Guidance for Industry.'' This guidance addresses the regulatory requirements for determining donor

eligibility that apply to establishments that collect blood and blood components (blood establishments) intended solely for autologous use. On May 22, 2015, in order to better assure the safety of the nation's blood supply and to help protect donor health, FDA finalized its revision of the applicable requirements for blood establishments to test donors for infectious disease, and to determine that donors are eligible to donate and that donations are suitable for transfusion or further manufacture (''Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use'' (donor eligibility rule)). The donor eligibility rule includes requirements related to current good manufacturing practice, donation testing, donor eligibility, and donation suitability. It became effective on May 23, 2016.

FDA has developed this guidance in response to questions from blood establishments concerning the applicability of the donor eligibility rule to autologous donations. The guidance explains the conditions under which FDA does not intend to take regulatory action for a blood establishment's failure to comply with certain donor eligibility determination requirements in collecting blood and blood components intended solely for autologous use.

DATES: The Agency is soliciting public comment, but is implementing this guidance immediately because the Agency has determined that prior public participation is not feasible or appropriate. Submit either electronic or written comments on Agency guidances at any time.

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–2016–D–2071 for ''Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use—Compliance Policy; 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 guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jonathan McKnight, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Requirements for Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use—Compliance Policy; Guidance for Industry.'' We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's good guidance practices regulation.

This guidance addresses the regulatory requirements for determining donor eligibility that apply to blood establishments that collect blood and blood components intended solely for autologous use described in the final

rule entitled, ''Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use,'' 80 FR 29842 (donor eligibility rule)) that became effective on May 23, 2016.

A small proportion of collections of blood and blood components are intended for autologous transfusion. In those instances, the autologous donor presents with a physician's prescription for the collection of the donor's blood for the donor's own upcoming medical (*e.g.,* surgical) procedure. If the donor ultimately does not need the blood, blood establishments may, in some instances, use these donations for allogeneic (*i.e.* intended for transfusion to a recipient other than the donor) transfusions. This is referred to as ''cross-over.''

Blood establishments have requested clarification on certain requirements of the donor eligibility rule and the applicability of certain sections of the donor eligibility rule to the collection of blood and blood components intended for autologous use. To address these questions, FDA has developed this guidance to clarify the Agency's policy with respect to the requirements for autologous donors of blood and blood components intended solely for autologous use, (*i.e.,* not subject to cross-over). Specifically, the guidance describes FDA's policy with respect to the following: The requirements in 21 CFR 630.10 related to screening autologous donors for relevant transfusion-transmitted infections; the requirement in 21 CFR 630.15(a)(1)(ii) that the responsible physician examine the autologous donor to permit more frequent collections; and, the requirement in 21 CFR 630.20(a) that the responsible physician determine and document that the autologous donor's health permits the collection of blood and blood components intended for autologous use.

Autologous donors have long been permitted to donate blood for their own use even if they do not meet certain donor eligibility criteria that apply to allogeneic donors because autologous donors are not exposed to new transfusion-transmitted infections in receiving their own blood. For example, FDA does not require testing of autologous donations for Relevant Transfusion-Transmitted Infection (RTTI) unless the donations are used for allogeneic transfusion or shipped to another establishment (21 CFR 610.40(d)). Consistent with this approach to testing autologous donations, FDA does not believe it is necessary to assess autologous donors for risks for RTTI as required in certain provisions in § 630.10 if the donation is intended solely for autologous use.

Sections 630.15(a) and 630.20(a) describe conditions for which a responsible physician must examine and determine and document that the autologous donor's health permits a collection procedure. Autologous donors are under the care of the physician who prescribes the autologous donation. In light of the medical oversight provided by the autologous donor's physician, FDA believes blood establishments can appropriately protect autologous donors' health by following standard operating procedures that are approved by the responsible physician of the blood establishment and that define criteria for when the autologous donation may proceed and the conditions under which the responsible physician must be consulted.

The guidance explains the conditions under which FDA does not intend to take regulatory action for a blood establishment's failure to comply with the donor eligibility determination requirements in collecting blood and blood components intended solely for autologous use.

The guidance represents the current thinking of the 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.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 630 have been approved under OMB control number 0910–0795.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: July 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18183 Filed 8–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–P–0974]

Determination That SAMSCA (Tolvaptan) Tablets, 60 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that SAMSCA (tolvaptan) tablets, 60 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for tolvaptan tablets, 60 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Christopher Koepke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6214, Silver Spring, MD 20993–0002, 240–402–3543.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of

safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

SAMSCA (tolvaptan) tablets, 60 mg, are the subject of NDA 22–275, held by Otsuka America Pharmaceutical, and initially approved on May 19, 2009. SAMSCA is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium <125 milliequivalents/liter or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and syndrome of inappropriate antidiuretic hormone (SIADH).

Otsuka America Pharmaceutical has never marketed SAMSCA (tolvaptan) tablets, 60 mg. In previous instances (see, *e.g.,* 72 FR 9763 (March 5, 2007), 61 FR 25497 (May 21, 1996)), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Gordon Johnston Regulatory Consultants, LLC, submitted a citizen petition dated March 15, 2016 (Docket No. FDA–2016–P–0974), under 21 CFR 10.30, requesting that the Agency determine whether SAMSCA (tolvaptan) tablets, 60 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that SAMSCA (tolvaptan) tablets, 60 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that SAMSCA (tolvaptan) tablets, 60 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of SAMSCA (tolvaptan) tablets, 60 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list SAMSCA (tolvaptan) tablets, 60 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to SAMSCA (tolvaptan) tablets, 60 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18139 Filed 8–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Food and Drug Administration

[Docket No. FDA–2016–D–1605]

Institutional Review Board Written Procedures: Guidance for Institutions and Institutional Review Boards; Draft Guidance; Availability

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, HHS, and the Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, and the Food and Drug Administration (FDA) are announcing the availability of a draft guidance entitled ''Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs.'' The purpose of this draft guidance is to assist IRB administrators, IRB chairpersons, and other institutional officials responsible for preparing and maintaining written procedures for IRBs. The draft guidance is intended for IRBs and institutions responsible for review and oversight of human subject research under the HHS or FDA regulations, or both.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 3, 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–2016–D–1605 for ''Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs.'' 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 Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Janet Donnelly, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5167, Silver Spring, MD 20993–0002, 301–796–4187; or Irene Stith-Coleman, Office for Human Research Protections, 1101 Wootton Pkwy., Suite 200, Rockville, MD 20852, 240–453–6900.

SUPPLEMENTARY INFORMATION:

I. Background

OHRP and FDA are announcing the availability of a draft guidance document entitled ''Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs.'' This guidance is intended to assist IRB administrators, IRB chairpersons, and other institutional officials responsible for preparing and maintaining written procedures for IRBs.

OHRP and FDA frequently receive requests for clarification regarding the scope and content of IRB written procedures. We recognize that procedures may vary among institutions and IRBs due to differences in the type of research studies reviewed by the IRB, institutional policy or administrative practices, number of IRBs at the institution, affiliation with an institution, and local and State laws and regulations. In order to provide guidance on the appropriate content of written procedures, while taking into account these variations, we created an IRB Written Procedures Checklist to assist IRBs in preparing and maintaining detailed written procedures suitable for their institutions. The IRB Written Procedures Checklist incorporates the HHS and FDA regulatory requirements for IRB written procedures and additional topics that we recommend including in written procedures. The draft guidance, when finalized, will supersede OHRP's July 1, 2011, ''Guidance on Written IRB Procedures'' and FDA's 1998 ''Appendix H: A Self-Evaluation Checklist for IRBs,'' (formerly part of FDA's Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors).

To enhance human subject protection and reduce regulatory burden, OHRP and FDA have been actively working to harmonize the Agencies' regulatory requirements and guidance for human subject research. This guidance document was developed as a part of these efforts. OHRP and FDA believe that it will be most helpful to the regulated community to issue a joint guidance document that will clearly demonstrate the Agencies' harmonized approach to the topic of preparing and maintaining IRB written procedures.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent OHRP's and FDA's current thinking on IRB written procedures. It does not establish any rights for any person and is not binding on OHRP, FDA, or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information referenced in this guidance that are related to IRB recordkeeping requirements under 21 CFR 56.115, including the information collection activities in the provisions in 21 CFR 56.108(a)(1) and (b), have been approved under OMB control number 0910–0130. The collections of information referenced in this guidance that are related to IRB recordkeeping requirements under 45 CFR 46.115, including the information collection activities in the provisions in 45 CFR 46.103(b)(4) and (5) have been approved under OMB control number 0990–0260.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm, http://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/index.html*, or *http://www.regulations.gov.*

Dated: July 27, 2016.

Leslie Kux,

Associate Commissioner for Policy, U.S. Food and Drug Administration.

Dated: July 15, 2016.

Karen B. DeSalvo,

Acting Assistant Secretary for Health, U.S. Department of Health and Human Services.

[FR Doc. 2016–18191 Filed 8–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer's Research, Care, and Services provides advice on how to prevent or reduce the

burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. The Advisory Council will hear from a number of CMS's HCIA awardees about their projects and their results. Additional presentations in the afternoon will include an overview of the 2016 Update to the National Plan, updates on progress towards a Care and Services Summit, and Federal workgroup updates.

DATES: The meeting will be held on August 1, 2016 from 9 a.m. to 5 p.m. EDT.

ADDRESSES: The meeting will be held in Room 620/630, Building 35A (Porter Building) of the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892.

Comments: Time is allocated in the afternoon on the agenda to hear public comments. The time for oral comments will be limited to two (2) minutes per individual. In lieu of oral comments, formal written comments may be submitted for the record to Rohini Khillan, ASPE, 200 Independence Avenue SW., Room 424E, Washington, DC 20201. All comments should be submitted to *napa@hhs.gov* for the record and to share with the Advisory Council by April 20, 2016. Those submitting comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Rohini Khillan (202) 690–5932, *rohini.khillan@hhs.gov.* Note: Seating may be limited. Those wishing to attend the meeting must send an email to *napa@hhs.gov* and put ''August 1 Meeting Attendance'' in the Subject line by Friday, July 22, 2016 so that their names may be put on a list of expected attendees and forwarded to the security officers the Humphrey Building. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: The Advisory Council will hear from a number of CMS's HCIA awardees about their projects and their results. Additional presentations in the afternoon will include an overview of the 2016 Update to the National Plan, updates on progress towards a Care and Services Summit, and federal workgroup updates.

Procedure and Agenda: This meeting is open to the public. Please allow 45 minutes to go through security and walk to the meeting room. The meeting will also be webcast at *www.hhs.gov/live*.

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: July 8, 2016.

Kathryn E. Martin,

Acting Assistant Secretary for Planning and Evaluation.

[FR Doc. 2016–18273 Filed 8–1–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the National Center for Advancing Translational Sciences.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or 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 grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cures Acceleration Network Review Board.

Date: September 15, 2016.

Time: 8:30 a.m. to 2:30 p.m.

Agenda: Report from the Institute Director.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, 1 Democracy Plaza, Room 1072, Bethesda, MD 20892, 301–435–0809, *anna.ramseyewing@nih.gov*.

Name of Committee: National Center for Advancing Translational Sciences Advisory Council.

Date: September 15, 2016.

Open: 8:30 a.m. to 2:30 p.m.

Agenda: Report from the Institute Director and other staff.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Closed: 3:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, 1 Democracy Plaza, Room 1072, Bethesda, MD 20892, 301–435–0809, *anna.ramseyewing@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: July 27, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18291 Filed 8–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day Comment Request; NCI's Center for Cancer Training Application Form for Graduate Student Recruitment Program (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the

proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) 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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Ofelia Olivero, Chief Intramural Diversity Workforce Branch, Center for Cancer Training, NCI, 9609 2W108, Rockville, MD 20850 or call non-toll-free number (240)276–6890 or Email your request, including your address to: *oliveroo@exchange.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: NCI's Center for Cancer Training Application Form for Graduate Student Recruitment Program (CCT) (NCI), 0925–NEW—National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Center for Cancer Training (CCT) is supporting NCI's goal of training cancer researchers for the 21st century. To support that goal, CCT created a Graduate Student Recruitment Program (GSRP) with the purpose of recruiting outstanding young scientists to postdoctoral positions at the NCI. The proposed information collection involves brief online applications completed by applicants to the full time and summer curriculum programs. This information is essential to the program to determine the eligibility and quality of potential selected individuals. The information is for internal use to make decisions about candidates invited to visit NCI and interview with scientist as potential postdoctoral trainees.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 225.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form	Estimated number of respondents	Estimated number of responses annually per respondent	Estimated total annual burden hours	Estimated total annual burden hours
Student Applicants	CCT Application	100	1	1	100
Professors	Reference Recommendation Letters	300	1	25/60	125
Total		400	400		225

Dated: July 27, 2016.

Karla Bailey,

Project Clearance Liaison, National Cancer Institute, NIH.

[FR Doc. 2016–18294 Filed 8–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Contract Review.

Date: August 16, 2016.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7353, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Time-Sensitive.

Date: August 18, 2016.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7353, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK Program Project (P01).

Date: September 1, 2016.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7111, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *yangj@extra.niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: July 27, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18293 Filed 8–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: September 7, 2016.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: To present the Director's Report and other scientific presentations.

Place: National Institutes of Health, Building 31, C Wing 6th Floor, Conference Center, Room 10, 31 Center Drive, Bethesda, MD 20892.

Closed: 3:45 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, C Wing 6th Floor, Conference Center, Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 7323, MSC 5452, Bethesda, MD 20892, (301) 594–8843, *stanfibr@niddk.nih.gov.*

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Digestive Diseases and Nutrition Subcommittee.

*Date:*September 7, 2016.

Open: 1:00 p.m. to 2:00 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Building 31, C Wing 6th Floor, Conference Center, Room 6, 31 Center Drive, Bethesda, MD 20892.

Closed: 2:15 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, C Wing 6th Floor, Conference Center, Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd. Room 7323, MSC 5452, Bethesda, MD 20892, (301) 594–8843, *stanfibr@niddk.nih.gov.*

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Diabetes, Endocrinology and Metabolic Diseases Subcommittee.

Date: September 7, 2016.

Closed: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, C Wing 6th Floor, Conference Center, Room 10, 31 Center Drive, Bethesda, MD 20892.

Open: 2:00 p.m. to 3:30 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Building 31, C Wing 6th Floor, Conference Center, Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 7323, MSC 5452, Bethesda, MD 20892, (301) 594–8843, *stanfibr@niddk.nih.gov.*

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Kidney, Urologic and Hematologic Diseases Subcommittee.

Date: September 7, 2016.

Open: 1:00 p.m. to 3:00 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Center, Room 7, 31 Center Drive, Bethesda, MD 20892.

Closed: 3:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Center, Room 7, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 7323, MSC 5452, Bethesda, MD 20892, (301) 594–8843, *stanfibr@niddk.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.niddk.nih.gov/fund/divisions/DEA/Council/coundesc.htm.,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: July 27, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18292 Filed 8–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory General Medical Sciences Council.

The meeting will be open to the public as indicated below, with a short public comment period at the end. Attendance is limited by the space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will also be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (*http://videocast.nih.gov/*).

The meeting will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory General Medical Sciences Council.

Date: September 15–16, 2016.

Closed: September 15, 2016, 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 45 Center Drive, Bethesda, MD 20892.

Open: September 16, 2016, 8:30 a.m. to 12:00 p.m.

Agenda: For the discussion of program policies and issues; opening remarks; report of the Director, NIGMS; and other business of the Council.

Place: National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Ann A. Hagan, Ph.D., Associate Director for Extramural Activities, NIGMS, NIH, DHHS, 45 Center Drive, Room 2AN24H, MSC6200, Bethesda, MD 20892–6200, (301) 594–4499, *hagana@nigms.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.nigms.nih.gov/About/Council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: July 26, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18159 Filed 8–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2); 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 purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for the treatment of cancer. The outcome of the evaluation will provide information to internal NCI committees that will decide whether NCI should support requests and make available contract resources for development of the potential therapeutic to improve the treatment of various forms of cancer. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; June 2016 Cycle 23 NExT SEP Committee Meeting.

Date: August 25, 2016.

Time: 8:30 a.m. to 4:30 p.m.

Agenda: To evaluate the NCI Experimental Therapeutics Program Portfolio.

Place: National Institutes of Health, 9000 Rockville Pike, Campus Building 31, Conference Room 6C10, Bethesda, MD 20892.

Contact Persons:

Barbara Mroczkowski, Ph.D., Executive Secretary, Discovery Experimental Therapeutics Program, National Cancer Institute, NIH 31 Center Drive, Room 3A44, Bethesda, MD 20817, (301) 496–4291, *mroczkoskib@mail.nih.gov*.

Toby Hecht, Ph.D., Executive Secretary, Development Experimental Therapeutics Program, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 3W110, Rockville, MD 20850, (240) 276–5683, *toby.hecht2@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.3, Cancer Control, National Institutes of Health, HHS)

Dated: July 27, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18164 Filed 8–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Council of Research Advocates.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (*http://videocast.nih.gov*).

Name of Committee: National Cancer Institute Council of Research Advocates.

Date: September 26, 2016.

Time: 9:00 a.m. to 4:30 p.m.

Agenda: Cancer Moonshot Initiative—Blue Ribbon Panel Recommendations; NCI's Moonshot Implementation Plans and Strategies; Advocate Engagement in Advancing the Cancer Moonshot.

Place: National Institutes of Health, 35 Convent Drive, Building 35, Conference Rooms 620/630, Bethesda, MD 20892.

Contact Person: Amy Williams, NCI Office of Advocacy Relations, National Cancer Institute, NIH, 31 Center Drive, Building 31, Room 11A48, Bethesda, MD 20892, 301–594–3194, *williaam@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: NCRA: *http://deainfo.nci.nih.gov/advisory/ncra/ncra.htm,* where an agenda and any additional

information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 27, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18163 Filed 8–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The 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 on Aging Special Emphasis Panel; Healthy Aging.

Date: August 26, 2016.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Alicja L. Markowska, Ph.D., DSC, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–496–9666, *markowsa@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Establishment of Multigenotypic Aged Rat Colony.

Date: August 29, 2016.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Maurizio Grimaldi, MD, Ph.D., Scientific Review Officer, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Room 2C218, Bethesda, MD 20892, 301–496–9374, *grimaldim2@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: July 26, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18165 Filed 8–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Council of Research Advocates.

The meeting will be held as a teleconference call only and is open to the public to dial-in for participation. Individuals who plan to dial-in to the meeting and need special assistance or other reasonable accommodations in order to do so, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Council of Research Advocates.

Date: August 22, 2016.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: Update on the Vice President's Cancer Moonshot Initiative—Progress and Next Steps.

Place: National Institutes of Health, 31 Center Drive, Building 31, Rooms 11A48, Bethesda, MD 20892 (Telephone Conference Call), 877–972–9420 Access Code: 1039054.

Contact Person: Amy Williams NCI Office of Advocacy Relations National Cancer Institute, NIH 31 Center Drive Building 31, Room 11A48 Bethesda, MD 20892, 301–594–3194 *williaam@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 27, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18162 Filed 8–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Aging.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Aging.

Date: September 27–28, 2016.

Closed: September 27, 2016, 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, C Wing 6th Floor Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

Open: September 28, 2016, 8:00 a.m. to 12:45 p.m.

Agenda: Call to order and report from the Director; discussion of future meeting dates; consideration of minutes of last meeting; reports from Task Force on Minority Aging Research; Working Group on Program; Program Highlights

Place: National Institutes of Health, Building 31, C Wing 6th Floor Conference

Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Robin Barr, Director, National Institute on Aging, Office of Extramural Activities, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20814, (301) 496–9322, *barr@nia.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.nih.gov/nia/naca/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: July 26, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18166 Filed 8–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5907–N–32]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), call the toll-free Title V information line at 800–927–7588 or send an email to *title5@hud.gov.*

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to: Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 5B–17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–2265 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.,* acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *AGRICULTURE:* Ms. Debra Kerr, Department of Agriculture, OPPM, Property Management Division, Agriculture South Building, 300 7th Street SW., Washington, DC 20024, (202) 720–8873; *ENERGY:* Mr. David Steinau, Department of Energy, Office of Asset Management (MA–50), 1000 Independence Ave. SW., Washington, DC 20585, (202) 287–1503; *GSA:* Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040 Washington, DC 20405, (202) 501–0084; *INTERIOR:* Mr. Michael Wright, Acquisition & Property Management, Department of the Interior, 3960 N. 56th Ave. #104, Hollywood, FL 33021; (443) 223–4639; *NASA:* Mr. William Brodt, National Aeronautics AND Space Administration, 300 E Street SW., Room 2P85, Washington, DC 20546, (202) 358–1117; *NAVY:* Mr. Steve Matteo, Department of the Navy, Asset Management Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374; (202) 685–9426 (These are not toll-free numbers).

Dated: July 28, 2016.

Brian P. Fitzmaurice,

Director, Division of Community Assistance, Office of Special Needs Assistance Programs.

Title V, Federal Surplus Property Program Federal Register Report for 08/05/2016

Suitable/Available Properties

Building

Alabama

Material Pole Shed
11288 Horseshoe Rd.
Daviston AL 36256
Landholding Agency: Interior
Property Number: 61201630008
Status: Excess
Comments: off-site removal only; 764 sq. ft.; 29+ months vacant; not built to any construction code; contamination; remediation needed; contact Interior for more information

Tractor Pole Shed
11288 Horseshoe bend Rd
Daviston AL 36256
Landholding Agency: Interior
Property Number: 61201630010
Status: Excess
Comments: off-site removal only; removal difficult due to size; not built to any construction code; contact Interior for more information

California

El Cariso Hot Shot Camp
1357 B3 El Cariso Hot Shot Barracks Trailer
Lake Elsinore CA 92530
Landholding Agency: Agriculture
Property Number: 15201630005
Status: Unutilized
Directions: Gifford Pinchot Lane Hwy 74 to Long Canyon Rd.; off-site removal only; no future agency need; 1,335 sq. ft.; residential; 101+ months vacant; water restrictions; poor conditions;
Comments: mold/bacterial growth in walls & floor cavities & insulation; extensive repairs to make it useable; several use limitations; contact Agriculture for more information

New Mexico

Cuba Leased Office Site
04B County Rd. 11
Cuba NM 87013
Landholding Agency: Agriculture
Property Number: 15201630006
Status: Excess
Comments: 560 sq. ft.; 18+ months vacant; interior finishes need replacement; needs repainting; modular stud wall bldg.; contact Agriculture for more information

Texas

Building 43 Office
620240B043; 2881 F& B Rd.
College Station TX
Landholding Agency: Agriculture
Property Number: 15201630008
Status: Unutilized
Directions: Off-site removal only; no future agency need
Comments: 1,100 sq. ft.; office/cotton field research; 12+ months vacant; moderate conditions; minor repairs & painting; needs new HVAC; contact Agriculture for more details

Washington

USMC Reserve Center
1702 Tahoma Ave.,
Yakima WA 98902
Landholding Agency: GSA
Property Number: 54201630004
Status: Excess
GSA Number: 9–D–WA–1278AA
Directions: Landholding Agency: USMC; Disposal Agency: GSA
Comments: 4 Buildings & 1 Structure ranging from 270 to 20,000 sq. ft.; 48+ months vacant; sits on 4.64 acres; contact GSA for more information

Unsuitable Properties

Building

Alabama

Sign Shed
11288 Horseshoe bend Rd.
Daviston AL 36256
Landholding Agency: Interior
Property Number: 61201630009
Status: Excess
Comments: documented deficiencies: structural integrity compromised; clear threat to physical safety
Reasons: extensive deterioration

3 Buildings
Marshall Space Flight Center
MSFC AL 35812
Landholding Agency: NASA
Property Number: 71201630006
Status: Underutilized
Directions: 4558 (Structural Test Facility); 4567 (Pump & Boiler House); 4201 (Office Building)
Comments: public access denied and no alternative method to gain access without comprising national security
Reasons: Secured Area

4353 Imaging Services
Marshall Space Flight Center
MSFC AL 35812
Landholding Agency: NASA
Property Number: 71201630007
Status: Underutilized
Directions: Located on Digney Rd.
Comments: public access denied and no alternative method to gain access without compromising national security
Reasons: Secured Area

Alabama

4728 Shop & Storage Building
Marshall Space Flight Center
MSFC AL 35812
Landholding Agency: NASA
Property Number: 71201630008
Status: Underutilized
Directions: Located on Rideout Rd.
Comments: public access denied and no alternative method to gain access without compromising national security
Reasons: Secured Area

4467 Lidar Facility
Marshall Space Flight Center
MSFC AL 35812
Landholding Agency: NASA
Property Number: 71201630009
Status: Underutilized
Comments: public access denied and no alternative method to gain access without compromising national security
Reasons: Secured Area

California

Silverado Fire Station
1355 G Silverado Barracks Trailer
Silverado CA 92676
Landholding Agency: Agriculture
Property Number: 15201630009
Status: Unutilized
Directions: 27172 Silverado Canyon Rd.
Comments: documented deficiencies: severe rodent infestation; clear threat to physical safety
Reasons: Extensive deterioration

Kessler Springs Ranch
Mobile Home
(Building #303); 58274 Cima Rd.
Cima CA 92323
Landholding Agency: Interior
Property Number: 61201630006
Status: Excess
Comments: documented deficiencies: structural integrity compromised; clear threat to physical safety
Reasons: Extensive deterioration

Florida

Roberts House Loop Road Apts.
Big Cypress National Preserve
34141, N 25 45 19.7, W 080 58 56.6
Ochopee FL 34141
Landholding Agency: Interior
Property Number: 61201630002
Status: Unutilized
Comments: roof & wall sections have collapsed; damaged caused by tropical storm & hurricane events; clear threat to physical safety; located within floodway which has not been corrected or contained
Reasons: Floodway; Extensive deterioration

Quarters 8
Big Cypress National Preserve
26777 Birdon Rd.
Ochopee FL 34141
Landholding Agency: Interior

Property Number: 61201630003
Status: Unutilized
Comments: damage caused by tropical storm & hurricane events; no windows; therefore, rodent infestation; located within floodway which has not been correct or contained
Reasons: Floodway; Extensive deterioration

Quarters #8 Barn
Big Cypress National Preserve
26777 Birdon Rd.
Ochopee FL 34141
Landholding Agency: Interior
Property Number: 61201630004
Status: Unutilized
Comments: documented deficiencies: roof & wall sections collapsed; damaged caused by tropical storm & hurricane event; clear threat to safety; located within floodway which has not been corrected or contained
Reasons: Extensive deterioration; Floodway

Loop Road Building #31
Big Cypress Preserve
Loop Rd.
Ochopee FL 34141
Landholding Agency: Interior
Property Number: 61201630005
Status: Unutilized
Comments: roof & wall sections collapsed; damaged caused by tropical storm & hurricane events; clear threat to safety; located within floodway which has not been corrected or contained
Reasons: Extensive deterioration; Floodway

Loop Road Building #30
Loop Rd.
Ochopee FL 34141
Landholding Agency: Interior
Property Number: 61201630007
Status: Unutilized
Directions: N 25 58 97, W 080 14 78
Comments: documented deficiencies: damaged caused by tropical storm & hurricane events; clear threat to safety; located w/in floodway where has not been corrected or contained
Reasons: Floodway; Extensive deterioration

Loop House Building #29
Loop Rd.
Ochopee FL 34141
Landholding Agency: Interior
Property Number: 61201630011
Status: Unutilized
Directions: N 25 58 97, W 080 14 78
Comments: documented deficiencies: damaged caused by tropical storm & hurricane; clear threat to safety; located within floodway which has not been correct or contained
Reasons: Floodway; Extensive deterioration

Loop Road Building #31
Big Cypress National Preserve
Loop Rd.
Ochopee FL 34141
Landholding Agency: Interior
Property Number: 61201630012
Status: Unutilized
Comments: documented deficiencies: damaged caused by tropical storm & Hurricane events; threat to safety; located in floodway which has not been corrected or contained
Reasons: Extensive deterioration; Floodway

Yellow Water
a Special Area of NAS Jacksonville
Jasonville FL 32221
Landholding Agency: Navy
Property Number: 77201630003
Status: Unutilized
Directions: YW3064; YW3064LS; YW3067; YW3069; YW3072; YW3072LS; YW3073; YW3073LS
Comments: documented deficiencies: severely damaged by vandals; car accident which caused substantial damage; fire set by arsonist; decay/overgrown w/vegetation; clear threat to physical safety
Reasons: Extensive deterioration

Guam

60 Housing Units
4 Puntan At Nimitz Hill
Family Housing Area
Nimitz Hill Housing GU
Landholding Agency: Navy
Property Number: 77201630006
Status: Excess
Comments: public access denied and no alternative method to gain access without compromising national security
Reasons: Secured Area

Hawaii

4 Buildings
Marine Corps Base
Kaneohe HI 96863
Landholding Agency: Navy
Property Number: 77201630004
Status: Excess
Directions: 3094; 6029; 6073; 6074; located at the east end of Mokapu Rd.
Comments: public access denied and no alternative method to gain access without compromising national security
Reasons: Secured Area

Hawaii

2 Buildings
Marine Corps Base
Kaneohe HI 96863
Landholding Agency: Navy
Property Number: 77201630005
Status: Excess
Directions: 850; 852; located north of the guard shack at Manana Family housing area adjacent to the exiting tennis courts
Comments: public access denied and no alternative method to gain access without compromising national security
Reasons: Secured Area

Texas

72/1047/159 Boiler Building
No. 2; Building 22F; Lyndon B. Johnson
Space Center; 2101 NASA Parkway
Houston TX 77058
Landholding Agency: NASA
Property Number: 71201630010
Status: Unutilized
Comments: public access denied and no alternative method to gain access w/out compromising national security
Reasons: Secured Area

72/1047/129; Rectifier
Building, Building 22A
Lyndon B. Johnson Space Center
Houston TX 77058
Landholding Agency: NASA
Property Number: 71201630011
Status: Unutilized
Directions: 2101 NASA Parkway
Comments: public access denied and no alternative method to gain access w/out compromising national security
Reasons: Secured Area

72/1047/131, Atmospheric
Re-Entry Materials & Structures Evaluation
Facility, Building 222
Houston TX 77058
Landholding Agency: NASA
Property Number: 71201630012
Status: Unutilized
Directions: 2101 NASA Parkway
Comments: public access denied and no alternative method to gain access w/out compromising national security
Reasons: Secured Area

West Virginia

Building 9
3610 Collins Ferry Rd.
Morgantown WV 26507
Landholding Agency: Energy
Property Number: 41201630002
Status: Excess
Comments: public access denied and no alternative method to gain access without compromising national security
Reasons: Secured Area

[FR Doc. 2016–18289 Filed 8–1–16; 8:45 am]
BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5913–N–15; OMB Collection No.: 2502–0555]

60-Day Notice of Proposed Information Collection: Request for Withdrawals From Replacements Reserves/ Residual Receipts Funds

AGENCY: Office of the Assistant Secretary for Housing, Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* October 3, 2016

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Harry Messner, Program Analyst, Program Administration Office: Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email *harry.messner@hud.gov* or telephone 202–402–2626. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Request for Withdrawals from Replacements Reserves/Residual Receipts Funds.

OMB Approval Number: 2502–0555.

Type of Request: Extension of currently approved collection.

Form Number: HUD–9250.

Description of the need for the information and proposed use: Project owners are required to submit this information and required supporting documentation when requesting a withdrawal for funds from the Reserves for Replacement and/or Residual Receipt Funds. HUD reviews this information to ensure that funds are withdrawn and used in accordance with regulatory and administrative policy.

Respondents: Affected public.

Estimated Number of Respondents: 28,412.

Estimated Number of Responses: 7,671.

Frequency of Response: Various.

Average Hours per Response: 2.25.

Total Estimated Burden: 17,260.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: July 27, 2016.

Janet M. Golrick,

Associate General Deputy Assistant Secretary for Housing-Associate Deputy Federal Housing Commissioner.

[FR Doc. 2016–18349 Filed 8–1–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5916–N–12]

60-Day Notice of Proposed Information Collection;

Assessing Public Housing Authorities (PHAs) Compliance with Insurance Requirements Under the Consolidated Annual Contributions Contract and Regulations

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, PIH, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* October 3, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Arlette Mussington, Office of Policy, Programs and Legislative Initiatives, PIH, Department of Housing and Urban Development, 451 7th Street SW., (L'Enfant Plaza, Room 2206), Washington, DC 20410; telephone 202–402–4109, (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Information Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Mussington.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Assessing Compliance with ACC and Regulatory Insurance Requirements.

OMB Approval Number: Pending OMB Approval.

Type of Request: New.

Form Number: None.

Description of the need for the information and proposed use: the information collected will be used to assess PHAs compliance with ACC and regulatory insurance requirements. PHAs are required to have appropriate property/casualty insurance coverage needed to protect Federal interest in PHA properties and operations.

Respondents (i.e. affected public): PHAs.

Estimated Number of Respondents: 300.

Estimated Number of Responses: 300.

Frequency of Response: Once (This is a one-time survey).

Average Hours per Response: The expected average response time for the survey is 20 minutes. (Some of the questions have only binary responses: __Yes __No).

Total Estimated Burdens: 100.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: July 22, 2016.

Merrie Nichols-Dixon,

Deputy Director, Office of Policy, Programs and Legislative Initiatives.

[FR Doc. 2016–18296 Filed 8–1–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCO956000 L14400000.BJ0000 16X]

Notice of Filing of Plats of Survey; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey; Colorado

SUMMARY: The Bureau of Land Management (BLM) Colorado State Office is publishing this notice to inform the public of the intent to officially file the survey plats listed below and afford a proper period of time to protest this action prior to the plat filing. During this time, the plats will be available for review in the BLM Colorado State Office.

DATES: Unless there are protests of this action, the filing of the plats described in this notice will happen on September 1, 2016.

ADDRESSES: BLM Colorado State Office, Cadastral Survey, 2850 Youngfield Street, Lakewood, CO 80215–7093.

FOR FURTHER INFORMATION CONTACT: Randy Bloom, Chief Cadastral Surveyor for Colorado, (303) 239–3856.

Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The plat, in 2 sheets, and field notes of the dependent resurvey and survey in fractional Township 14 South, Range 98 West, Sixth Principal Meridian, Colorado, were accepted on June 30, 2016.

The plat and field notes of the dependent resurvey and survey in Township 15 South, Range 71 West, Sixth Principal Meridian, Colorado, were accepted on July 5, 2016.

The plat and field notes of the dependent resurvey in Township 2 North, Range 86 West, Sixth Principal Meridian, Colorado, were accepted on July 14, 2016.

The plat and field notes of the dependent resurvey and survey in Township 47 North, Range 1 West, New Mexico Principal Meridian, Colorado, were accepted on March 7, 2016.

The plat incorporating the field notes of the remonumentation of certain corners in Township 8 North, Range 71 West, Sixth Principal Meridian, Colorado, was accepted on July 21, 2016.

Dale E. Vinton,

Acting Chief Cadastral Surveyor for Colorado.

[FR Doc. 2016–18276 Filed 8–1–16; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[FY16.LLAZA00000.L17110000.DF0000. 241A]

Notice of Termination of Uinkaret Mountains Landscape Restoration Project Environmental Impact Statement, Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The preparation of an Environmental Impact Statement (EIS) for the proposed Uinkaret Mountains Landscape Restoration Project is no longer required and the process is hereby terminated. Pursuant to the National Environmental Policy Act of 1969, as implemented by the Council on Environmental Quality (CEQ) regulations, the Bureau of Land Management (BLM) on October 21, 2014, published a notice of intent (NOI) to prepare an EIS. The EIS would have analyzed proposed vegetation treatments in the Uinkaret Mountains Landscape Restoration Project area.

DATES: Termination of the EIS process for the Uinkaret Mountains Landscape Restoration Project is effective immediately.

FOR FURTHER INFORMATION CONTACT: Richard Spotts, Planning and Environmental Coordinator, (435) 688–3207; *rspotts@blm.gov.*

SUPPLEMENTARY INFORMATION: The BLM's Arizona Strip District Office has determined it is appropriate to terminate the Uinkaret Mountains Landscape Restoration Project EIS and prepare an Environmental Assessment (EA) instead. The NOI to prepare an EIS was published in the **Federal Register** on October 21, 2014 (79 FR 62954) and announced the scoping period for the proposed project. The initial project proposal listed a variety of potential vegetative treatments, including manual, mechanical, chemical, wildfire management for resource benefit, prescribed fire, and seeding for the overall project area of approximately 128,535 acres, located on lands managed by the Arizona Strip Field

Office and Grand Canyon Parashant National Monument, within the Arizona Strip District.

Preliminary issues from internal and external public scoping include but are not limited to: Excessive fuel loading leading to increased wildfire risk; impacts from past management activities such as grazing and fire suppression; pinyon and juniper encroachment into sagebrush and ponderosa communities; soil erosion; and the need to treat decadent sagebrush stands.

After careful consideration of preliminary issues, public scoping comments, and field-verification of existing resource conditions, BLM modified the proposed action to specific vegetation treatment units within the overall project area, of which 18,675 acres is proposed to receive manual, mechanical, seeding, erosion control, and chemical treatments and 38,713 acres are proposed to receive fire treatments. The proposed action and one other action alternative, which would implement only the fire treatments, were developed. Design features, applicable to all action alternatives, were also modified to include special resource protections to mitigate the environmental impacts, such as avoiding all known cultural resources following intensive surveys, treating areas when soils are not saturated to minimize soil compaction, ensuring mechanical treatment equipment is cleaned prior to use to minimize the spread of noxious weeds, avoiding old growth ponderosa stands, and designing treatments in irregular shapes to reduce visual contrast.

The BLM evaluated the modified the proposed action, no action, and an alternative action, against the CEQ significance criteria (40 CFR 1508.27) and determined that the anticipated effects from the treatment methods are consistent with the preparation of an EA rather than an EIS.

Thus, the BLM hereby terminates preparation of an EIS for the proposed Uinkaret Mountains Landscape Restoration Project. National Environmental Policy Act public involvement procedures will be adhered to in the development on the Uinkaret Mountains Landscape Restoration Project EA.

Authority: 40 CFR 1506.6, 40 CFR 1506.10

Timothy J. Burke,

District Manager.

[FR Doc. 2016–18272 Filed 8–1–16; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Alaaeldin A. Babiker, M.D.; Decision and Order

On January 21, 2015, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Alaaeldin A. Babiker, M.D. (hereinafter, Registrant), of Yuma, Arizona. The Show Cause Order proposed the revocation of Registrant's DEA Certificate of Registration BB7566461, pursuant to which he is authorized to dispense controlled substances in schedules II through V as a practitioner, as well as the denial of any applications, on two grounds. GX 1, at 1.

First, the Show Cause Order alleged that on October 4, 2014, the Arizona Medical Board issued Registrant an ''Order for Decree of Censure, Probation, and Practice Restriction and Consent to the Same'' which ''restricted [him] from prescribing any controlled substances.'' *Id.* The Show Cause Order thus alleged that because Registrant does not have authority to dispense controlled substances in Arizona, the State in which he is registered with DEA, his registration is subject to revocation. *Id.* (citing 21 U.S.C. 802(21), 823(f), 824(a)(3)).

Second, based on various findings of fact and legal conclusions contained in the Board's Order, the Show Cause Order alleged that Registrant had committed acts which render his registration ''inconsistent with the public interest'' in that he ''did not comply with applicable state law related to controlled substances.'' *Id.* at 2 (citing 21 U.S.C. 823(f)(4)). More specifically, the Show Cause Order alleged that: (1) ''[F]rom 2008 through 2012, [Registrant] issued controlled substance prescriptions to [his] wife''; and that (2) on December 8, 2012, he was ''diagnosed with opioid dependence, Xanax abuse and Adderall abuse.'' *Id.* Ariz. Rev. Stat. § 32–1401(27)(h) & (g)).

The Show Cause Order then made multiple allegations regarding Registrant's prescribing of narcotics to patient B.S. These included that: (1) During the period he prescribed oxycodone to B.S., he ''added morphine to the patient's medications'' and also increased B.S.'s oxycodone prescriptions without explaining why he did so in B.S.'s chart; (2) he ''did not treat [B.S.'s] chronic pain with additional evaluations or other therapeutic interventions''; and (3) that he ''deviated from the standard of care by failing to address'' lab results which suggested that B.S. was using marijuana as well as by failing to adequately document B.S.'s marijuana usage. *Id.* (citing Ariz. Rev. Stat. § 32–1401(27)(e) & (q)).

Finally, the Show Cause Order notified Registrant of his right to request a hearing on the allegations or to submit a written statement of position while waiving his right to a hearing, the procedure for electing either option, and the consequence of failing to elect either option. GX 1, at 2–3 (citing 21 CFR 1301.43; *id.* § 1301.46).

On January 29, 2015, a Special Agent went to an address in Yuma, Arizona which was identified as Registrant's address by a lawyer who had represented him before the Arizona Medical Board. According to the Special Agent, he arrived at the residence at 4:30 p.m. at which time he ''encountered no persons at the residence'' and there were ''[n]o vehicles or indications of any persons at the residence during the time'' he was present. GX 7, at 1. The Special Agent reported that he left a copy of the Show Cause Order ''in the door jamb of the front door in plain sight.'' *Id.* However, at this juncture, the Government undertook no other steps to effect service.

Several months later, the Government submitted a Request for Final Agency Action contending that 30 days had passed since Registrant was served with the Show Cause Order and that neither he, nor anyone representing him, had requested a hearing or sent any correspondence to DEA. Request for Final Agency Action, at 7–8. On review by my Office, service was deemed to be inadequate and the Government was directed to re-serve Registrant with the Show Cause Order.

On October 2, 2015, a Diversion Investigator mailed the Show Cause Order to Registrant at his residence address (as identified by his lawyer) by first class mail. GX 9, at 2 (Supplemental Declaration of DI). Thereafter, ''[o]n or about January 20, 2016,'' the DI mailed the Show Cause Order to Registrant by Certified Mail, Return Receipt Requested addressed to him at the same address as well as at two other reported addresses. *Id.* However, each of these mailings was returned unclaimed. *Id.* Subsequently, on April 6, 2016, the DI re-mailed the Show Cause Order to Registrant by regular First Class Mail to each of the three addresses. *Id.* According to the affidavit of a Legal Assistant with the Office of Chief Counsel, as of July 13, 2016, the Office of Administrative Law Judges had not received either a hearing

request or a written statement of position from him.

Based on the above, I find that the Government has satisfied its obligation under the Due Process Clause ''to provide 'notice reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections.' '' *Jones* v. *Flowers,* 547 U.S. 220, 226 (2006) (quoting *Mullane* v. *Central Hanover Bank & Trust Co.,* 339 U.S. 306, 314 (1950)). As more than 30 days have now passed since Registrant was served with the Show Cause Order and neither Registrant nor anyone representing him has either requested a hearing or submitted a written statement of position, I find that Registrant has waived his right to a hearing or to submit a written statement. I therefore issue this Decision and Order based on relevant evidence contained in the Investigative File. I make the following findings.

Findings of Fact

Registrant is the holder of DEA Certificate of Registration BB7566461, pursuant to which he is authorized to dispense controlled substances in schedules II through V, as a practitioner, at the registered address of 2140 W. 24th St., Suite A, Yuma, Arizona. GX 2. Registrant's registration does not expire until July 31, 2016. *Id.*

Registrant also previously held a medical license issued by the Arizona Medical Board. GX 3, at 1. While as of the date on which the Show Cause Order was issued, Registrant still had a license, albeit one which was restricted to prohibit him from prescribing controlled substances, on March 17, 2016, Registrant entered into an Order For Surrender Of License And Consent To The Same with the Board, which the latter approved on April 7, 2016. GX 9, at 9,11.

Therein, the Board found that pursuant to its October 3, 2014 Order for Decree of Censure, Probation, and Practice Restriction and Consent to the Same, Registrant was required to participate in the Board's Physician Health Program (PHP).[1] *Id.* at 5. Pursuant to the Order, Registrant was required to ''submit to random biological fluid, hair, or nail testing to ensure compliance with the PHP'' and call in to a hotline ''on a daily basis to determine if he [wa]s required to submit to a drug test.'' *Id.* Registrant did not, however, call in ''[f]rom February 3 through February 8, 2015,'' and ''completely ceased checking in with the hotline on February 12, 2015.'' *Id.* Based on his noncompliance with the PHP and the Board's Order, on February 26, 2015, Registrant entered into an Interim Consent Agreement for Practice Restriction with the Board which barred him from practicing medicine in the State. *Id.* at 5–6.

In the October 3, 2014 Order, the Board also made various findings regarding Registrant's prescribing of controlled substances to both his wife and patient B.S. GX 3, at 1–2, 4–5. As to the former, the Board found that Registrant ''had prescribed controlled substances to his wife on multiple occasions beginning in 2008'' and that in an August 2013 ''interview with Board staff, [he] said that he had only prescribed controlled substances to [her] a few times starting in 2012.'' *Id.* at 1. The Board also found that Registrant only ''began to maintain medical records for his wife in 20011'' and ''did not maintain complete records for'' her. *Id.* at 2.

As to his patient B.S., the Board found that Registrant first treated B.S. in April 2012, when the latter ''requested prescriptions so he could continue with the same dosing of Alprazolam 1mg (TID), oxycodone 30mg 6/day, and oxycodone 15mg 6/day'' and that Registrant kept B.S. on this regimen until September 2012, when he added morphine sulfate 30mg 2/day. *Id.* at 4. The Board found, however, that Registrant did not document an explanation in B.S.'s chart for adding the morphine. *Id.*

The Board further found that in May 2013, Registrant prescribed ''an additional 60 pills of oxycodone 30mg and an additional 60 pills of OxyContin 80mg for the month.'' *Id.* at 4–5. While the Board found that ''this was the only month in which the increase occurred, there [was] no explanation in the patient's chart to explain the change.'' *Id.*

The Board also found that Registrant conducted drug testing on B.S. several times during the course of treatment. While the Board found that B.S. properly tested positive for the medications he was prescribed, ''he also tested positive for THC, suggesting marijuana usage.'' *Id.* The Board further found that while the positive test for marijuana ''was circled on *one* of the lab reports,'' it was ''not otherwise documented in the chart.'' *Id.* (emphasis added).

The Board then found that Registrant deviated from the standard of care in multiple ways. First, he deviated by failing to address B.S.'s positive test for marijuana. *Id.* Second, he deviated ''by managing B.S.'s chronic pain with pain medications without additional evaluations or other therapeutic interventions.'' *Id.* Third, he deviated ''by dramatically increasing B.S.'s pain medication in May 2013,'' and that ''[a]s a result of the dramatic increase, B.S. could have suffered an accidental overdose.'' *Id.* Finally, the Board found that Registrant ''failed to maintain adequate, legible medical records.'' *Id.* at 6.

Based on these findings, the Board found that Registrant had engaged in multiple forms of unprofessional conduct. These included by: (1) ''failing or refusing to maintain adequate records on a patient''; (2) ''habitual intemperance in the use of alcohol or habitual substance abuse''; (3) ''using controlled substances except if prescribed by another physician for use during a prescribed course of treatment''; (4) ''prescribing or dispensing controlled substances to members of the physician's immediate family''; (5) engaging in ''[a]ny conduct or practice that is or might be harmful or dangerous to the health of the patient or the public''; and (6) ''making a false or misleading statement to the board.'' *Id.* at 6 (citing Ariz. Rev. Stat. § 32–1401(27) (e), (f), (g), (h), (q), and (jj)).[2]

[1] The October 2014 Order found that in December 2013, Registrant underwent a clinical evaluation and was diagnosed ''with opioid dependence, alcohol abuse, Xanax abuse, and Adderall abuse.'' GX 3, at 2–3. After Registrant completed inpatient and outpatient treatment, the Board determined that he could resume practicing, subject to probationary terms and restrictions, if he was ''enrolled in the PHP for a five year term.'' *Id.* at 3.

[2] In agreeing to the Order, Registrant waived ''any rights to a hearing or judicial review in state or federal court on the matters alleged.'' GX 3, at 13. He also agreed that ''[t]his Order is a public record that will be publicly disseminated as a formal disciplinary action of the Board.'' *Id.* at 14. Thus, as between Registrant and the Board, the Order was entitled to preclusive effect even though the issues were not litigated. *See Chaney Building Co.,* v. *City of Tuscon,* 716 P.2d 28, 30 (Ariz. 1986) (en banc) (even where a judgment is entered by stipulation or consent, it ''may be conclusive, with respect to one or more issues, if the parties have entered an agreement manifesting such intention'')(citing *Restatement (Second) of Judgments* § 27 comment e)). The Order nonetheless states that:

> [a]ll admissions made by [Registrant] are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and [Registrant]. Therefore, said admissions by [Registrant] are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, civil or criminal court proceeding, in the State of Arizona or any other state or federal court.

GX 3, at 13.

Notwithstanding this language, I give preclusive effect to the findings of the October 2014 Board Order. Notably, most of the findings discussed above do not appear to be based on admissions made by Registrant but on other evidence. *See David A. Ruben,* 78 FR 38363, 38366–66 n.7 (2013), *pet. for review denied, Ruben* v. *DEA,* 617 Fed.

Discussion

Loss of State Authority

Pursuant to 21 U.S.C. 824(a)(3), ''[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' This Agency has further held that notwithstanding that this provision grants the Agency authority to suspend or revoke a registration, other provisions of the Controlled Substances Act ''make plain that a practitioner can neither obtain nor maintain a DEA registration unless the practitioner currently has authority under state law to handle controlled substances.'' *James L. Hooper,* 76 FR 71371, 71372 (2011), *pet. for rev. denied, Hooper* v. *Holder,* 481 F. App'x 826 (4th Cir. 2012). *See also Frederick Marsh Blanton, M.D.,* 43 FR 27616, 27617 (1978) (''State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration.'').

These provisions include section 102(21), which defines the term ''practitioner'' to ''mean[ ] a physician . . . licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice,'' 21 U.S.C. 802(21), as well as section 303(f), which directs that ''[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' *Id.* § 823(f). As the Supreme Court has explained, ''[i]n the case of a physician, this scheme contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice.'' *United States* v. *Moore,* 423 U.S. 122, 140–41 (1975).

Here, the evidence shows that Registrant has been without state authority since the Board's October 3, 2014 Order restricted his prescribing authority and the Board has since ordered Registrant to surrender his medical license. I therefore find that Registrant is without authority to dispense controlled substances in Arizona, the State in which he is registered. Because Registrant no longer meets the CSA's prerequisite for maintaining a practitioner's registration, I will order that his registration be revoked and that any pending application be denied.

Public Interest Grounds

Under the CSA, ''[a] registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). The Act further provides that in determining ''the public interest'' with respect to a practitioner, the following factors are to be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f).

''[T]hese factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). It is well settled that I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem appropriate in determining whether a registration should be revoked.'' *Id.; see also MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222 (quoting *Hoxie,* 419 F.3d at 482)).[3]

The Government has the burden of proving, by a preponderance of the evidence, that the requirements for revocation or suspension pursuant to 21 U.S.C. 824(a) are met. 21 CFR 1301.44(e). This is so even in a non-contested case.

In this matter, the Government argues that the Board's findings of fact and conclusions of law are entitled to preclusive effect and establish that Registrant ''violated applicable controlled substance state laws under'' factor four of the public interest standard. Request for Final Agency Action, at 6 (citing 21 U.S.C. 823(f)(4)). I agree that Registrant failed to comply with state laws related to controlled substances as evidenced by the findings that he prescribed controlled substances to his wife, notwithstanding that under Arizona law, ''[p]rescribing or dispensing controlled substances to members of the physician's immediate family'' is ''unprofessional conduct.'' Ariz. Rev. Stat. § 32–1401(27)(h). Based on the plain language of this provision, I conclude that even though it is found in the State's medical practice act, it is a law ''relating to controlled substances.'' 21 U.S.C. 823(f)(4).

The Board also found that Registrant has been diagnosed as dependent on opioids, and that he has abused both Xanax (alprazolam), a schedule IV benzodiazepine, and Adderall, (amphetamine and dextroamphetamine), a schedule II stimulant. *See* 21 CFR 1308. 14(c)(2); *id.* 1308.12 (d)(1). Based on these findings, the Board concluded that Registrant has committed ''unprofessional conduct'' by engaging in ''habitual substance abuse'' and ''using controlled substances except if prescribed by another physician for use during a prescribed course of treatment.'' Ariz. Rev. Stat. § 32–1301(27)(f) & (g). Here too, while these provisions are located in the State's medical practice act, the plain language of these provisions supports the conclusion that they are laws ''relating to controlled substances.'' 21 U.S.C. 823(f) (4).[4]

Appx. 837, 838–39 (Mem.) (9th Cir. 2015). To the extent any of these findings relied on Registrant's admissions, neither the Arizona Medical Board nor Registrant can dictate to an Agency of the United States what weight it can attach to the Order's findings. *Cf. id.* at 38365–67.

[3] While I have considered all of the factors, the Government does not argue that any of the other factors are relevant in making the public interest determination in this matter. Be that as it may, ''this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *See MacKay,* 664 F.3d at 821.

[4] While not cited by the Government, DEA has long held that a practitioner's self-abuse of a controlled substance is actionable under factor five as ''[s]uch other conduct which may threaten public health and safety.'' *See Tony T. Bui,* 75 FR 49979, 49989 (2010) (citing cases).

The Board also made several findings that Registrant deviated from the standard of care when he prescribed narcotic controlled substances to B.S. and which are highly suggestive of a finding that

Continued

The Board's conclusions of law that Registrant committed unprofessional conduct by prescribing controlled substances to his wife, as well as by engaging in habitual substance abuse and using controlled substances which were not prescribed to him by another physician in the course of treatment, support the conclusion that he has committed such acts as to render his registration ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). These findings provide an additional and independent basis to revoke Registrant's registration.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a) and 823(f), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration BB7566461 issued to Alaaeldin Babiker, M.D., be, and it hereby is, revoked. I further other that any application of Alaaeldin Babiker, M.D., to renew or modify this registration, or for any other registration, be, and it hereby is denied. This Order is effective immediately.[5]

he acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing to B.S. 21 CFR 1306.04(a). These include that he failed to address B.S.'s positive test for marijuana, that he did not perform additional evaluations or use therapeutic interventions other than prescribing controlled substances, that he dramatically increased B.S.'s pain medications and did not document an explanation for doing so, and that he failed to maintain adequate and legible medical records.

The Board did not, however, find that Registrant engaged in ''[p]rescribing, dispensing, or administering any controlled substance . . . for other than accepted therapeutic purposes,'' Ariz. Rev. Stat. § 32–1401(27)(j), a standard similar to that of 21 CFR 1306.04(a). *See* GX 3, at 6; *see also Kenneth Harold Bull,* 78 FR 62666, 62674 (2013) (holding that physician's violation of a State's ''injudicious prescribing'' standard did not establish a violation of 21 CFR 1306.4(a) when the State also had a standard prohibiting ''prescribing . . . or dispensing of narcotic, stimulant or hypnotic drugs for other than accepted therapeutic purposes'' but did not find a violation). Instead, the Board found that he committed unprofessional conduct by engaging in ''[a]ny conduct or practice that is or might be harmful or dangerous to the health of the patient or the public.'' GX 3, at 6 (citing Ariz. Rev. Stat. § 32–1401(27)(q)).

In its Request for Final Agency Action, the Government did not allege that the Board's findings with respect to B.S. supported a finding that Registrant violated 21 CFR 1306.04(a). Nor did it argue that the Board's findings establish reckless or negligent conduct in the handling of controlled substances, which is a basis to revoke a registration under *Paul J. Caragine,* 63 FR 51592, 51601 (1998).

Moreover, the Government offers no argument as to why the Board's standard of ''[a]ny conduct or practice that is or might be harmful or dangerous to the health of the patient or the public'' is a law related to controlled substances under factor four. I therefore do not consider whether this provision falls within factor four. Nor do I consider the Board's findings with respect to B.S.

[5] For the same reasons which led the Board to order Registrant to immediately surrender his state license, I conclude that this Order should be effective immediately. GX 9, at 9; *see also* 21 CFR 1316.67.

Dated: July 22, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–18278 Filed 8–1–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On July 27, 2016, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Eastern District of Tennessee in the lawsuit entitled *United States and Knox County, Tennessee, Ex Rel, Lynne Liddington, Director Of Air Quality Management For Knox County, Tennessee* v. *Cemex Inc., et al.,* Civil Action No. 3:16–cv–471.

This case involves claims for alleged violations of the Prevention of Significant Deterioration (''PSD'') program of the Clean Air Act (''CAA''), CAA's Title V operating permit requirements, and related Tennessee and Texas state law requirements at Portland cement facilities in Knoxville, Tennessee and Odessa, Texas owned or operated by Cemex, Inc. or related corporate entities (collectively, ''Cemex''). The complaint seeks injunctive relief for installation of control technology to reduce emissions of nitrogen oxides (NO_X), civil penalties, and mitigation of past excess NO_X emissions. The settlement resolves the liability at these facilities and also resolves similar potential liability at additional Cemex cement plants in New Braunfels, Texas, Louisville, Kentucky and Demopolis, Alabama, and requires Cemex to install pollution control equipment, agree to federally enforceable limits for NO_X and SO_2 emissions, pay $1,690,000 in civil penalties, and perform an environmental mitigation project.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and Knox County, Tennessee, Ex Rel, Lynne Liddington, Director Of Air Quality Management For Knox County, Tennessee* v. *Cemex Inc., et al.,* D.J. Ref. No. 90–5–2–1–09716. All comments must be submitted no later than thirty (30) days after the publication date of this notice.

Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By e-mail	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $13.50 (25 cents per page reproduction cost) payable to the United States Treasury.

Henry Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2016–18161 Filed 8–1–16; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Parole Commission

Sunshine Act Meeting; Record of Vote of Meeting Closure (Pub. L. 94–409) (5 U.S.C. 552b)

I, J. Patricia W. Smoot, of the United States Parole Commission, was present at a meeting of said Commission, which started at approximately 11:00 p.m., on Wednesday, July 27, 2016 at the U.S. Parole Commission, 90 K Street NE., Third Floor, Washington, DC 20530. The purpose of the meeting was to discuss six original jurisdiction cases pursuant to 28 CFR 2.27. Three Commissioners were present, constituting a quorum when the vote to close the meeting was submitted.

Public announcement further describing the subject matter of the meeting and certifications of the General Counsel that this meeting may be closed by votes of the Commissioners present were submitted to the Commissioners prior to the conduct of any other business. Upon motion duly made, seconded, and carried, the following Commissioners voted that the meeting be closed: J. Patricia W. Smoot, Patricia Cushwa and Charles T. Massarone.

IN WITNESS WHEREOF, I make this official record of the vote taken to close this meeting and authorize this record to be made available to the public.

Dated: July 27, 2016.

J. Patricia W. Smoot,

Chairman, U.S. Parole Commission.

[FR Doc. 2016–18450 Filed 7–29–16; 4:15 pm]

BILLING CODE 4410–31–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Sale of Securities To Reduce Indebtedness of Party in Interest, Prohibited Transaction Class Exemption 1980–83

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) will submit the Employee Benefits Security Administration (EBSA) sponsored information collection request (ICR) titled, ''Sale of Securities to Reduce Indebtedness of Party in Interest, Prohibited Transaction Class Exemption 1980–83,'' to the Office of Management and Budget (OMB) on July 29, 2016, for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before September 1, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201607-1210-001* (this link will only become active on July 30, 2016) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–EBSA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Sale of Securities to Reduce Indebtedness of Party in Interest, Prohibited Transaction Class Exemption 1980–83 (PTE 80–83) information collection. This PTE allows an employee benefit plan to purchase securities that may aid the issuer of the securities to reduce or retire indebtedness to a party in interest. Without the relief provided by the class exemption, Employee Retirement Income Security Act of 1974 (ERISA) prohibited transaction provisions would bar a standard type of financial/business transaction between a financial service provider and an employee benefit plan. This exemption also provides relief from Internal Revenue Code section 4975 prohibited transaction provisions.

In order to take advantage of the relief provided by this PTE, an employee benefit plan must comply with all applicable exemption conditions, including keeping records sufficient to establish that exemption conditions have been met for exemption-covered transactions. The records must be maintained for a period of at least six years from a covered transaction and must be made reasonably available for inspection upon request by specified interested persons—including plan fiduciaries, participants and beneficiaries, sponsoring employers, DOL and Internal Revenue Service representatives, and contributing employers. ERISA, section 408(a) authorizes this information collection. *See* 29 U.S.C. 1108(a).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1210–0064.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on November 23, 2015 (80 FR 72990).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1210–0064. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–EBSA.

Title of Collection: Sale of Securities to Reduce Indebtedness of Party in Interest, Prohibited Transaction Class Exemption 1980–83.

OMB Control Number: 1210–0064.

Affected Public: Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 25.

Total Estimated Number of Responses: 25.

Total Estimated Annual Time Burden: 15 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: July 27, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–18189 Filed 8–1–16; 8:45 am]

BILLING CODE 4510–29–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation

ACTION: Notice of permit applications received under the Antarctic Conservation Act of 1978.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at Title 45 Part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by September 1, 2016. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Division of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Nature McGinn, ACA Permit Officer, at the above address or *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

APPLICATION DETAILS:

1. *Applicant*—Permit Application: 2017–007.

Maris Wicks, 81 Electric Avenue #3, Somerville, MA 02144.

Activity for Which Permit is Requested

Enter Antarctic Specially Protected Area. The applicant is a participant in the Antarctic Artists & Writers program and plans to travel to Antarctica to gather information and images for an educational publication that will document the research supported through the U.S. Antarctic Program. The applicant is requesting access to Cape Royds, ASPA 121; Backdoor Bay, ASPA 157; and Arrival Heights, ASPA 122, in order to observe and interview scientists, document their work and environs, and make photographs and sketches. While in the penguin colony at Cape Royds, the applicant will only observe, photograph, and sketch the penguins such that no take or harmful interference will occur. The applicant will be accompanied by researchers while in the ASPAs. The results of this work is expected to be useful for outreach and education about Antarctica and the scientific research conducted there.

Location

Cape Royds, ASPA 121; Backdoor Bay, ASPA 157; Arrival Heights, ASPA 122.

Dates

November 1, 2016–January 15, 2017.

Nadene G. Kennedy,

Polar Coordination Specialist, Division of Polar Programs.

[FR Doc. 2016–18281 Filed 8–1–16; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0001]

Sunshine Act Meeting Notice

DATE: August 1, 8, 15, 22, 29, September 5, 2016.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and closed.

Week of August 1, 2016

There are no meetings scheduled for the week of August 1, 2016.

Week of August 8, 2016—Tentative

There are no meetings scheduled for the week of August 8, 2016.

Week of August 15, 2016—Tentative

There are no meetings scheduled for the week of August 15, 2016.

Week of August 22, 2016—Tentative

There are no meetings scheduled for the week of August 22, 2016.

Week of August 29, 2016—Tentative

There are no meetings scheduled for the week of August 29, 2016.

Week of September 5, 2016—Tentative

There are no meetings scheduled for the week of September 5, 2016.

* * * * *

The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.*

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or email *Brenda.Akstulewicz@nrc.gov* or *Patricia.Jimenez@nrc.gov.*

Dated: July 28, 2016.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2016–18312 Filed 7–29–16; 11:15 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0151]

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 July 5, 2019, to July 19, 2016. The last biweekly notice was published on July 19, 2016 (81 FR 46958).

DATES: Comments must be filed by September 1, 2016. A request for a hearing must be filed by October 3, 2016.

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

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0151. 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: Lynn Ronewicz, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–1927, email: *Lynn.Ronewicz@nrc.gov.*

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0151, facility name, unit number(s), plant docket number, application date, and subject 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–2016–0151.

• *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 this document.

• *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–2016–0151, facility name, unit number(s), plant docket number, 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 will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, 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 into ADAMS.

I. 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 if 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. If the Commission takes 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. If the Commission makes 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 to support its position on this issue. 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 the 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 September 19, 2016. 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 10 CFR 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. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

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, as amended at 77 FR 46562, August 3, 2012). 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 to the NRC,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/electronic-sub-ref-mat.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 Electronic Filing 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.

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/electronic-sub-ref-mat.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 Electronic Filing 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 Electronic Filing Help Desk is available between 9 a.m. and 7 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 stating why there is good cause for not filing electronically and 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 hearing request and petition 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.

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 obtaining information related to this document, see the ''Obtaining Information and Submitting Comments'' section of this document.

Duke Energy Carolinas, LLC, Docket Nos. 50–413 and 50–414, Catawba Nuclear Station (CNS), Units 1 and 2, York County, South Carolina

Date of amendment request: May 26, 2016. A publicly-available version is in ADAMS under Accession No. ML16147A105.

Description of amendment request: The amendments would revise Sections 8.3.1, ''AC Power Systems''; 9.2.1, ''Nuclear Service Water System''; 9.4.1, ''Control Room Area Ventilation''; and 9.4.3, ''Auxiliary Building Ventilation System,'' of the updated final safety analysis report (UFSAR), to clarify how a shutdown unit supplying either its normal or emergency power source may be credited for operability of shared components supporting the operating unit.

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 only involves a change to the UFSAR to reflect how shared systems at CNS can be powered from offsite or onsite power sources. The proposed change does not modify any plant equipment and does not impact any failure modes that could lead to an accident. Additionally, the proposed change does not impact the consequence of any analyzed accident since the change does not adversely affect any equipment related to accident mitigation.

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 only involves a change to the UFSAR to reflect how shared systems at CNS can be powered from offsite or onsite power sources. The proposed change does not modify any plant equipment and there is no impact on the capability of the existing equipment to perform their intended functions. No system set points are being modified and no changes are being made to the method in which plant operations are conducted. No new failure modes are introduced by the proposed change and the proposed amendment does not introduce accident initiators or malfunctions that would cause a new or different kind of accident.

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 only involves a change to the UFSAR to reflect how shared systems at CNS can be powered from offsite or onsite power sources. The proposed change to the UFSAR does not affect any of the assumptions used in the CNS accident analysis, nor does it affect any operability requirements for equipment important to safety.

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: Kate B. Nolan, Deputy General Counsel, Duke Energy Carolinas, LLC, 550 South Tryon Street—DEC45A, Charlotte, NC 28202–1802.

NRC Branch Chief: Michael T. Markley.

FirstEnergy Nuclear Operating Company, et al., Docket Nos. 50–334 and 50–412, Beaver Valley Power Station, Unit Nos. 1 and 2, Beaver County, Pennsylvania

FirstEnergy Nuclear Operating Company, et al., Docket No. 50–346, Davis-Besse Nuclear Power Station, Unit No. 1, Ottawa County, Ohio

FirstEnergy Nuclear Operating Company, et al., Docket No. 50–440, Perry Nuclear Power Plant, Unit No. 1, Lake County, Ohio

Date of amendment request: May 24, 2016. A publicly-available version is in ADAMS under Accession No. ML16148A047.

Description of amendment request: The amendment would eliminate Technical Specification (TS), Section 5.5, ''Inservice Testing Program,'' to remove requirements duplicated in American Society of Mechanical Engineers (ASME) Code for Operations and Maintenance of Nuclear Power Plants (OM Code), Case OMN–20, ''Inservice Test Frequency.'' A new defined term, ''INSERVICE TESTING PROGRAM,'' will be added to TS Section 1.1, ''Definitions.'' The proposed change to the TS is consistent with TSTF–545, Revision 3, ''TS Inservice Testing Program Removal & Clarify SR Usage Rule Application to Section 5.5 Testing.''

Using the consolidated line-item improvement process, the NRC staff issued a notice of availability in the **Federal Register** on March 28, 2016 (81 FR 17208), for a possible proposed change that modifies the Standard Technical Specification (STS) to eliminate Chapter 5.0, ''Administrative Controls,'' specification Section 5.5, ''Inservice Testing Program,'' to remove requirements duplicated in ASME Code, Case OMN–20, ''Inservice Test Frequency.'' ASME Code, Case OMN–20, provides similar definitions and allowances as in the current STS Inservice Testing Program. The notice of availability added a new defined term, ''Inservice Testing Program (IST),'' to the STS, Section 1.1, ''Definitions.'' Also, the STS, Section 3.0, ''Surveillance Requirement (SR) Applicability,'' and STS Bases were revised to explain the application of the usage rules to the Section 5.5 testing requirements. Existing uses of the term ''Inservice Testing Program'' in the STS and STS Bases were capitalized to indicate that it is now a defined term. The FR notice included the model application, No Significant Hazards Consideration (NSHC) Determination, and the model safety evaluation for referencing in license amendment applications. The licensee affirmed the applicability of the model NSHC determination in its application dated May 24, 2016, which is presented below.

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, along with NRC edits in square brackets:

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 TS Chapter 5, ''Administrative Controls,'' Section 5.5, ''Programs and Manuals,'' by eliminating the ''Inservice Testing Program'' specification. Most requirements in the Inservice Testing Program are removed, as they are duplicative of requirements in the ASME OM Code, as clarified by Code Case OMN–20, ''Inservice Test Frequency.'' The remaining requirements in the Section 5.5 Inservice Testing Program are eliminated because the NRC has determined their inclusion in the TS is contrary to regulations. A new defined term, ''INSERVICE TESTING PROGRAM,'' is added to the TS, which references the requirements of 10 CFR 50.55a(f).

Performance of inservice testing is not an initiator to any accident previously evaluated. As a result, the probability of occurrence of an accident is not significantly affected by the proposed change. Inservice test frequencies under Code Case OMN–20 are equivalent to the current testing period allowed by the TS with the exception that testing frequencies greater than 2 years may be extended by up to 6 months to facilitate test scheduling and consideration of plant operating conditions that may not be suitable for performance of the required testing. The testing frequency extension will not affect the ability of the components to mitigate any accident previously evaluated as the components are required to be operable during the testing period extension. Performance of inservice tests utilizing the allowances in OMN–20 will not significantly affect the reliability of the tested components. As a result, the availability of the affected components, as well as their ability to mitigate the consequences of accidents previously evaluated, is not affected.

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 previously evaluated?

Response: No.

The proposed change does not alter the design or configuration of the plant. The proposed change does not involve a physical alteration of the plant; no new or different kind of equipment will be installed. The

proposed change does not alter the types of inservice testing performed. In most cases, the frequency of inservice testing is unchanged. However, the frequency of testing would not result in a new or different kind of accident from any previously evaluated since the testing methods are not altered.

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 change involve a significant reduction in a margin of safety?

Response: No

The proposed change eliminates some requirements from the TS in lieu of requirements in the ASME Code, as modified by use of Code Case OMN–20. Compliance with the ASME Code is required by 10 CFR 50.55a. The proposed change also allows inservice tests with frequencies greater than 2 years to be extended by 6 months to facilitate test scheduling and consideration of plant operating conditions that may not be suitable for performance of the required testing. The testing frequency extension will not affect the ability of the components to respond to an accident as the components are required to be operable during the testing period extension. The proposed change will eliminate the existing TS SR 3.0.3 allowance to defer performance of missed inservice tests up to the duration of the specified testing frequency, and instead will require an assessment of the missed test on equipment operability. This assessment will consider the effect on a margin of safety (equipment operability). Should the component be inoperable, the Technical Specifications provide actions to ensure that the margin of safety is protected. The proposed change also eliminates a statement that nothing in the ASME Code should be construed to supersede the requirements of any TS. The NRC has determined that statement to be incorrect. However, elimination of the statement will have no effect on plant operation or safety.

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 W. Jenkins, FirstEnergy Nuclear Operating Company, FirstEnergy Corporation, 76 South Main Street, Mail Stop A–GO–15, Akron, OH 44308.

NRC Acting Branch Chief: G. Edward Miller.

Florida Power & Light Company, et al., Docket No. 50–389, St. Lucie Plant, Unit No. 2, St. Lucie County, Florida

Date of amendment request: June 21, 2016. A publicly-available version is in ADAMS under Accession No. ML16190A118.

Description of amendment request: The amendment would update the Technical Specifications to revise the emergency diesel generator (EDG) engine-mounted fuel tank minimum volume from 200 gallons of fuel each to 238 gallons of fuel each.

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 EDGs engine-mounted fuel oil tanks are part of a system used to mitigate the consequences of an accident and do not increase the probability of an accident previously evaluated. The increase in minimum fuel oil requirements enables operation of the EDGs to remain unchanged for ULSD [ultra low sulfur diesel] fuel oil, thus the EDGs continue to be capable of performing their design functions. Acceptance criteria continue to be satisfied. Accordingly, the proposed change does not increase the consequences of an accident.

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.

No new accident scenarios, failure mechanisms, or limiting single failures are introduced as a result of the increase in minimum EDGs engine-mounted fuel oil tank volume. The proposed change has no adverse effect on any safety-related system and does not change the performance or integrity of any safety-related equipment. No new safety-related equipment is being added or replaced as a result of the proposed change.

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 calculation for EDG fuel consumption shows that with the minimum day tank volume of 238 gallons of ULSD fuel, the requirement for two day tanks to provide a usable volume which is sufficient for at least 1 hour 100% load operation of one diesel generator set, plus a minimum margin of 10% is met. The day tank minimum volumes with the DOST [diesel oil storage tank] minimum volume is sufficient for the EDG loading increase due to potential operation at the upper frequency limit of 60.6 HZ [Hertz] (60 HZ, +1%) and the EPU [extended power uprate] requirements. The EDG fuel consumption analyses demonstrate that the EDG design continues to satisfy its safety function. The design basis limits for the accident and transient analyses will continue to meet their design criteria.

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 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 Acting Branch Chief: Tracy J. Orf.

Pacific Gas and Electric Company, Docket Nos. 50–275 and 50–323, Diablo Canyon Nuclear Power Plant, Units 1 and 2, San Luis Obispo County, California

Date of amendment request: May 12, 2016. A publicly-available version is in ADAMS under Package Accession No. ML16146A100.

Description of amendment request: The amendments would revise Technical Specification (TS) 5.5.6, ''Containment Leakage Rate Testing Program,'' to allow the following:

- Increase in the existing 10 CFR part 50, Appendix J, ''Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors,'' Type A test interval from 10 years to 15 years in accordance with Nuclear Energy Institute (NEI) 94–01, Revision 2–A, ''Industry Guideline for Implementing Performance-Based Option of 10 CFR part 50, Appendix J,'' October 2008 (ADAMS Accession No. ML100620847).
- Adopt the use of American National Standards Institute/American Nuclear Society (ANSI/ANS) 56.8–2002, ''Containment System Leakage Testing Requirements,'' as referenced in NEI 94–01, Revision 2–A.
- Adopt an allowable test interval extension of 9 months, which is shorter than the currently allowed 25 percent grace, for the 10 CFR 50, Appendix J, Type A, Type B, and Type C leakage tests in accordance with NEI 94–01, Revision 2–A.

The proposed changes would revise TS 5.5.16 to replace the reference to NRC Regulatory Guide 1.163, ''Performance-Based Containment Leak-Test Program,'' September 1995 (ADAMS Accession No. ML003740058), and 10 CFR 50, Appendix J, Option B,

''Performance-Based Requirements,'' with a reference to NEI 94–01, Revision 2–A.

In addition, the proposed amendments would modify TS 5.5.16 to remove an exception under paragraph 5.16.a.3 for a one-time 15-year Type A test interval beginning May 4, 1994, for Unit 1 and April 30, 1993, for Unit 2.

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 license amendment adopts the Nuclear Regulatory Commission (NRC)-accepted guidelines of Nuclear Energy Institute (NEI) Report 94–01, Revision 2–A, ''Industry Guideline for Implementing Performance-Based Option of 10 CFR part 50, Appendix J,'' for development of the Diablo Canyon Power Plant (DCPP) Units 1 and 2 performance-based Technical Specification 5.5.16, ''Containment Leakage Rate Testing Program.'' NEI 94–01 allows, based on risk and performance, an extension of Type A containment leak test intervals. Implementation of these guidelines continues to provide adequate assurance that during design basis accidents, the containment and its components will limit leakage rates to less than the values assumed in the plant safety analyses.

The findings of the DCPP risk assessment confirm the general findings of previous studies that the risk impact with extending the containment leak rate is small, per the guidance provided in Regulatory Guide (RG) 1.174, Revision 2 ''An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,'' May 2011 (ADAMS Accession No. ML100910006).

Since the license amendment is implementing a performance-based containment testing program, the proposed license amendment does not involve either a physical change to the plant or a change in the manner in which the plant is operated or controlled. The requirements for leakage rate tests and acceptance criteria will not be changed by this license amendment.

Therefore, the containment will continue to perform its design function as a barrier to fission product releases.

The proposed license amendment also deletes an exception previously granted to allow one time extensions of the Type A test frequency for DCPP. This exception was for an activity that has already taken place; therefore, the deletion is solely an administrative action that has no effect on any component and no physical impact on how the units are operated.

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 accident from any accident previously evaluated?

Response: No.

The proposed license amendment to implement a performance-based Type A testing program does not change the design or operation of structures, systems, or components of the plant. In addition, the proposed changes would not impact any other plant system or component.

The proposed license amendment would continue to ensure containment integrity and would ensure operation within the bounds of existing accident analyses. There are no accident initiators created or affected by the proposed changes.

The proposed license amendment also deletes an exception previously granted to allow one time extensions of the Type A test frequency for DCPP. This exception was for an activity that has already taken place; therefore, the deletion is solely an administrative action and does not change how the units are operated or maintained.

Therefore, the proposed license amendment does not create the possibility of a new or different accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed license amendment to implement the performance-based Type A testing program does not affect plant operations, design functions, or any analysis that verifies the capability of a structure, system, or component of the plant to perform a design function. In addition, this change does not affect safety limits, limiting safety system setpoints, or limiting conditions for operation.

The specific requirements and conditions of Technical Specification 5.5.16, ''Containment Leakage Rate Testing Program,'' exist to ensure that the degree of containment structural integrity and leak-tightness that is considered in the plant safety analysis is maintained. The overall containment leak rate limit specified by the Technical Specifications is maintained. This ensures that the margin of safety in the plant safety analysis is maintained. The proposed amendment will ensure that the design, operation, testing methods and acceptance criteria for Type A tests specified in applicable codes and standards would continue to be met since these are not affected by implementation of a performance based Type A testing interval.

The proposed amendment also deletes an exception previously granted to allow one time extensions of the Type A test frequency for DCPP. This exception was for an activity that has taken place; therefore, the deletion is solely an administrative action and does not change how the unit is operated and maintained.

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: Jennifer Post, Esq., Pacific Gas and Electric Company, P.O. Box 7442, San Francisco, CA 94120.

NRC Branch Chief: Robert J. Pascarelli.

South Carolina Electric and Gas Company and South Carolina Public Service Authority, Docket Nos. 52–027 and 52–028, Virgil C. Summer Nuclear Station, Units 2 and 3, Fairfield County, South Carolina

Date of amendment request: June 16, 2016, as supplemented by letter dated July 7, 2016. Publicly-available versions are in ADAMS under Accession Nos. ML16168A282 and ML16189A453, respectively.

Description of amendment request: The amendments propose changes to the Updated Final Safety Analysis Report (UFSAR) in the form of departures from the incorporated plant-specific Design Control Document Tier 2* and associated Tier 2 information. Specifically, the proposed departures consist of changes to the UFSAR to revise the details of the structural design of auxiliary building floors within module CA20 at approximate design elevations of 82′-6″ and 92′-6″.

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 design functions of the auxiliary building floors are to provide support, protection, and separation for the seismic Category I mechanical and electrical equipment located in the auxiliary building. The auxiliary building is a seismic Category I structure and is designed for dead, live, thermal, pressure, safe shutdown earthquake loads, and loads due to postulated pipe breaks. The proposed changes to UFSAR descriptions are intended to address changes in the detail design of floors in the auxiliary building. The thickness and strength of the auxiliary building floors are not reduced. As a result, the design function of the auxiliary building structure is not adversely affected by the proposed changes. There is no change to plant systems or the response of systems to postulated accident conditions. There is no change to the predicted radioactive releases due to postulated accident conditions. The plant response to previously evaluated accidents or external events is not

adversely affected, nor do the changes described create any new accident precursors.

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 changes to UFSAR descriptions are proposed to address changes in the detail design of floors in the auxiliary building. The thickness, geometry, and strength of the structures are not adversely altered. The concrete and reinforcement materials are not altered. The properties of the concrete are not altered. The changes to the design details of the auxiliary building structure do not create any new accident precursors. As a result, the design function of the auxiliary building structure is not adversely affected by the proposed changes.

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 criteria and requirements of American Concrete Institute (ACI) 349 and American Institute of Steel Construction (AISC) N690 provide a margin of safety to structural failure. The design of the auxiliary building structure conforms to criteria and requirements in ACI 349 and AISC N690 and therefore maintains the margin of safety. Analysis of the connection design confirms that code provisions are appropriate to the floor to wall connection. The proposed changes to the UFSAR address changes in the detail design of floors in the auxiliary building. The proposed changes also incorporate the requirements for development and anchoring of headed reinforcement which were previously approved. There is no change to design requirements of the auxiliary building structure. There is no change to the method of evaluation from that used in the design basis calculations. There is not a significant change to the in structure response spectra.

Therefore, the proposed amendment does not result in 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: M. Stanford Blanton, Balch & Bingham LLP, 1710 Sixth Avenue North, Birmingham, AL 35203–2015.

NRC Acting Branch Chief: Jennifer Dixon-Herrity.

South Carolina Electric and Gas Company and South Carolina Public Service Authority, 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: July 5, 2016. A publicly-available version is in ADAMS under Accession No. ML16187A392.

Description of amendment request: The amendment request relates to changes to the slab thickness between Column Lines I to J–1 and 2 to 4 at plant elevation 153′-0″. The changes involve changes to incorporated AP1000 Design Control Document Tier 1 information and corresponding departures to Tier 2* Updated Final Safety Analysis Report information and conforming changes to the Combined License, Appendix C.

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, with NRC staff edits in square brackets:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The design functions of the nuclear island structures are to provide support, protection, and separation for the seismic Category I mechanical and electrical equipment located in the nuclear island. The nuclear island structures are structurally designed to meet seismic Category I requirements as defined in Regulatory Guide 1.29. The change of the thickness of the floor above the [Component Cooling Water System (CCS)] Valve room in the auxiliary building meets criteria and requirements of American Concrete Institute (ACI) 349 and American Institute of Steel Construction (AISC) N690, does not have an adverse impact on the response of the nuclear island structures to safe shutdown earthquake ground motions or loads due to anticipated transients or postulated accident conditions. The proposed changes do not impact the support, design, or operation of mechanical and fluid systems. There is no change to plant systems or the response of systems to postulated accident conditions. There is no change to the predicted radioactive releases due to normal operation or postulated accident conditions. The plant response to previously evaluated accidents or external events is not adversely affected, nor does the change described create any new accident precursors.

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 proposed change is to revise the thickness of the floor above the CCS Valve room in the auxiliary building. The proposed changes do not change the design requirements of the nuclear island structures. The proposed changes do not change the design function, support, design, or operation of mechanical and fluid systems. The proposed changes do not result in a new failure mechanism for the nuclear island structures or new accident precursors. As a result, the design function of the nuclear island structures is not adversely affected by the proposed change.

Therefore, the proposed amendment does not create the possibility of a new or different kind of accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

No safety analysis or design basis acceptance limit/criterion is challenged or exceeded by the proposed changes, thus, no margin of safety is reduced.

Therefore, the proposed amendment does not involve a significant reduction in a margin of safety previously evaluated.

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.

Acting NRC Branch Chief: Jennifer Dixon-Herrity.

Southern California Edison Company, et al., Docket Nos. 50–361 and 50–362, San Onofre Nuclear Generating Station, Units 2 and 3, San Diego County, California

Date of amendment request: June 16, 2016. A publicly-available version is in ADAMS under Accession No. ML16172A075.

Description of amendment request: The amendments would extend the scheduled implementation date for Milestone 8 of the San Onofre Nuclear Generating Station, Units 2 and 3, Cyber Security Plan to December 31, 2019, in order to more fully reflect the permanent shutdown status of the facility and accommodate ongoing decommissioning activities.

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 to the San Onofre Nuclear Generating Station (SONGS) Cyber Security Plan Implementation Schedule is administrative in nature. This change does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in which systems are operated, maintained, modified, tested, or inspected. The proposed change does not require any plant modifications which affect the performance capability of the structures, systems, and components (SSCs) relied upon to mitigate the consequences of postulated accidents, and has no impact on the probability or consequences of an accident previously evaluated.

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 proposed change to the SONGS Cyber Security Plan Implementation Schedule is administrative in nature. This proposed change does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in which systems are operated, maintained, modified, tested, or inspected. The proposed change does not require any plant modifications which affect the performance capability of the SSCs relied upon to mitigate the consequences of postulated accidents, and does not create the possibility of a new or different kind of accident from any accident previously evaluated.

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 change involve a significant reduction in a margin of safety?

Response: No.

Plant safety margins are established through limiting conditions for operation, limiting safety system settings, and safety limits specified in the technical specifications. The proposed change to the SONGS Cyber Security Plan Implementation Schedule is administrative in nature. Since the proposed change is administrative in nature, there is no change to these established safety margins.

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: Walker A. Matthews, Esquire, Southern California Edison Company, 2244 Walnut Grove Avenue, Rosemead, CA 91770.

NRC Branch Chief: Bruce Watson.

Southern Nuclear Operating Company, Docket Nos. 52–025 and 52–026, Vogtle Electric Generating Plant (VEGP), Units 3 and 4, Burke County, Georgia

Date of amendment request: March 4, 2016. A publicly-available version is in ADAMS under Accession No. ML16064A352.

Description of amendment request: The amendment proposes to change the VEGP, Units 3 and 4, License Conditions 2.D(12)(d) and submits the new plant-specific Emergency Action Level (EAL) scheme for both units.

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 requested amendment proposes changes to the Vogtle Electric Generating Plant (VEGP) Units 3 and 4 License Conditions 2.D(12)(d) and submits the new plant-specific Emergency Action Level (EAL) scheme for both units. The proposed changes, including the modification of VEGP Units 3 and 4 License Condition 2.D(12)(d) and submittal of the new plant-specific EALs for both units, do not impact the physical function of plant structures, systems, or components (SSCs) or the manner in which SSCs perform their design function. The proposed changes neither adversely affect accident initiators or precursors, nor alter design assumptions. The proposed changes do not alter or prevent the ability of SSCs to perform their intended function to mitigate the consequences of an initiating event within assumed acceptance limits. No operating procedures or administrative controls that function to prevent or mitigate accidents are affected by the proposed changes.

Therefore, the requested 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 proposed changes, including the modification of VEGP Units 3 and 4 License Conditions 2.D(12)(d) and submittal of the new plant-specific EALs for both units, do not involve a physical alteration of the plant (*i.e.,* no new or different type of equipment will be installed or removed) or a change in the method of plant operation. The proposed changes will not introduce failure modes that could result in a new accident, and the changes do not alter assumptions made in the safety analysis. The proposed changes are not initiators of any accidents.

Therefore, the requested 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.

Margin of safety is associated with the ability of the fission product barriers (*i.e.,* fuel cladding, reactor coolant system pressure boundary, and containment structure) to limit the level of radiation dose to the public. The proposed changes to the plant-specific EALs and the modification of VEGP Units 3 and 4 License Conditions 2.D(12)(d) do not impact operation of the plant or its response to transients or accidents. The proposed changes do not affect the Technical Specifications. The proposed changes do not involve a change in the method of plant operation, and no accident analyses will be affected by the proposed changes.

Additionally, the proposed changes will not relax any criteria used to establish safety limits and will not relax any safety system settings. The safety analysis acceptance criteria are not affected by these proposed changes. The proposed changes will not result in plant operation in a configuration outside the design basis. The proposed changes do not adversely affect systems that respond to safely shut down the plant and to maintain the plant in a safe shutdown condition.

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: Mr. M. Stanford Blanton, Balch & Bingham LLP, 1710 Sixth Avenue North, Birmingham, AL 35203–2015.

NRC Acting Branch Chief: Jennifer Dixon-Herrity.

Southern Nuclear Operating Company, Docket Nos. 52–025 and 52–026, Vogtle Electric Generating Plant (VEGP), Units 3 and 4, Burke County, Georgia

Date of amendment request: April 26, 2016. A publicly-available version is in ADAMS under Accession No. ML16117A531.

Description of amendment request: The amendments would change the certified AP1000 Design Control Document (DCD) Tier 1 information and depart from the plant-specific Tier 2 and Tier 2* information in the Updated Final Safety Analysis Report (UFSAR) for VEGP, Units 3 and 4, by modifying the overall design of the Central Chilled Water subsystem to relocate the Air Cooled Chiller Pump 3 (VWS–MP–03)

and associated equipment from the Auxiliary Building to the Annex Building, for each unit respectively. The proposed changes include information in the Combined License, Appendix C. An exemption request relating to the proposed changes to the AP1000 DCD Tier 1 is included with the request.

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 Central Chilled Water System (VWS) performs the nonsafety-related function of supplying chilled water to the heating, ventilation, and air conditioning (HVAC) systems. The only safety-related function of the VWS is to provide isolation of the VWS lines penetrating the containment. The low capacity VWS subsystem is non-seismically designed. The change to relocate an air cooled chiller pump and associated equipment and add a chemical feed tank to this pump does not adversely affect the capability of either low capacity VWS subsystem loop to perform the system design function. This change does not have an adverse impact on the response to anticipated transient or postulated accident conditions because the low capacity VWS subsystem is a nonsafety-related and non-seismic system. No safety-related structure, system, component (SSC) or function is involved with or affected by this change. The changes to the low capacity VWS subsystem do not involve an interface with any SSC accident initiator or initiating sequence of events, and thus, the probabilities of the accidents evaluated in the plant-specific UFSAR [Updated Final Safety Analysis Report] are not affected. The proposed VWS change does not involve a change to the predicted radiological releases due to postulated accident conditions, thus, 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 proposed changes to the nonsafety-related low capacity VWS subsystem do not affect any safety-related equipment, nor do they add any new interfaces to safety-related SSCs. No system or design function or equipment qualification is affected by these changes. The changes do not introduce a new failure mode, malfunction or sequence of events that could affect safety related equipment.

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 VWS is a nonsafety-related system that performs the defense-in-depth function of providing a reliable source of chilled water to various HVAC subsystems and unit coolers and the safety-related function of providing isolation of the VWS lines penetrating the containment. The changes to the VWS do not affect the VWS containment penetrations or any other safety related equipment or fission product barriers. The requested changes will not affect any design code, function, design analysis, safety analysis input or result, or design/safety margin. No safety analysis or design basis acceptance limit/criterion is challenged or exceeded by the requested changes.

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: M. Stanford Blanton, Balch & Bingham LLP, 1710 Sixth Avenue North, Birmingham, AL 35203–2015.

NRC Acting Branch Chief: Jennifer Dixon-Herrity.

Southern Nuclear Operating Company, Docket Nos. 52–025 and 52–026, Vogtle Electric Generating Plant, Units 3 and 4, Burke County, Georgia

Date of amendment request: May 27, 2016. A publicly-available version is in ADAMS under Accession No. ML16148A631.

Description of amendment request: The amendment request proposes changes to the Combined License (COL), Appendix A, Technical Specifications (TSs), and Updated Final Safety Analysis Report (UFSAR) in the form of departures from the incorporated plant-specific Design Control Document Tier 2 information. Specifically, the proposed departures consist of changes to the UFSAR adding compensation for changes in reactor coolant density using the ''delta T'' power signal to the reactor coolant flow input signal for the low reactor coolant flow trip function of the Reactor Trip System (RTS). Additionally, TS Surveillance Requirement (SR) 3.3.1.3 is added to the surveillances required for the Reactor Coolant Flow·Low reactor trip in TS Table 3.3.1–1, Function 7.

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 adds compensation, for changes in reactor coolant density using the [delta T] power signal, to the reactor coolant flow input signal for the low reactor coolant flow reactor trip function of the RTS. The proposed change also adds TS SR 3.3.1.3 to the surveillances required for the Reactor Coolant Flow-Low reactor trip specified in TS Table 3.3.1–1. SR 3.3.1.3 compares the calorimetric heat balance to the calculated [delta T] power in each Protection and Safety Monitoring System (PMS) division every 24 hours to assure acceptable [delta T] power calibration. As such, the surveillance is also required to support operability of the Reactor Coolant Flow-Low trip function. This change to the low reactor coolant flow trip input signal assures that the reactor will trip on low reactor coolant flow when the requisite conditions are met, and minimize spurious reactor trips and the accompanying plant transients. The change to the COL Appendix A Table 3.3.1–1 aligns the surveillance of the Reactor Coolant Flow-Low trip with the addition of the compensation, for changes in reactor coolant density using [delta T] power to the flow input signal to the trip. These changes do not affect the operation of any systems or equipment that initiate an analyzed accident or alter any structures, systems, and components (SSC) accident initiator or initiating sequence of events.

These changes have no adverse impact on the support, design, or operation of mechanical and fluid systems. The response of systems to postulated accident conditions is not adversely affected and remains within response time assumed in the accident analysis. There is no change to the predicted radioactive releases due to normal operation or postulated accident conditions. Consequently, the plant response to previously evaluated accidents or external events is not adversely affected, nor does the proposed change create any new accident precursors.

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 proposed changes do not affect the operation of any systems or equipment that may initiate a new or different kind of accident, or alter any SSC such that a new accident initiator or initiating sequence of events is created. The proposed change adds compensation, for changes in reactor coolant density using [delta T] power signal, to the reactor coolant flow input signal to the low reactor coolant flow reactor trip function of the RTS. The proposed change also adds TS

SR 3.3.1.3 to the surveillances required for the Reactor Coolant Flow-Low reactor trip specified in TS Table 3.3.1–1. SR 3.3.1.3 compares the calorimetric heat balance to the calculated [delta T] power in each PMS division every 24 hours to assure acceptable [delta T] power calibration. As such, the surveillance is also required to support operability of the Reactor Coolant Flow-Low trip function. The proposed change to the low reactor coolant flow reactor trip input signal does not alter the design function of the low flow reactor trip. The change to the COL Appendix A Table 3.3.1–1 aligns the surveillance of the Reactor Coolant Flow-Low trip with the addition of compensation, for changes in reactor coolant density using [delta T] power to the flow input signal to the trip. Consequently, because the low reactor coolant flow trip functions are unchanged, there are no adverse effects that could create the possibility of a new or different kind of accident from any previously evaluated in the UFSAR.

Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

4. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change adds compensation, for changes in reactor coolant density using [delta T] power signal, to the reactor coolant flow input signal for the low reactor coolant flow trip function of the RTS. The proposed change also adds TS SR 3.3.1.3 to the surveillances required for the Reactor Coolant Flow-Low reactor trip specified in TS Table 3.3.1–1. SR 3.3.1.3 compares the calorimetric heat balance to the calculated [delta T] power in each PMS division every 24 hours to assure acceptable [delta T] power calibration. As such, the surveillance is also required to support operability of the Reactor Coolant Flow-Low trip function. The proposed changes do not alter any applicable design codes, code compliance, design function, or safety analysis. Consequently, no safety analysis or design basis acceptance limit/criterion is challenged or exceeded by the proposed change, thus the margin of safety is not reduced.

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: M. Stanford Blanton, Balch & Bingham LLP, 1710 Sixth Avenue North, Birmingham, AL 35203–2015.

NRC Acting Branch Chief: Jennifer Dixon-Herrity.

Southern Nuclear Operating Company, Docket Nos. 52–025 and 52–026, Vogtle Electric Generating Plant, Units 3 and 4, Burke County, Georgia

Date of amendment request: June 14, 2016, as supplemented by letter dated July 1, 2016. Publicly-available versions are in ADAMS under Accession Nos. ML16166A409 and ML16183A394, respectively.

Description of amendment request: The amendment request proposes changes to the Updated Final Safety Analysis Report (UFSAR) in the form of departures from the incorporated plant-specific Design Control Document Tier 2* and associated Tier 2 information. Specifically, the proposed departures consist of changes to the UFSAR to revise the details of the structural design of auxiliary building floors within module CA20 at approximate design elevations of 82′-6″ and 92′-6″.

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 design functions of the auxiliary building floors are to provide support, protection, and separation for the seismic Category I mechanical and electrical equipment located in the auxiliary building. The auxiliary building is a seismic Category I structure and is designed for dead, live, thermal, pressure, safe shutdown earthquake loads, and loads due to postulated pipe breaks. The proposed changes to UFSAR descriptions are intended to address changes in the detail design of floors in the auxiliary building. The thickness and strength of the auxiliary building floors are not reduced. As a result, the design function of the auxiliary building structure is not adversely affected by the proposed changes. There is no change to plant systems or the response of systems to postulated accident conditions. There is no change to the predicted radioactive releases due to postulated accident conditions. The plant response to previously evaluated accidents or external events is not adversely affected, nor do the changes described create any new accident precursors. 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 changes to UFSAR descriptions are proposed to address changes in the detail design of floors in the auxiliary building. The thickness, geometry, and strength of the structures are not adversely altered. The concrete and reinforcement materials are not altered. The properties of the concrete are not altered. The changes to the design details of the auxiliary building structure do not create any new accident precursors. As a result, the design function of the auxiliary building structure is not adversely affected by the proposed changes.

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 criteria and requirements of American Concrete Institute (ACI) 349 and American Institute of Steel Construction (AISC) N690 provide a margin of safety to structural failure. The design of the auxiliary building structure conforms to criteria and requirements in ACI 349 and AISC N690 and therefore maintains the margin of safety. Analysis of the connection design confirms that code provisions are appropriate to the floor to wall connection. The proposed changes to the UFSAR address changes in the detail design of floors in the auxiliary building. The proposed changes also incorporate the requirements for development and anchoring of headed reinforcement which were previously approved. There is no change to design requirements of the auxiliary building structure. There is no change to the method of evaluation from that used in the design basis calculations. There is not a significant change to the in structure response spectra.

Therefore, the proposed amendment does not result in 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: M. Stanford Blanton, Balch & Bingham LLP, 1710 Sixth Avenue North, Birmingham, AL 35203–2015.

NRC Acting Branch Chief: Jennifer Dixon-Herrity.

Southern Nuclear Operating Company, Docket Nos. 52–025 and 52–026, Vogtle Electric Generating Plant, Units 3 and 4, Burke County, Georgia

Date of amendment request: June 3, 2016. A publicly-available version is in ADAMS under Accession No. ML16155A366.

Description of amendment request: The amendment request proposes changes to correct editorial errors in Combined License (COL) Appendix C (and plant-specific Tier 1) and promote consistency with the Updated Final Safety Analysis Report (UFSAR) Tier 2

information. Additionally, one of the proposed changes to plant-specific Tier 1 information also requires an involved change to UFSAR Tier 2 information. Pursuant to the provisions of 10 CFR 52.63(b)(1), an exemption from elements of the design as certified in the 10 CFR part 52, Appendix D, design certification rule is also requested for the plant-specific Tier 1 material departures. The requested amendment also contains a proposed editorial correction to COL paragraph 2.D.

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 consistency and editorial Combined License (COL) Appendix C (and plant-specific Tier 1) and involved Tier 2 changes, along with one COL paragraph 2.D change, do not involve a technical change, (*e.g.* there is no design parameter or requirement, calculation, analysis, function or qualification change). No structure, system, component design or function would be affected. No design or safety analysis would be affected. The proposed changes do not affect any accident initiating event or component failure, thus the probabilities of the accidents previously evaluated are not affected. No function used to mitigate a radioactive material release and no radioactive material release source term is involved, thus the radiological releases in the accident analyses 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 proposed consistency and editorial COL Appendix C (and plant-specific Tier 1) and involved Tier 2 changes, along with one COL paragraph 2.D change, would not affect the design or function of any structure, system, component (SSC), but will instead provide consistency between the SSC designs and functions currently presented in the Updated Final Safety Analysis Report (UFSAR) and the Tier 1 information. The proposed changes would not introduce a new failure mode, fault or sequence of events that could result in a radioactive material release.

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 proposed consistency and editorial COL Appendix C (and plant-specific Tier 1) and involved Tier 2 update, along with one COL paragraph 2.D change, is non-technical, thus would not affect any design parameter, function or analysis. There would be no change to an existing design basis, design function, regulatory criterion, or analysis. No safety analysis or design basis acceptance limit/criterion is involved.

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: M. Stanford Blanton, Balch & Bingham LLP, 1710 Sixth Avenue North, Birmingham, AL 35203–2015.

NRC Acting Branch Chief: Jennifer Dixon-Herrity.

Tennessee Valley Authority Docket Nos. 50–259, 50–260, and 50–296, Browns Ferry Nuclear Plant (BFN), Unit 1, 2 and 3, Limestone County Alabama

Tennessee Valley Authority (TVA), Docket Nos. 50–327 and 50–328, Sequoyah Nuclear Plant (SQN), Units 1 and 2, Hamilton County, Tennessee

Date of amendment request: April 14, 2016. A publicly-available version is in ADAMS under Accession No. ML16105A287.

Description of amendment request: The amendments would revise the BFN Units 1, 2, and 3, and the SQN, Units 1 and 2, Technical Specification (TS) 5.3, ''Unit Staff Qualifications,'' to delete the references to Regulatory Guide 1.8, Revision 2, and replace it with references to the TVA Nuclear Quality Assurance Plan (NQAP). The proposed changes would ensure consistent regulatory requirements regarding staff qualifications for the TVA nuclear fleet. The proposed changes would further allow TVA to implement standard procedures related to staff qualifications. Additionally, the proposed TS changes are consistent with the intent of NRC Administrative Letter 95–06 in that the relocated requirements are adequately controlled by 10 CFR 50, Appendix B, and the quality assurance change control process in 10 CFR 50.54(a).

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 consequence of an accident previously evaluated?

Response: No.

The Unit Staff Qualifications that are being removed from BFN TS 5.3.1 and SQN TS 5.3.1 are redundant to requirements contained in Appendix B to the TVA NQAP and are consistent with the Watts Bar (WBN) Unit 1 and Unit 2 Technical Specifications (TS). Changes to the TVA NQAP are controlled by 10 CFR 50.54(a). These changes do not affect any of the design basis accidents.

Therefore, the proposed changes do not involve an 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 Unit Staff Qualifications that are being removed from BFN TS 5.3.1 and SQN TS 5.3.1 are redundant to requirements contained in Appendix B to the TVA NQAP and are consistent with the WBN Unit 1 and Unit 2 TS. Changes to the TVA NQAP are controlled by 10 CFR 50.54(a). These changes do not affect any of the design basis accidents. No modifications to any plant equipment are involved. There is no effect on system interactions made by these changes.

Therefore, the proposed changes do 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 Unit Staff Qualifications that are being removed from BFN TS 5.3.1 and SQN TS 5.3.1 are redundant to requirements contained in Appendix B to the TVA NQAP and are consistent with the WBN Unit 1 and Unit 2 TS. Changes to the TVA NQAP are controlled by 10 CFR 50.54(a). The margin of safety as reported in the basis for the TS is not reduced.

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: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, 6A West Tower, Knoxville, TN 37902.

NRC Acting Branch Chief: Tracy J. Orf.

Tennessee Valley Authority, Docket Nos. 50–327 and 50–328, Sequoyah Nuclear Plant (SQN), Units 1 and 2, Hamilton County, Tennessee

Date of amendment request: May 26, 2016. A publicly-available version is in ADAMS under Accession No. ML16148A175.

Description of amendment request: The amendments would modify the SQN, Units 1 and 2, Technical Specification (TS) 3.8.1, ''AC [Alternating Current] Sources—Operating,'' by revising the acceptance criteria for the diesel generator (DG) steady-state frequency acceptance criteria specified in the TS Surveillance Requirements (SRs). The frequency would be changed to address the non-conservative TS recently identified.

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 consequence of an accident previously evaluated?

Response: No.

The DGs are required to be operable in the event of a design basis accident coincident with a loss of offsite power to mitigate the consequences of the accident. The DGs are not accident initiators and, therefore, these changes do not involve a significant increase in the probability of an accident previously evaluated.

The accident analyses assume that at least the boards in one load group are provided with power either from the offsite circuits or the DGs. The change proposed in this license amendment request will continue to assure that the DGs have the capacity and capability to assume their maximum design basis accident loads. The proposed change does not significantly alter how the plant would mitigate an accident previously evaluated.

The proposed change does not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, and configuration of the facility or the manner in which the plant is operated and maintained. The proposed change does not adversely affect the ability of structures, systems, and components (SSC) to perform their intended safety function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed change does not affect the source term, containment isolation, or radiological release assumptions used in evaluating the radiological consequences of any accident previously evaluated. Further, the proposed change does not increase the types and amounts of radioactive effluent that may be released offsite, nor significantly increase individual or cumulative occupational/public radiation exposure.

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 involve a change in the plant design, system operation, or the use of the DGs. The proposed change requires the DGs to meet SR acceptance criteria that envelope the actual demand requirements for the DGs during design basis conditions. These revised acceptance criteria continue to demonstrate the capability and capacity of the DGs to perform their required functions. There are no new failure modes or mechanisms created due to testing the DGs within the proposed acceptance criteria. Testing of the DGs at the proposed acceptance criteria does not involve any modification in the operational limits or physical design of plant systems. There are no new accident precursors generated due to the proposed test loadings.

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 amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change will continue to demonstrate that the DGs meet the TS definition of operability, that is, the proposed acceptance criteria will continue to demonstrate that the DGs will perform their safety function. The proposed testing will also continue to demonstrate the capability and capacity of the DGs to supply their required loads for mitigating a design basis accident.

The proposed change does not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. The safety analysis acceptance criteria are not affected by this change. The proposed change will not result in plant operation in a configuration outside the design basis.

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: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, 6A West Tower, Knoxville, TN 37902.

NRC Acting Branch Chief: Tracy J. Orf.

Tennessee Valley Authority, Docket Nos. 50–390 and 50–391, Watts Bar Nuclear Plant (WBN), Units 1 and 2, Rhea County, Tennessee

Date of amendment request: June 7, 2016. A publicly-available version is in ADAMS under Accession No. ML16159A208.

Description of amendment request: The amendments would revise the WBN, Unit 2, Technical Specification (TS) 3.7.10, ''Control Room Emergency Ventilation System (CREVS),'' to include specific shutdown Required Actions and associated Completion Times during conditions to be taken due to a tornado warning. The proposed TS changes would be consistent with the current TS 3.7.10 for WBN, Unit 1. Additionally, the amendments would revise several administrative-related inconsistencies identified in the WBN, Units 1 and 2, TSs.

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 modify WBN Unit 1 TS 3.7.10 to resolve a potential conflict in applying the appropriate actions for not meeting the Required Action and associated Completion Time of Condition E and request administrative changes to correct inconsistencies in TS Applicability statements.

The proposed changes do not affect the structures, systems, or components (SSCs) of the plant, affect plant operations, or any design function or an analysis that verifies the capability of an SSC to perform a design function. No change is being made to any of the previously evaluated accidents in the WBN Unit 1 Updated Final Safety Analysis Report (UFSAR) and the WBN Unit 2 FSAR [Final Safety Analysis Report]. These proposed changes are administrative or provide specific shutdown actions instead of using default shutdown actions.

The proposed changes do not (1) require physical changes to plant systems, structures, or components; (2) prevent the safety function of any safety-related system, structure, or component during a design basis event; (3) alter, degrade, or prevent action described or assumed in any accident described in the WBN Unit 1 UFSAR and the WBN Unit 2 FSAR from being perform[ed] because the safety-related systems, structures, or components are not modified; (4) alter any assumptions previously made in evaluating radiological consequences; or (5) affect the integrity of any fission product barrier.

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 changes do not introduce any new accident causal mechanisms, since no physical changes are being made to the plant, nor do they impact any plant systems that are potential accident initiators.

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 amendment involve a significant reduction in a margin of safety?

Response: No.

The margin of safety associated with the acceptance criteria of any accident is unchanged. The proposed changes will have no effect on the availability, operability, or performance of safety-related systems and components. The proposed change will not adversely affect the operation of plant equipment or the function of equipment assumed in the accident analysis.

The proposed amendment does not involve changes to any safety analyses assumptions, safety limits, or limiting safety system settings. The changes do not adversely affect plant-operating margins or the reliability of equipment credited in the safety analyses.

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: Sherry Quirk, Executive Vice President and General Counsel, Tennessee Valley Authority, 400 West Summit Hill Dr., 6A West Tower, Knoxville, TN 37902.

NRC Acting Branch Chief: Tracy J. Orf.

III. Previously Published Notices of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The following notices were previously published as separate individual notices. The notice content was the same as above. They were published as individual notices either because time did not allow the Commission to wait for this biweekly notice or because the action involved exigent circumstances. They are repeated here because the biweekly notice lists all amendments issued or proposed to be issued involving no significant hazards consideration.

For details, see the individual notice in the **Federal Register** on the day and page cited. This notice does not extend the notice period of the original notice.

Duke Energy Progress, Inc., Docket No. 50–400, Shearon Harris Nuclear Power Plant, Unit 1, Wake and Chatham Counties, North Carolina

Date of amendment request: August 18, 2015, as supplemented by letters dated September 29, 2015; February 5, 2016; April 28, 2016; and May 19, 2016. Publicly-available versions are in ADAMS under Accession Nos. ML15236A265 (Package), ML15272A443, ML16036A091, ML16119A326, and ML16141A048, respectively.

Brief description of amendment request: The amendment would revise the Technical Specifications (TSs) by relocating specific surveillance frequencies to a licensee-controlled program with the implementation of Nuclear Energy Institute document NEI 04–10, ''Risk-Informed Technical Specifications Initiative 5b, Risk-Informed Method for Control of Surveillance Frequencies'' (ADAMS Accession No. ML071360456). Additionally, a new program, the Surveillance Frequency Control Program, would be added to TS Section 6, ''Administrative Controls.''

Date of publication of individual notice in ***Federal Register:*** July 15, 2016 (81 FR 46119).

Expiration date of individual notice: August 15, 2016 (public comments); September 13, 2016 (hearing requests).

Tennessee Valley Authority, Docket Nos. 50–327 and 50–328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee

Date of amendment request: May 16, 2016. A publicly-available version is in ADAMS under Accession No. ML16138A247.

Brief description of amendment request: The amendments would revise the Cyber Security Plan implementation schedule for Milestone 8 and revise the associated license condition in the Facility Operating Licenses.

Date of publication of individual notice in the ***Federal Register:*** July 8, 2016 (81 FR 44665).

Expiration date of individual notice: August 8, 2016 (public comments); September 6, 2016 (hearing requests).

IV. 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 Commission's 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.

Exelon Generation Company, LLC and PSEG Nuclear LLC, Docket Nos. 50–277 and 50–278, Peach Bottom Atomic Power Station, Units 2 and 3, York and Lancaster Counties, Pennsylvania

Date of amendment request: October 2, 2015, as supplemented by letter dated March 23, 2016.

Brief description of amendments: The amendments (1) revised the allowable test pressure band in the technical specification (TS) surveillance requirements (SRs) for the pump flow testing of the high pressure coolant injection system and the reactor core isolation system; (2) revised the surveillance frequency requirements for verifying the sodium pentaborate enrichment of the standby liquid control system; and (3) deleted SRs associated with verifying the manual transfer capability of the normal and alternate power supplies for certain motor-operated valves associated with the suppression pool spray and drywell spray sub-systems of the residual heat removal system.

Date of issuance: July 5, 2016.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendments Nos.: 308 (Unit 2) and 312 (Unit 3). A publicly-available version is in ADAMS under Accession No. ML16159A148; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–44 and DPR–56: The amendments revised the Renewed Facility Operating Licenses and TSs.

Date of initial notice in ***Federal Register:*** December 8, 2015 (80 FR 76320). The supplemental letter dated March 23, 2016, 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 July 5, 2016.

No significant hazards consideration comments received: No.

NextEra Energy Duane Arnold, LLC, Docket No. 50–331, Duane Arnold Energy Center, Linn County, Iowa

Date of amendment request: July 24, 2015.

Brief description of amendment: The amendment revised Technical Specification 1.4, ''Frequency,'' by correcting Example 1.4–1 to be consistent with Technical Specifications Task Force (TSTF) Traveler TSTF–485, ''Correct Example 1.4–1,'' Revision 0. In addition, the amendment revised Example 1.4–5 and Example 1.4–6 to be consistent with Amendment No. 258 to the Renewed Facility Operating License.

Date of issuance: July 13, 2016.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment No.: 293. A publicly-available version is in ADAMS under Accession No. ML15246A408; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–49: The amendment revised the Technical Specifications.

Date of initial notice in ***Federal Register:*** November 10, 2015 (80 FR 69713).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 13, 2016.

No significant hazards consideration comments received: No.

South Carolina Electric and Gas Company and the South Carolina Public Service Authority, 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.

Brief description of amendment: The amendments consisted of changes to the Facility Combined License, Appendix C, ''Inspections, Tests, Analyses, and Acceptance Criteria [ITAAC].'' Specifically, the changes to the plant-specific Emergency Planning ITAAC removed and replaced current references to AP1000 Design Control Document Table 7.5–1, and Final Safety Analysis Report (FSAR) Table 7.5–201 on the post-accident monitoring system, with references to proposed updated FSAR 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.

Date of issuance: May 2, 2016.

Effective date: As of the date of issuance and shall be implemented within 30 days of issuance.

Amendment Nos.: 46. A publicly-available version is in ADAMS under Package Accession No. ML16074A234. Documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Combined License Nos. NPF–93 and NPF–94: Amendments revised the Facility Combined Licenses.

Date of initial notice in ***Federal Register:*** November 24, 2015 (80 FR 73241).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 2, 2016.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Inc., Docket Nos. 50–424 and 50–425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia

Date of amendment request: July 18, 2014, as supplemented by letters dated February 27, 2015; May 2, 2016; and June 14, 2016.

Brief description of amendments: The amendments changed Technical Specification 3.9.4, ''Containment Penetrations,'' to allow containment penetrations to be un-isolated under administrative controls during core alterations or movement of irradiated fuel assemblies within containment by adopting a previously NRC-approved Technical Specification Task Force (TSTF) Change Traveler TSTF–312, Revision 1, ''Administratively Control Containment Penetrations.''

Date of issuance: July 15, 2016.

Effective date: As of the date of issuance and shall be implemented within 120 days of issuance.

Amendment Nos.: 181 (Unit 1) and 162 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML16165A195; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. NPF–68 and NPF–81: Amendments revised the Renewed Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register:*** March 3, 2015 (80 FR 11480). The supplemental letters dated February 27, 2015; May 2, 2016; and June 14, 2016, 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 July 15, 2016.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 22nd day of July 2016.

For the Nuclear Regulatory Commission.

Anne T. Boland,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–18290 Filed 8–1–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0143]

Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving Proposed No Significant Hazards Considerations and Containing Sensitive Unclassified Non-Safeguards Information and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; notice of opportunity to comment, request a hearing, and petition for leave to intervene; order imposing procedures.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) received and is considering approval of four

amendment requests. The amendment requests are for the Shearon Harris Nuclear Power Plant, Unit 1; H. B. Robinson Steam Electric Plant, Unit No. 2; Palisades Nuclear Plant; and Hope Creek Generating Station. For each amendment request, the NRC proposes to determine that they involve no significant hazards consideration. Because each amendment request contains sensitive unclassified non-safeguards information (SUNSI), an order imposes procedures to obtain access to SUNSI for contention preparation.

DATES: Comments must be filed by September 1, 2016. A request for a hearing must be filed by October 3, 2016. Any potential party as defined in § 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR), who believes access to SUNSI is necessary to respond to this notice must request document access by August 12, 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–2016–0143. 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: Lynn 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 the Docket ID NRC–2016–0143, facility name, unit number(s), plant docket number (*e.g.,* 50–XXX), application date, and subject 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–2016–0143.
- *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 below.
- *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 the Docket ID NRC–2016–0143, facility name, unit number(s), plant docket number (*e.g.,* 50–XXX), 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 will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, 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 into ADAMS.

II. Background

Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the NRC is publishing this 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 notice includes notices of amendments containing SUNSI.

III. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, 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 if 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. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish a notice of issuance in the **Federal Register**. If the Commission makes 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 to support its position on the issue. 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 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 October 3, 2016. 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. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

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, as amended at 77 FR 46562, August 3, 2012). 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 Electronic Filing 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 Electronic Filing 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 Electronic Filing 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 stating why there is good cause for not filing electronically and 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 hearing request and petition 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.

For further details with respect to this amendment action, see the application for amendment which is available for public inspection at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Publicly available documents created or received at the NRC are accessible electronically through ADAMS in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR's Reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*

Duke Energy Progress, Inc., Docket No. 50–400, Shearon Harris Nuclear Power Plant, Unit 1 (Harris), Wake and Chatham Counties, North Carolina

Duke Energy Progress, Inc., Docket No. 50–261, H. B. Robinson Steam Electric Plant, Unit No. 2 (Robinson), Darlington County, South Carolina

Date of amendment request: August 19, 2015, as supplemented by letter dated May 4, 2016. Publicly-available versions are in ADAMS under Accession Nos. ML15236A044 and ML16125A420, respectively.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguards information (SUNSI). The proposed amendment, as supplemented, requests plant-specific review and approval of the following reactor core design methodology reports: (1) DPC–NE–1008–P, Revision 0, ''Nuclear Design Methodology Using CASMO–5/SIMULATE–3 for Westinghouse Reactors;'' (2) DPC–NF–2010, Revision 3, ''Nuclear Physics Methodology for Reload Design;'' and (3) DPC–NE–2011–P, Revision 2, ''Nuclear Design Methodology Report for Core Operating Limits of Westinghouse Reactors.'' The proposed amendment would also revise the Harris Technical Specification (TS) Section 6.1.9.6, ''Core Operating Limits Report,'' and the Robinson TS Section 5.6.5, ''Core Operating Limits Report (COLR),'' to include the reports. The supplement, dated May 4, 2016, added the latter two design methodology reports.

The license amendment request, dated August 19, 2015, was previously noticed in the **Federal Register** (81 FR 5492; February 2, 2016). This notice supersedes the August 19, 2015, notice in its entirety to include the expanded scope of both the amendment request and the no significant hazards consideration determination.

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 requests review and approval of DPC–NE–1008–P, Revision 0, ''Nuclear Design Methodology Using CASMO–5/SIMULATE–3 for Westinghouse Reactors,'' to be applied to Shearon Harris Nuclear Power Plant (SHNPP) and H. B. Robinson Steam Electric Plant (HBRSEP). The CASMO–5 and SIMULATE–3 codes are not used in the operation of any plant equipment. The benchmark calculations performed confirm the accuracy of the codes and develop a methodology for calculating power distribution uncertainties for use in reload design calculations. The use of power distribution uncertainties in conjunction with predicted peaking factors ensures that thermal accident acceptance criteria are satisfied. The proposed use of this methodology does not affect the performance of any equipment used to mitigate the consequences of an analyzed accident. There is no impact on the source term or pathways assumed in accidents previously assumed. No analysis assumptions are violated and there are no adverse effects on the factors that contribute to offsite or onsite dose as the result of an accident.

The proposed change also requests review and approval of DPC NF–2010, Revision 3, ''Nuclear Physics Methodology for Reload Design,'' and DPC–NE–2011–P, Revision 2, ''Nuclear Design Methodology Report for Core Operating Limits of Westinghouse Reactors'' to be applied to Shearon Harris Nuclear Power Plant (SHNPP) and H. B. Robinson Steam Electric Plant (HBRSEP). The proposed change supports the use of revised McGuire and Catawba reload design methodologies for performance of reload design analyses at Harris and Robinson Nuclear Plants. Implementation of the methodologies will occur following approval by the NRC. The proposed amendments will have no impact upon the probability of occurrence of any design basis accident, nor will they affect the performance of any plant equipment used to mitigate the consequences of an analyzed accident. There will be no significant impact on the source term or pathways assumed in accidents previously evaluated. No analysis assumptions will be violated and there will be no adverse effects on the factors that contribute to offsite or onsite dose as the result of an accident.

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 proposed change requests review and approval of DPC–NE–1008–P, Revision 0, ''Nuclear Design Methodology Using CASMO–5/SIMULATE–3 for Westinghouse Reactors,'' to be applied to Shearon Harris Nuclear Power Plant (SHNPP) and H. B. Robinson Steam Electric Plant (HBRSEP). It does not change any system functions or maintenance activities. The change does not involve physical alteration of the plant, that is, no new or different type of equipment will be installed. The software is not installed in any plant equipment, and therefore the software is incapable of initiating an equipment malfunction that would result in a new or different type of accident from any previously evaluated. The change does not alter assumptions made in the safety analyses but ensures that the core will operate within safe limits. This change does not create new failure modes or mechanisms which are not identifiable during testing, and no new accident precursors are generated.

The proposed change also requests review and approval of DPC NF–2010, Revision 3, ''Nuclear Physics Methodology for Reload Design,'' and DPC–NE–2011–P, Revision 2, ''Nuclear Design Methodology Report for Core Operating Limits of Westinghouse Reactors'' to be applied to Shearon Harris Nuclear Power Plant (SHNPP) and H. B. Robinson Steam Electric Plant (HBRSEP). The proposed amendments do not change the methods used for normal plant operation, nor are the methods used to respond to plant transients modified. Use of the DPC–NF–2010 and DPC–NE–2011–P methodologies does not result in a new or different type of accident from any previously evaluated. There are no changes to any system functions or maintenance activities. The change does not physically alter the plant, that is, no new or different type of equipment will be installed. This change does not create new failure modes or mechanisms which are not identifiable during testing, and no new accident precursors are generated.

Therefore, the proposed changes do 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.

Margin of safety is related to the confidence in the ability of the fission product barriers to perform their design functions during and following an accident. These barriers include the fuel cladding, the reactor coolant system, and the containment system. The proposed change requests review and approval of DPC–NE–1008–P, Revision 0, ''Nuclear Design Methodology Using CASMO–5/SIMULATE–3 for Westinghouse Reactors,'' to be applied to Shearon Harris Nuclear Power Plant (SHNPP) and H. B. Robinson Steam Electric Plant (HBRSEP). As with the existing methodology, the qualification of the methods therein and the use of power distribution uncertainties ensure the acceptability of analytical limits under normal, transient, and accident conditions. The use of the proposed methodology revision once it has been approved by the NRC will ensure that all applicable design and safety limits are satisfied such that the fission product barriers will continue to perform their design functions.

The proposed change also requests review and approval of DPC NF–2010, Revision 3, ''Nuclear Physics Methodology for Reload Design,'' and DPC–NE–2011–P, Revision 2, ''Nuclear Design Methodology Report for Core Operating Limits of Westinghouse Reactors'' to be applied to Shearon Harris Nuclear Power Plant (SHNPP) and H. B. Robinson Steam Electric Plant (HBRSEP). Application of the DPC NF–2010 and DPC–NE–2011–P methodologies will assure the acceptability of thermal limits assumed in the cycle reload safety analyses. As with the existing methodology, the Duke Energy methodology will continue to ensure (a) the acceptability of analytical limits under normal, transient, and accident conditions, and (b) that all applicable design and safety

limits are satisfied such that the fission product barriers will continue to perform their design functions.

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: Lara S. Nichols, Deputy General Counsel, Duke Energy Corporation, 550 South Tyron Street, Mail Code DEC45A, Charlotte, North Carolina 28202.

NRC Acting Branch Chief: Tracy J. Orf.

Entergy Nuclear Operations, Inc., Docket No. 50–255, Palisades Nuclear Plant (PNP), Van Buren County, Michigan

Date of amendment request: March 3, 2016, as supplemented by letter dated June 7, 2016. Publicly-available versions are in ADAMS under Accession Nos. ML16075A103 and ML16159A230, respectively.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguards information (SUNSI). The proposed amendment would revise the PNP Technical Specification (TS) Section 5.5.8, ''Steam Generator (SG) Program,'' and Section 5.6.8, ''Steam Generator Tube Inspection Report.'' Specifically, the licensee requested to implement an alternate repair criteria (ARC) that invokes a C—Star inspection length (C*), on a permanent basis for the cold-leg side of the SGs' tubesheet and to clarify the intent and improve interpretation of the PNP TSs regarding the previously incorporated ARC for the hot-leg side of the SGs' tubesheet which was approved by Amendment No. 225 (ADAMS Accession No. ML071420216).

The license amendment request was noticed in the **Federal Register** on June 7, 2016 (81 FR 36604). The notice is being reissued in its entirety to include a revised description of the amendment request and associated changes to the no significant hazards consideration determination.

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.

Previously evaluated accidents are initiated by the failure of plant structures, systems, or components. The proposed change alters the SG cold-leg repair criteria by limiting tube inspection length in the cold-leg tubesheet, to the safety significant section, C* length, and, as such, does not have a detrimental impact on the integrity of any plant structure, system, or component that initiates an analyzed event. Therefore, the proposed change has no significant effect upon previously evaluated accident probabilities or consequences.

The proposed amendment to revise the PNP SG tube repair criteria in TS 5.5.8c, does not involve a significant increase in the probability of an accident previously evaluated. Alternate repair criteria are being proposed for the cold-leg side of the SGs that is consistent with the current alternate repair criteria for the hot-leg side of the SGs, in TS 5.5.8c.1. The proposed SG tube inspection length maintains the existing design limits of the SGs and therefore does not increase the probability or consequences of an accident involving a tube rupture or primary to secondary accident-induced leakage, as previously evaluated in the PNP Updated Final Safety Analysis Report (UFSAR). Also, the Nuclear Energy Institute (NEI) *Steam Generator Program Guidelines* (NEI 97–06) [(ADAMS Accession No. ML111310708)] performance criteria for structural integrity and accident-induced leakage, which are incorporated in PNP TS 5.5.8, would continue to be satisfied.

Implementing an alternate repair criteria would allow SG tubes with flaws below the C* length to remain in service. The potential consequences to leaving these flawed tubes inservice are tube burst, tube pullout, and accident induced tube leakage. Tube burst is prevented for a tube with defects within the tubesheet region because of the constraint provided by the tubesheet. Tube pullout could result from the axial forces induced by primary to secondary differential pressures that occur during the bounding event of the main steam line break. A joint industry test program report, WCAP–16208–P, *NDE Inspection Length for CE Steam Generator Tubesheet Region Explosive Expansions,* Revision 1, May 2005 [(Non-proprietary version at ADAMS Accession No. ML051520417)], has defined the non-degraded tube to tubesheet joint length (C*) required to preclude tube pullout and maintain acceptable primary to secondary accident-induced leakage, conservatively assuming a 360 degree circumferential through wall crack exists immediately below this C* length.

The PNP UFSAR Sections 14.14, *Steam Line Rupture Incident,* 14.15, *Steam Generator Tube Rupture with a Loss of Offsite Power,* and 14.16, *Control Rod Ejection,* primary coolant system leakage limit is 0.3 gallon per minute (gpm) (432 gallons per day) in the unaffected SG. For the tube rupture accident, this 0.3 gpm leakage is in addition to the break flow rate associated with the rupture of a single SG tube. The WCAP–16208–P report used a primary to secondary accident-induced leakage criteria value of 0.1 gpm to derive the C* length. Use of 0.1 gpm ensures that the PNP TS limiting accident-induced leakage of 0.3 gpm is met.

For PNP, the derived C* length for the cold-leg side of the SGs is 13.67 inches. Any degradation below the C* length is shown by test results and analysis to meet the NEI 97–06 performance criteria, thereby precluding an increased probability of a tube rupture event, or an increase in the consequences of a steam line rupture incident or control rod ejection accident.

Therefore, the C* lengths for the SG cold-legs provide assurance that the NEI 97–06 requirements for tube burst and leakage are met and that the conservatively derived maximum combined leakage from both tubesheet joints (hot and cold-legs) is less than 0.2 gpm at accident conditions. This combined leakage criterion of 0.2 gpm in the faulted loop retains margin against the PNP TS allowable accident-induced leakage of 0.3 gpm per SG.

In summary, the proposed changes to the PNP TS maintain existing design limits, meet the performance criteria of NEI 97–06 and Regulatory Guide 1.121, and the proposed [amendment] does not involve a significant increase in the probability or consequences of an accident previously evaluated in the UFSAR.

Therefore, operation of the facility in accordance with the proposed amendment would 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 amendment provides for an alternate repair criteria that excludes the lower portion of the steam generator cold-leg tubes from inspection below a C* length by implementing an alternate repair criteria. It does not affect the design of the SGs or their method of operation. It does not impact any other plant system or component. Plant operation will not be altered, and all safety functions will continue to perform as previously assumed in the accident analysis.

The proposed amendment does not introduce any new equipment, change existing equipment, create any new failure modes for existing equipment, nor introduce any new malfunctions resulting from tube degradation. SG tube integrity is shown to be maintained for all plant conditions upon implementation of the proposed alternate repair criteria for the SG cold-leg tubesheet region.

The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated because SG tube leakage limits and structural integrity would continue to be maintained during all plant conditions upon implementation of the proposed alternate repair criteria to the PNP TSs. The alternate repair criteria does not introduce any new mechanisms that might result in a different kind of accident from those previously evaluated. Even with the limiting

circumstances of a complete circumferential separation (360 degree through wall crack) of a tube below the C* length, tube pullout is precluded and leakage is predicted to be maintained with the TS and accident analysis limits during all plant conditions.

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 proposed change provides an alternate repair criteria for the SG cold-leg that invokes a C* inspection length criteria. The proposed amendment does not involve a significant reduction in a margin of safety since design SG primary to secondary leakage limits have been analyzed to continue to be met. This will ensure that the SG cold-legs tubes continue to function as a primary coolant system boundary by maintaining their integrity. Tube integrity includes both structural and leakage integrity. The proposed cold-leg tubesheet inspection C* depth, of 13.67 inches below the bottom of the cold-leg expansion transition or top of the cold-leg tubesheet, whichever is lower, would ensure tube integrity is maintained during normal and accident conditions because any degradation below C* is shown by test results and analyses to be acceptable.

Operation with potential tube degradation below the proposed C* cold-leg inspection length within the tubesheet region of the SG tubing meets the recommendation of NEI 97–06 SG program guidelines. Additionally, the proposed changes also maintain the structural and accident-induced leakage integrity as required by NEI 97–06.

The total leakage from an undetected flaw population below the C* inspection length for the cold-leg tubesheet under postulated accident conditions is accounted for, in order to assure it is within the bounds of the accident analysis.

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: Jeanne Cho, Senior Counsel, Entergy Services, Inc., 440 Hamilton Ave., White Plains, New York 10601.

NRC Branch Chief: David J. Wrona.

PSEG Nuclear LLC, Docket No. 50–354, Hope Creek Generating Station (HCGS), Salem County, New Jersey

Date of amendment request: June 8, 2016. A publicly-available version is in ADAMS under Accession Nos. ML16181A193 and ML16181A194.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguards information (SUNSI). The amendment would revise the Technical Specifications (TSs) to incorporate a revised Safety Limit Minimum Critical Power Ratio (SLMCPR) for single recirculation loop (SLO) due to the cycle-specific analysis for the HCGS Cycle 21.

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 required SLMCPRs for HCGS Cycle 21 are calculated using NRC-approved methodology. The SLMCPR values, contained in TS Section 2.1, Safety Limits, ensure at least 99.9% of all fuel rods in the core do not experience transition boiling during normal operation and analyzed transients, preserving fuel cladding integrity. The proposed change to the SLMCPR value for SLO ensures this criterion continues to be met, and therefore does not increase the probability or consequences of an accident previously evaluated. In addition, no plant hardware or operational changes are required with this proposed change.

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 required SLMCPRs for HCGS Cycle 21 are calculated using NRC-approved methodology. The SLMCPR values, contained in TS Section 2.1, ensure at least 99.9% of all fuel rods in the core do not experience transition boiling during normal operation and analyzed transients. The proposed change to the SLMCPR value for SLO does not involve any plant hardware or operational changes and does not create any new precursors to an accident.

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 required SLMCPRs for HCGS Cycle 21 are calculated using NRC-approved methodology. The SLMCPR values, contained in TS Section 2.1, ensure at least 99.9% of all fuel rods in the core do not experience transition boiling during normal operation and analyzed transients, preserving fuel cladding integrity. The revised SLMCPR value for SLO ensures this criterion continues to be met. In addition, the proposed change to the SLMCPR for SLO does not adversely affect the design basis function or performance of a structure, system, or component as described in the HCGS UFSAR [Updated Final Safety Analysis Report].

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: Jeffrie J. Keenan, PSEG Nuclear LLC—N21, P.O. Box 236, Hancocks Bridge, New Jersey 08038.

NRC Branch Chief: Douglas A. Broaddus.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

Duke Energy Progress, Inc., Docket No. 50–400, Shearon Harris Nuclear Power Plant, Unit 1, Wake and Chatham Counties, North Carolina

Duke Energy Progress, Inc., Docket No. 50–261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Entergy Nuclear Operations, Inc., Docket No. 50–255, Palisades Nuclear Plant, Van Buren County, Michigan

PSEG Nuclear LLC, Docket No. 50–354, Hope Creek Generating Station, Salem County, New Jersey

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing SUNSI.

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request such access. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requester shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Associate

General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *OGCmailcenter@nrc.gov,* respectively.[1] The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requester's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly-available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order[2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after the requestor is provided access to that information. However, if more than 25 days remain between the date the petitioner is provided access to the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline. This provision does not extend the time for filing a request for a hearing and petition to intervene, which must comply with the requirements of 10 CFR 2.309.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and need for access, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requester may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an administrative law judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) an officer if that officer has been designated to rule on information access issues.

H. Review of Grants of Access. A party other than the requester may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed with the Chief Administrative Judge within 5 days of the notification by the NRC staff of its grant of access.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3]

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have proposed contentions meeting the specificity and basis requirements in 10 CFR part 2. Attachment 1 to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Dated at Rockville, Maryland, this 18th day of July, 2016.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING

Day	Event/activity
0	Publication of **Federal Register** notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: Supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).

[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

[2] Any Motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge, if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[3] Requesters should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562, August 3, 2012) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING—Continued

Day	Event/activity
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requester of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no ''need'' or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds ''need'' for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78422; File No. SR–NYSEARCA–2016–102]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change for a New NYSE Arca Rule 13.9 and a New NYSE Arca Equities Rule 11.9 and To Make Conforming Changes to NYSE Arca Rule 3.2 and NYSE Arca Equities Rule 3.2

July 27, 2016.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 14, 2016, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes a new NYSE Arca Rule 13.9 and a new NYSE Arca Equities Rule 11.9 governing the failure to meet eligibility or qualification standards or prerequisites for access to services based on rules of the Exchange's affiliates New York Stock Exchange, LLC and NYSE MKT LLC, and (2) to make conforming changes to NYSE Arca Rule 3.2 and NYSE Arca Equities Rule 3.2. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes a new NYSE Arca Rule 13.9 (''Rule 13.9'') and a new NYSE Arca Equities Rule 11.9 (''Rule 11.9'') governing the failure to meet the eligibility or qualification standards or prerequisites for access to services based on Rules 9555 (Failure to Meet the Eligibility or Qualification Standards or Prerequisites for Access to Services) and 9559 (Hearing Procedures for Expedited Proceedings Under the Rule 9550 Series) of the Exchange's affiliates New York Stock Exchange, LLC (''NYSE'') and NYSE MKT LLC (''NYSE MKT'').

The Exchange also proposes conforming changes to NYSE Arca Rule 3.2 (Options Committees) and NYSE Arca Equities Rule 3.2 (Equity Committees), which set forth the authority and jurisdiction of the NYSE Arca Ethics and Business Conduct Committee (''EBCC'') and the NYSE Arca Equities Business Conduct Committee (''BCC''), respectively.

Background

In 2013, the NYSE adopted disciplinary rules that are, with certain exceptions, substantially the same as the

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

Financial Industry Regulatory Authority, Inc. (''FINRA'') Rule 8000 Series and Rule 9000 Series, and which set forth rules for conducting investigations and enforcement actions.[4] The NYSE disciplinary rules were implemented on July 1, 2013.[5] In 2016, NYSE MKT also adopted the Rule 8000 Series and Rule 9000 Series, which rules are, with certain exceptions, substantially the same as those of NYSE and FINRA.[6] The NYSE MKT disciplinary rules were implemented on April 15, 2016.[7]

NYSE and NYSE MKT Rule 9555 (''Rule 9555''), which NYSE Arca and NYSE Arca Equities propose to adopt in substantially the same form as approved by the Commission for NYSE and as published for immediate effectiveness by NYSE MKT, govern the failure to meet the eligibility or qualification standards, or prerequisites for access to services offered by the Exchange.

Under Rule 9555, if a member organization or covered person[8] does not meet the eligibility or qualification standards set forth in the NYSE and NYSE MKT's rules,[9] staff may provide written notice to such covered person or member organization stating that the failure to become eligible or qualified will result in a suspension or cancellation of membership or a suspension or bar from associating with any member organization.

In addition, under Rule 9555, if a member organization or covered person does not meet the prerequisites for access to services offered by the NYSE and NYSE MKT or a member organization thereof or cannot be permitted to continue to have access to services offered by NYSE and NYSE MKT or a member organization thereof with safety to investors, creditors, members, or the Exchange, staff may provide written notice to such member organization or covered person limiting or prohibiting access to services offered by the NYSE and NYSE MKT or a member organization thereof.

The limitation, prohibition, suspension, cancellation, or bar referenced in the notice becomes effective 14 days after service of the notice unless the member organization or covered person requests a hearing during that time, except that the effective date for a notice of a limitation or prohibition on access to services shall be upon service of the notice. The text of NYSE and NYSE MKT Rule 9555 is substantially the same as FINRA's counterpart rule, except for certain conforming and technical changes.[10]

NYSE and NYSE MKT Rule 9559 (''Rule 9559'') set forth hearing procedures for expedited proceedings under the NYSE and NYSE MKT Rule 9550 Series, including for proceedings under Rule 9555, and is substantially similar to FINRA's counterpart rule. Currently, NYSE Arca and NYSE Arca Equities do not have a comparable procedural rule. As described below, the Exchange proposes to include procedural aspects of Rule 9559 that are applicable to expedited proceedings under Rule 9555 within the proposed rules for NYSE Arca and NYSE Arca Equities.

Proposed Rule Change

NYSE Arca and NYSE Arca Equities propose to adopt a new Rule 13.9 and 11.9, respectively, that would be substantially the same as Rule 9555 and that would incorporate certain procedural requirements for expedited hearings under Rule 9555 drawn from Rule 9559. NYSE Arca and NYSE Arca Equities are not proposing to adopt Rule 9559 in its entirety. Rule 9559 contains a number of provisions that do not relate to hearing procedures under Rule 9555.

NYSE Arca Rule 13.9

Proposed Rule 13.9 would govern when an OTP Firm, OTP Holder or Associated Person of an OTP Firm or OTP Holder does not meet the eligibility or qualification standards set forth in the Exchange's rules;[11] does not meet the prerequisites for access to services offered by the Exchange or an OTP Firm or OTP Holder thereof; or cannot be permitted to continue to have access to services offered by the Exchange or an OTP Firm or OTP Holder thereof with safety to investors, creditors, OTP Firms, OTP Holders, or the Exchange. Like Rule 9555, the proposed Rule would be divided into separate subsections describing the notice; service of the notice; the contents of the notice; the effective date of the limitation, prohibition, suspension, cancellation or bar; requests for a hearing; failure to request a hearing; and a request for termination of the limitation, prohibition or suspension. Proposed Rule 13.9 would have a section describing certain procedures, based on Rule 9559, to be followed when a party requests a hearing.

Proposed Rule 13.9(a) (Notice to OTP Firms, OTP Holders or Associated Persons of an OTP Firm or OTP Holder of Suspension, Cancellation, Bar, or Limitation or Prohibition on Access to Services) would provide that if an OTP Firm, OTP Holder or Associated Person of an OTP Firm or OTP Holder does not meet the eligibility or qualification standards set forth in the Exchange's Rules, Exchange staff may provide written notice to such OTP Firm, OTP Holder or Associated Person of an OTP Firm or OTP Holder stating that the failure to become eligible or qualified will result in a suspension or cancellation of trading privileges or a suspension or bar from associating with an OTP Firm or OTP Holder.[12]

Further, the proposed rule would provide that if an OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder does not meet the prerequisites for access to services offered by the Exchange or an OTP Firm or OTP Holder thereof or cannot be

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[4] *See* Securities Exchange Act Release Nos. 68678 (January 16, 2013), 78 FR 5213 (January 24, 2013) (SR–NYSE–2013–02) (''2013 Notice''), 69045 (March 5, 2013), 78 FR 15394 (March 11, 2013) (SR–NYSE–2013–02) (''2013 NYSE Approval Order''), and 69963 (July 10, 2013), 78 FR 42573 (July 16, 2013) (SR–NYSE–2013–49).

[5] *See* NYSE Information Memorandum 13–8 (May 24, 2013).

[6] *See* Securities Exchange Act Release Nos. 77241 (February 26, 2016), 81 FR 11311 (March 3, 2016) (SR–NYSEMKT–2016–30) (''2016 MKT Notice'').

[7] *See* NYSE MKT Information Memorandum 16–02 (March 14, 2016).

[8] Under NYSE and NYSE MKT Rules, a member organization means a registered broker or dealer (unless exempt pursuant to the Act) that is a member of FINRA or another registered securities exchange. *See* NYSE Rule 2(b)(i) & NYSE MKT Rule 2(b)(i)—Equities. A covered person under the NYSE and NYSE MKT disciplinary rules means a member, principal executive, approved person, registered or non-registered employee of a member organization (and, in the case of NYSE MKT, an ATP Holder), or other person (excluding a member organization) subject to the jurisdiction of the NYSE and NYSE MKT, respectively. *See* NYSE Rule 9120(g); NYSE MKT Rule 9120(g).

In order to refer to the same individuals encompassed by the definitions of member organization and covered person under the NYSE and NYSE MKT Rules, NYSE Arca proposes to use the phrase ''OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder'' in proposed Rule 13.9. NYSE Arca Rule 1.1(d) defines an ''Associated Person'' as a person who is a partner, officer, director, member of a limited liability company, trustee of a business trust, employee of an OTP Firm or any person directly or indirectly controlling, controlled by or under common control with an OTP Firm. Similarly, NYSE Arca Equities would use the phrase ''ETP Holder or Associated Person of an ETP Holder'' in proposed Rule 11.9. Under NYSE Arca Equities Rule 1.1(f), ''Associated Person'' refers to a person who is a partner, officer, director, member of a limited liability company, trustee of a business trust, employee of an ETP Holder or any person directly or indirectly controlling, controlled by or under common control with an ETP Holder.

[9] *See, e.g.,* NYSE Rules 300–324 (Admission of Members); NYSE MKT Rules 300—Equities–324—Equities (Admission of Members); NYSE MKT Office Rules, Section 4 (Employees and Admission of Members and Member Organizations).

[10] *See* 2013 NYSE Approval Order, 78 FR at 15394; 2016 MKT Notice, 81 FR at 11333.

[11] *See, e.g.,* NYSE Arca Rule 2 (Options Trading Permits); NYSE Arca Equities Rule 2 (Equity Trading Permits).

[12] *See* Proposed Rule 13.9(a)(1).

permitted to continue to have access to services offered by the Exchange or an OTP Firm or OTP Holder thereof with safety to investors, creditors, member organizations, or the Exchange, Exchange staff may provide written notice to such OTP Firm, OTP Holder or Associated Person of an OTP Firm or OTP Holder limiting or prohibiting access to services offered by the Exchange or an OTP Firm or OTP Holder thereof.[13] Proposed Rule 13.9(a) is substantially the same as NYSE and NYSE MKT Rule 9555(a), except that it substitutes references to ''member organization or covered person'' with ''OTP Firm, OTP Holder or Associated Person of an OTP Firm or OTP Holder.''

Proposed Rule 13.9(b) (Service of Notice) would provide that Exchange staff shall serve the OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder with the notice described in subsection (a) and that a copy of the notice served on an Associated Person of an OTP Firm or OTP Holder also shall be served on such OTP Firm or OTP Holder. Further, the proposed Rule would provide that when counsel for the OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder agrees to accept service of such notice, Exchange staff shall [14] serve notice on counsel. Proposed Rule 13.9(b) is substantially the same as NYSE and NYSE MKT Rule 9555(b), except that it substitutes references to ''member organization or covered person'' with ''OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder.''

Proposed Rule 13.9(c) (Contents of Notice) would provide that a notice issued under Rule 13.9 shall state the specific grounds and include the factual basis for Exchange action. Further, the Rule would require that the notice state when the Exchange action will take effect and explain what the respondent must do to avoid such action as well as that the respondent may file a written request for a hearing.

The proposed Rule would also provide that the notice also shall inform the respondent of the applicable deadline for filing a request for a hearing and shall state that a request for a hearing must set forth with specificity any and all defenses to the Exchange action. In addition, the proposed Rule would require the notice to explain that the EBCC may approve, modify or withdraw any and all sanctions or limitations imposed by the notice, and may impose any other fitting sanction. Proposed Rule 13.9(c) is substantially the same as NYSE and NYSE MKT Rule 9555(c), except that it (1) substitutes references to ''member organization or covered person'' with ''OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder,'' and (2) eliminates the reference to the Office of Hearing Officers and replaces ''Hearing Officer, or, if applicable, Hearing Panel'' with ''EBCC.''

Proposed Rule 13.9(d) (Effective Date of Limitation, Prohibition, Suspension, Cancellation or Bar) would provide that the limitation, prohibition, suspension, cancellation or bar referenced in a notice issued under the proposed Rule shall become effective 14 days after service of the notice, except that the effective date for a notice of a limitation or prohibition on access to services offered by the Exchange or an OTP Firm or OTP Holder thereof with respect to services to which the OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder does not have access shall be upon service of the notice. Proposed Rule 13.9(d) would also provide that a request for a hearing shall stay the effectiveness of the notice, except that the effectiveness of a notice of a limitation or prohibition on access to services offered by the Exchange or an OTP Firm or OTP Holder thereof with respect to services to which the OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder does not have access shall not be stayed by a request for a hearing. Proposed Rule 13.9(d) is substantially the same as NYSE and NYSE MKT Rule 9555(d), except that it substitutes references to ''member organization or covered person'' with ''OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder.''

Proposed Rule 13.9(e) (Request for Hearing) would provide that an OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder served with a notice under the proposed Rule may file with EBCC a written request for a hearing. The proposed Rule would require that a request for a hearing shall be made within 14 days after service of the notice and must set forth with specificity any and all defenses to the Exchange action. Proposed Rule 13.9(e) is substantially the same as NYSE and NYSE MKT Rule 9555(e), except that it substitutes references to ''member organization or covered person'' with ''OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder.''

Proposed Rule 13.9(f) (Failure to Request Hearing) would provide that if an OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder does not timely request a hearing, the limitation, prohibition, suspension, cancellation or bar specified in the notice shall become effective 14 days after service of the notice, except that the effective date for a notice of a limitation or prohibition on access to services offered by the Exchange or an OTP Firm or OTP Holder with respect to services to which the OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder does not have access shall be upon service of the notice. The proposed Rule would further provide that notice shall constitute final Exchange action if the OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder does not request a hearing within 14 days after service of the notice. Proposed Rule 13.9(f) is substantially the same as NYSE and NYSE MKT Rule 9555(f), except that it substitutes references to ''member organization or covered person'' with ''OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder.''

Proposed Rule 13.9(g) (Request for Termination of the Limitation, Prohibition or Suspension) would provide that an OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder subject to a limitation, prohibition or suspension under the proposed Rule may file a written request for termination of the limitation, prohibition or suspension on the ground of full compliance with the notice or decision. Further, the proposed Rule would specify that such a request shall be filed with the head of the Exchange department or office that issued the notice or, if another department or office is named as the party handling the matter on behalf of the issuing department or office, with the head of the department or office that is so designated. Finally, the proposed Rule would provide that the appropriate head of the department or office may grant relief for good cause shown. Proposed Rule 13.9(g) is substantially the same as NYSE and NYSE MKT Rule 9555(g),

[13] *See* Proposed Rule 13.9(a)(2).

[14] Rule 9555 provides that Exchange staff ''may'' serve notice on counsel or other person authorized to represent others under NYSE or NYSE MKT Rule 9141 (Appearance and Practice; Notice of Appearance) as specified in NYSE or NYSE MKT Rule 9134 (Methods of, Procedures for Service). As adopted by NYSE and NYSE MKT, Rule 9134(b)(1) and (2) provides that when a natural person or entity, respectively, is represented by counsel or a representative, papers served on such person or entity, excluding a complaint or document initiating a proceeding, ''shall'' be served on such counsel or representative. The Exchange has not adopted Rule 9134 and does not have a similar requirement. Accordingly, the Exchange proposes to utilize ''shall'' in the proposed Rule rather than ''may,'' to reflect the requirement in the NYSE and NYSE MKT rules that papers served on a person or entity represented by counsel or representative be served on the counsel or representative.

except that it substitutes references to ''member organization or covered person'' with ''OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder.''

Finally, proposed Rule 13.9(h) would set forth the specific procedures that would apply to hearings under the proposed Rule. As noted, proposed subsection (h) is modeled on NYSE and NYSE MKT Rule 9559, which provides uniform hearing procedures for expedited proceedings under the NYSE and NYSE MKT Rule 9550 Series, including proceedings under Rule 9555. NYSE Arca does not currently have a procedural rule comparable to Rule 9559 and therefore proposes to adopt aspects of Rule 9559 that are applicable to hearings under Rule 9555.

Proposed Rule 13.9(h)(1) would provide that a hearing shall be held within 30 days after a Respondent subject to a notice files a written request under proposed Rule 13.9(e). This requirement is the same as Rule 9559(f)(3) (Time of Hearing).

Proposed Rule 13.9(h)(2) would provide that the EBCC shall issue a notice stating the date, time, and place of the hearing at least 21 days prior to the hearing. This requirement is the same as that contained in Rule 9559(g)(3) (Notice of Hearing). Further, proposed subsection (h)(2) would provide that not less than 14 days before the hearing, Exchange staff shall provide to the respondent who requested the hearing, all documents that were considered in issuing the notice. This requirement is the same as that contained in Rule 9559(h)(1) (Transmission of Documents) for Rule 9555 proceedings.

Proposed Rule 13.9(h)(3) would provide that, not less than seven days before the hearing, the parties shall exchange proposed exhibit and witness lists. The proposed Rule would require exhibit and witness lists to be served by overnight courier. These requirements are the same as those contained in Rule 9559(h)(2) (Transmission of Documents).

Proposed Rule 13.9(h)(4) would provide that the EBCC may approve, modify or withdraw any and all sanctions, requirements, restrictions or limitations imposed by the notice and may impose any fitting sanction. These requirements are the same as those contained in Rule 9559(n)(1) (Sanctions, Costs and Remands).

Proposed Rule 13.9(h)(5) would provide that the EBCC shall prepare a written decision within 60 days of the date of the close of the hearing and provide it to the Board of Directors. This is the same as the requirement in Rule 9559(o)(3) (Timing of Decision). Proposed subsection (h)(5) would further specify that the decision include the following elements:

- A statement describing the investigative or other origin of the notice issued under this Rule;[15]
- the specific statutory or rule provision alleged to have been violated or providing the authority for the Exchange action;[16]
- a statement setting forth the findings of fact with respect to any act or practice the respondent was alleged to have committed or omitted or any condition specified in the notice; [17]
- the conclusions of the EBCC regarding the alleged violation or condition specified in the notice; [18]
- a statement of the EBCC in support of the disposition of the principal issues raised in the proceeding; [19] and
- a statement describing any sanction, requirement, restriction or limitation imposed, the reasons therefore, and the date upon which such sanction, requirement, restriction or limitation shall become effective.[20]

These requirements are the same as those contained in Rule 9559(p)(1)–(6) (Contents of Decision).

Proposed Rule 13.9(h)(6) would provide that the Board of Directors may, on its own initiative, order review of a decision prepared by the EBCC pursuant to Rule 13.9 within 30 days after notice of the decision has been served on the OTP Firm, OTP Holder or an Associated Person of an OTP Firm or OTP Holder. The proposed Rule utilizes the same language and time period as current NYSE Arca Rule 10.8(d), which provides that the Board of Directors may, on its own initiative, order a review of a decision on appeal made under Rule 10.8(b) within 30 days after notice of the decision is served on a respondent. By incorporating those Board review requirements, proposed Rule 13.9(h)(6) parallels Rule 9559(q)'s provision for a call for review by the NYSE and NYSE MKT Board of Directors.

Finally, proposed Rule 13.9(h)(7) would provide that the right to have any action pursuant to this Rule reviewed by the SEC is governed by Section 19 of the Exchange Act. The filing of an application for review by the SEC shall not stay the effectiveness of final Exchange action, unless the SEC otherwise orders. This is the same as Rule 9559(r) (Application for SEC Review).

The Exchange is not adopting the remaining subsections of Rule 9559 in whole or in part because they are either inapplicable to Rule 9555 proceedings,[21] are already addressed in the NYSE Arca and NYSE Arca Equities Rules,[22] or find no analogue in the NYSE Arca and NYSE Arca Equities Rules relating to disciplinary proceedings.[23]

NYSE Arca Equities Rule 11.9

The Exchange proposes to make parallel changes to the NYSE Arca Equities Rules. Proposed Rule 11.9 would govern when an ETP Holder or Associated Person of an ETP Holder does not meet eligibility or qualification standards; does not meet prerequisites for access to services; or cannot be permitted to continue to have access to services with safety to investors, creditors, ETP Holders, or the Exchange. Like Rule 9555 and proposed NYSE Arca Rule 13.9, the proposed Rule would be divided into separate subsections describing the notice; service of the notice; the contents of the notice; the effective date of the limitation, prohibition, suspension, cancellation or bar; requests for a hearing; failure to request a hearing; and a request for termination of the limitation, prohibition or suspension. Like proposed NYSE Arca Rule 13.9, proposed Rule 11.9 would have a section describing procedures, based on Rule 9559, that apply if a party requests a hearing.

Proposed Rule 11.9(a) (Notice to ETP Holder or Associated Person of ETP Holder of Suspension, Cancellation, Bar, or Limitation or Prohibition on Access to Services) would provide that if an ETP Holder or an Associated Person of an ETP Holder does not meet the eligibility or qualification standards set forth in the Exchange's Rules, Exchange staff may provide written notice to such ETP Holder or Associated Person of an ETP Holder stating that the failure to become eligible or qualified will result in a suspension or cancellation of

[15] *See* Proposed Rule 13.9(h)(5)(A).

[16] *See* Proposed Rule 13.9(h)(5)(B).

[17] *See* Proposed Rule 13.9(h)(5)(C).

[18] *See* Proposed Rule 13.9(h)(5)(D).

[19] *See* Proposed Rule 13.9(h)(5)(E).

[20] *See* Proposed Rule 13.9(h)(5)(F).

[21] *See* Rule 9559 (f)(1) & (3) (Time of Hearing); (g)(1) & (2) (Notice of Hearing); (o)(1) & (2) (Timing of Decision).

[22] *See* Rule 9559(a) (Applicability); (b) (Computation of Time); (c) (Stays); (d) (Appointment and Authority of Hearing Officer and/or Hearing Panel); (i) (Evidence); (j) (Additional Information); (k) (Record of Hearing); (l) (Record of Proceeding); (m) (Failure to Appear at a Pre-Hearing Conference or Hearing or to Comply with a Hearing Officer Order Requiring the Production of Information); (n) (Sanctions, Costs and Remands).

[23] *See* Rule 9559(e) (Consolidation or Severance of Proceedings).

trading privileges or a suspension or bar from associating with any ETP Holder.[24]

Further, the proposed rule would provide that if an ETP Holder or Associated Person of an ETP Holder does not meet the prerequisites for access to services offered by the Exchange or an ETP Holder thereof or cannot be permitted to continue to have access to services offered by the Exchange or an ETP Holder thereof with safety to investors, creditors, member organizations, or the Exchange, Exchange staff may provide written notice to such ETP Holder or an Associated Person of an ETP Holder limiting or prohibiting access to services offered by the Exchange or an ETP Holder thereof.[25] Proposed Rule 11.9(a) is substantially the same as NYSE and NYSE MKT Rule 9555(a), except that it substitutes references to ''member organization or covered person'' with ''ETP Holder or Associated Person of an ETP Holder.''

Proposed Rule 11.9(b) (Service of Notice) would provide that Exchange staff shall serve the ETP Holder or an Associated Person of an ETP Holder with the notice described in subsection (a) and that a copy of the notice served on an Associated Person of an ETP Holder also shall be served on such ETP Holder. Further, the proposed Rule would provide that Exchange staff shall [26] serve notice on counsel when counsel for the ETP Holder or an Associated Person of an ETP Holder agrees to accept service of such notice. Proposed Rule 11.9(b) is substantially the same as NYSE and NYSE MKT Rule 9555(b), except that it substitutes references to ''member organization or covered person'' with ''ETP Holder or an Associated Person of an ETP Holder.''

Proposed Rule 11.9(c) (Contents of Notice) would provide that a notice issued under Rule 11.9 shall state the specific grounds and include the factual basis for Exchange action. Further, the Rule would require that the notice state when the Exchange action will take effect and explain what the respondent must do to avoid such action as well as that the respondent may file a written request for a hearing.

The proposed Rule would also provide that the notice also shall inform the respondent of the applicable deadline for filing a request for a hearing and shall state that a request for a hearing must set forth with specificity any and all defenses to the Exchange action. In addition, the proposed Rule would require the notice to explain that the BCC may approve, modify or withdraw any and all sanctions or limitations imposed by the notice, and may impose any other fitting sanction. Proposed Rule 11.9(c) is substantially the same as NYSE and NYSE MKT Rule 9555(c), except that it (1) substitutes references to ''member organization or covered person'' with ''ETP Holder or an Associated Person of an ETP Holder,'' and (2) eliminates the reference to the Office of Hearing Officers and replaces ''Hearing Officer, or, if applicable, Hearing Panel'' with ''BCC.''

Proposed Rule 11.9(d) (Effective Date of Limitation, Prohibition, Suspension, Cancellation or Bar) would provide that the limitation, prohibition, suspension, cancellation or bar referenced in a notice issued under the proposed Rule shall become effective 14 days after service of the notice, except that the effective date for a notice of a limitation or prohibition on access to services offered by the Exchange or an ETP Holder thereof with respect to services to which the ETP Holder or an Associated Person of an ETP Holder does not have access shall be upon service of the notice. Proposed Rule 11.9(d) would also provide that a request for a hearing shall stay the effectiveness of the notice, except that the effectiveness of a notice of a limitation or prohibition on access to services offered by the Exchange or an ETP Holder thereof with respect to services to which the ETP Holder or an Associated Person of an ETP Holder does not have access shall not be stayed by a request for a hearing. Proposed Rule 11.9(d) is substantially the same as NYSE and NYSE MKT Rule 9555(d), except that it substitutes references to ''member organization or covered person'' with ''ETP Holder or an Associated Person of an ETP Holder.''

Proposed Rule 11.9(e) (Request for Hearing) would provide that an ETP Holder or an Associated Person of an ETP Holder served with a notice under the proposed Rule may file with the BCC a written request for a hearing. The proposed Rule would require that a request for a hearing shall be made within 14 days after service of the notice and must set forth with specificity any and all defenses to the Exchange action. Proposed Rule 11.9(e) is substantially the same as NYSE and NYSE MKT Rule 9555(e), except that it substitutes references to ''member organization or covered person'' with ''ETP Holder or an Associated Person of an ETP Holder.''

Proposed Rule 11.9(f) (Failure to Request Hearing) would provide that if an ETP Holder or an Associated Person of an ETP Holder does not timely request a hearing, the limitation, prohibition, suspension, cancellation or bar specified in the notice shall become effective 14 days after service of the notice, except that the effective date for a notice of a limitation or prohibition on access to services offered by the Exchange or an ETP Holder with respect to services to which the ETP Holder or an Associated Person of an ETP Holder does not have access shall be upon service of the notice. The proposed Rule would further provide that notice shall constitute final Exchange action if the ETP Holder or an Associated Person of an ETP Holder does not request a hearing within 14 days after service of the notice. Proposed Rule 11.9(f) is substantially the same as NYSE and NYSE MKT Rule 9555(f), except that it substitutes references to ''member organization or covered person'' with ''ETP Holder or an Associated Person of an ETP Holder.''

Proposed Rule 11.9(g) (Request for Termination of the Limitation, Prohibition or Suspension) would provide that an ETP Holder or an Associated Person of an ETP Holder subject to a limitation, prohibition or suspension under the proposed Rule may file a written request for termination of the limitation, prohibition or suspension on the ground of full compliance with the notice or decision. Further, the proposed Rule would specify that such a request shall be filed with the head of the Exchange department or office that issued the notice or, if another department or office is named as the party handling the matter on behalf of the issuing department or office, with the head of the department or office that is so designated. Finally, the proposed Rule would provide that the appropriate head of the department or office may grant relief for good cause shown. Proposed Rule 11.9(g) is substantially the same as NYSE and NYSE MKT Rule 9555(g), except that it substitutes references to ''member organization or covered person'' with ''ETP Holder or an Associated Person of an ETP Holder.''

Finally, proposed Rule 11.9(h) would set forth specific procedures that would apply to hearings under the proposed Rule. As noted, proposed subsection (h) is modeled on NYSE and NYSE MKT Rule 9559, which provides uniform hearing procedures for expedited proceedings under the NYSE and NYSE MKT Rule 9550 Series, including proceedings under Rule 9555. NYSE Arca Equities does not currently have a procedural rule comparable to Rule 9559 and therefore proposes to adopt

[24] *See* Proposed Rule 11.9(a)(1).

[25] *See* Proposed Rule 11.9(a)(2).

[26] *See* note 14, *supra.*

aspects of Rule 9559 that are applicable to hearings under Rule 9555.

Proposed Rule 11.9(h)(1) would provide that a hearing shall be held within 30 days after a Respondent subject to a notice files a written request under proposed Rule 11.9(e). This requirement is the same as Rule 9559(f)(3) (Time of Hearing).

Proposed Rule 11.9(h)(2) would provide that the BCC shall issue a notice stating the date, time, and place of the hearing at least 21 days prior to the hearing. This requirement is the same as that contained in Rule 9559(g)(3) (Notice of Hearing). Further, proposed subsection (h)(2) would provide that not less than 14 days before the hearing, Exchange staff shall provide to the respondent who requested the hearing, all documents that were considered in issuing the notice. This requirement is the same as that contained in Rule 9559(h)(1) (Transmission of Documents) for Rule 9555 proceedings.

Proposed Rule 11.9(h)(3) would provide that not less than seven days before the hearing, the parties shall exchange proposed exhibit and witness lists. The proposed Rule would require exhibit and witness lists to be served by overnight courier. These requirements are the same as those contained in Rule 9559(h) (Transmission of Documents).

Proposed Rule 11.9(h)(4) would provide that the BCC may approve, modify or withdraw any and all sanctions, requirements, restrictions or limitations imposed by the notice and may impose any fitting sanction. These requirements are the same as those contained in Rule 9559(n)(1) (Sanctions, Costs and Remands).

Proposed Rule 11.9(h)(5) would provide that that the BCC prepare a written decision within 60 days of the date of the close of the hearing and provide it to the Board of Directors. This is the same as the requirement in Rule 9559(o)(3) (Timing of Decision). Proposed subsection (h)(5) would further specify that the decision include the following elements:

- A statement describing the investigative or other origin of the notice issued under this Rule; [27]
- the specific statutory or rule provision alleged to have been violated or providing the authority for the Exchange action; [28]
- a statement setting forth the findings of fact with respect to any act or practice the respondent was alleged to have committed or omitted or any condition specified in the notice; [29]
- the conclusions of the BCC regarding the alleged violation or condition specified in the notice; [30]
- a statement of the BCC in support of the disposition of the principal issues raised in the proceeding; [31] and
- a statement describing any sanction, requirement, restriction or limitation imposed, the reasons therefore, and the date upon which such sanction, requirement, restriction or limitation shall become effective.[32]

These requirements are the same as those contained in Rule 9559(p)(1)–(6) (Contents of Decision).

Proposed Rule 11.9(h)(6) would provide that the Board of Directors may, on its own initiative, order review of a decision prepared by the BCC pursuant to Rule 11.9 within 30 days after notice of the decision has been served on the ETP Holder or Associated Person of an ETP Holder. The proposed Rule utilizes the same language and time period as current NYSE Arca Equities Rule 10.8(d), which provides that the NYSE Arca Board of Directors [33] may, on its own initiative, order a review of a decision on appeal within 30 days after notice of the decision is served on a respondent. Proposed Rule 11.9(h)(6) parallels the requirement in Rule 9559(q) setting forth a call for review by the NYSE and NYSE MKT Board of Directors.

Finally, proposed Rule 11.9(h)(7) would provide that the right to have any action pursuant to this Rule reviewed by the SEC is governed by Section 19 of the Exchange Act. The filing of an application for review by the SEC shall not stay the effectiveness of final Exchange action, unless the SEC otherwise orders. This is the same as Rule 9559(r)(Application for SEC Review).

NYSE Arca Equities is not adopting the remaining subsections of Rule 9559 in whole or in part because they are either inapplicable to Rule 9555 proceedings,[34] are already addressed in the NYSE Arca and NYSE Arca Equities Rules,[35] or find no analogue in the NYSE Arca and NYSE Arca Equities Rules relating to disciplinary proceedings.[36]

Conforming Changes

NYSE Arca Rule 3.2(b)(1)(B) describes the functions and authority of the NYSE Arca EBCC. Under subsection (b)(1)(B)(ii), this includes the authority to conduct hearings and render decisions in summary disciplinary actions and proceedings pursuant to Rule 10.5 (Hearing). The Exchange proposes to amend NYSE Arca Rule 3.2(b)(1)(B)(ii) to add a clause specifying that the EBCC can also conduct hearings and render decisions in expedited proceedings pursuant to Rule 13.9.

NYSE Arca Equities Rule 3.2(b)(1)(B), like NYSE Arca Rule 3.2(b)(1)(B), describes the functions and authority of the NYSE Arca Equities BCC that, under subsection (b)(1)(B)(ii) includes the authority to conduct hearings and render decisions in summary disciplinary actions and proceedings. The Exchange proposes to amend NYSE Arca Equities Rule 3.2(b)(1)(B)(ii) to specify that the NYSE Arca Equities BCC can also conduct hearings and render decisions in expedited proceedings pursuant to Rule 11.9.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[37] in general, and furthers the objectives of Section 6(b)(5) of the Act,[38] in particular, because it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, to prevent fraudulent and manipulative acts and practices, and to protect investors and the public interest. In addition, the Exchange believes that the proposed rule change furthers the objectives of Section 6(b)(7) of the Act,[39] in particular, in that it provides fair procedures for the denial of membership to any person seeking membership therein, the barring of any person from becoming associated with a member thereof, and the prohibition or limitation by the Exchange of any person with respect to access to services

[27] *See* Proposed Rule 11.9(h)(5)(A).

[28] *See* Proposed Rule 11.9(h)(5)(B).

[29] *See* Proposed Rule 11.9(h)(5)(C).

[30] *See* Proposed Rule 11.9(h)(5)(D).

[31] *See* Proposed Rule 11.9(h)(5)(E).

[32] *See* Proposed Rule 11.9(h)(5)(F).

[33] NYSE Arca Equities Rule 10.8(d) refers to the ''NYSE Arca Board of Governors.'' The reference is outdated, and means the NYSE Arca Board of Directors. *See* Securities Exchange Act Release No. 77898 (May 24, 2016), 81 FR 34404, 34406 (May 31, 2016) (SR–NYSEArca–2016–11).

[34] *See* Rule 9559 (f)(1) & (3) (Time of Hearing); (g)(1) & (2) (Notice of Hearing); (o)(1) & (2) (Timing of Decision).

[35] *See* Rule 9559(a) (Applicability); (b) (Computation of Time); (c) (Stays); (d) (Appointment and Authority of Hearing Officer and/or Hearing Panel); (i) (Evidence); (j) (Additional Information); (k) (Record of Hearing); (l) (Record of Proceeding); (m) (Failure to Appear at a Pre-Hearing Conference or Hearing or to Comply with a Hearing Officer Order Requiring the Production of Information); (n) (Sanctions, Costs and Remands).

[36] *See* Rule 9559(e) (Consolidation or Severance of Proceedings).

[37] 15 U.S.C. 78f(b).

[38] 15 U.S.C. 78f(b)(5).

[39] 15 U.S.C. 78f(b)(7).

offered by the Exchange or a member thereof, including on a non-summary, but expedited, proceeding basis.[40]

The proposed changes will provide greater harmonization between NYSE Arca, NYSE Arca Equities, NYSE, and NYSE MKT rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance for common members. As previously noted, the proposed rule text is substantially the same as the rule text in effect for NYSE and NYSE MKT. The proposed rule change would enhance the ability of NYSE Arca and NYSE Arca Equities to have a direct and meaningful impact on its regulatory program for enforcing the eligibility or qualification standards as set forth in their respective rules by providing a mechanism and procedure for suspending or cancelling trading privileges or suspending or barring a person from associating with a trading privileges holder or firm, as appropriate. As such, the proposed rule change would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national market system.

The Exchange further believes that the proposed hearing procedures in subsection (h) of proposed Rules 11.9 and 13.9 are fair. The proposed procedural requirements are based on timeframes and requirements in Rule 9559, which governs expedited proceedings, including proceedings under Rule 9555, on the NYSE and NYSE MKT. The proposed Rules would provide the same time periods as Rule 9559 for when a hearing shall be held (30 days after a respondent subject to a notice files a written request for hearing); for when the date, time, and place of the hearing need to be announced (at least 21 days prior to the hearing); for producing to the respondent all documents considered in issuing the notice (not less than 14 days before the hearing); and for exchanging proposed exhibit and witness lists (not less than seven days before the hearing). In addition to these safeguards, the proposed Rules, like Rule 9559, would empower the body hearing the appeal to approve, modify or withdraw any and all sanctions, requirements, restrictions or limitations imposed by the notice and impose any fitting sanction, and would also require a written decision within a specific timeframe (60 days) from the close of the hearing. The Exchange believes that these incorporated procedural requirements would, similar to Rule 9559, provide adequate procedural protections to all parties and promote efficiency. The Exchange also believes that not adopting aspects of Rule 9559 that are not relevant to expedited proceedings under Rule 9555 also promotes a fair procedure for the denial of membership to any person seeking to become an Exchange permit holder, the barring of any person from becoming associated with an Exchange permit holder, and the prohibition or limitation by the Exchange of any person with respect to access to services offered by the Exchange or a permit holder thereof.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change is not intended to address competitive issues, but rather it is designed to (i) provide greater harmonization among NYSE Arca, NYSE Arca Equities, NYSE, and NYSE MKT rules of similar purpose; and (ii) enhance the quality of the regulatory program for enforcing eligibility or qualification standards on the Exchange, resulting in less burdensome and more efficient regulatory compliance and facilitating performance of regulatory functions.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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[41] and subparagraph (f)(6) of Rule 19b–4 thereunder.[42]

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–NYSEARCA–2016–102 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–NYSEARCA–2016–102. 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

[40] *See* 15 U.S.C. 78f(d)(1)–(3).

[41] 15 U.S.C. 78s(b)(3)(A)(iii).

[42] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

should refer to File Number SR–NYSEARCA–2016–102, and should be submitted on or before August 23, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[43]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–18201 Filed 8–1–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold a Closed Meeting on Thursday, August 4, 2016 at 2:00 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), 9(B) and (10) and 17 CFR 200.402(a)(3), (5), (7), 9(ii) and (10), permit consideration of the scheduled matter at the Closed Meeting.

Chair White, as duty officer, voted to consider the items listed for the Closed Meeting in closed session.

The subject matter of the Closed Meeting will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Adjudicatory matters; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact Brent J. Fields from the Office of the Secretary at (202) 551–5400.

Dated: July 28, 2016.

Lynn M. Powalski,

Deputy Secretary.

[FR Doc. 2016–18322 Filed 7–29–16; 11:15 am]

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[43] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78424; File No. SR–ISE Gemini-2015–17]

Self-Regulatory Organizations; ISE Gemini, LLC; Order Disapproving a Proposed Rule Change To Amend Rule 804(g)

July 27, 2016.

I. Introduction

On November 12, 2015, ISE Gemini, LLC (''ISE Gemini'' or ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to require Clearing Member [3] approval for a market maker [4] to resume trading after the activation of a market-wide speed bump under ISE Gemini Rule 804(g). The proposed rule change was published for comment in the **Federal Register** on November 30, 2015.[5]

On January 13, 2016, the Commission extended the time period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change to February 28, 2016.[6] On February 26, 2016, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act [7] to determine whether to approve or disapprove the proposed rule change.[8] Specifically, the Commission instituted proceedings to allow for additional analysis of, and input from commenters with respect to, the proposed rule change's consistency with Section 6(b)(5) of the Act.[9] On May 26, 2016, the Commission extended the time period for Commission action on the proceedings to determine whether to disapprove the proposed rule change.[10] The Commission did not receive any comments on the proposed rule change and the Exchange did not submit a response to the Commission's order instituting proceedings. This order disapproves the proposed rule change.

II. Description of the Proposal

The Exchange has an automated quotation adjustment functionality that is governed by its Rule 804(g). Pursuant to these Rules, the Exchange will automatically remove a market maker's quotations in all series of an options class when, during a specified time period, the market maker exceeds certain execution parameters.[11] All market makers are required by ISE Gemini to provide these specific parameters. Additionally, the Exchange will automatically remove a market maker's quotes in *all* classes when, during a specified time period, the total number of quote removal events (''curtailment events'') described in Rule 804(g)(1) exceed a specified market-wide parameter (''market-wide speed bump'').[12] As with the functionality to remove all option series of an options class, all market makers are required by ISE Gemini to specify a market-wide parameter. The market-wide speed bump is available for quotes only on ISE Gemini or across both ISE Gemini and ISE Gemini's affiliated exchange, International Securities Exchange, LLC.[13] The Exchange states that, after a market-wide speed bump is triggered and the trading system removes all of a market maker's quotes, the market maker may re-enter the market and resume trading upon notification to the Exchange's Market Operations.[14]

Under the proposal, the Exchange seeks to amend the process by which market makers can re-enter the market. Specifically, the proposal requires Clearing Member approval before a market maker can resume trading after triggering a market-wide speed bump.[15] Following a market-wide speed bump, the proposed rule requires: (1) A market maker to notify its Clearing Member(s) when it is ready to resume trading; and (2) each applicable Clearing Member to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A ''Clearing Member'' is a Member that is self-clearing or an Electronic Access Member that clears Exchange Transactions for other Members of the Exchange. *See* ISE Gemini Rule 100(a)(8). An ''Electronic Access Member'' is an Exchange Member that is approved to exercise trading privileges associated with EAM Rights. *See* Article XIII, Section 13.1(j) of the Constitution of ISE Gemini, LLC.

[4] ISE Gemini has two categories of market makers: Primary Market Makers (''PMMs'') and Competitive Market Makers (''CMMs''). A PMM is appointed to each options class traded on the Exchange, but a CMM may or may not be appointed to each such options class. *See* ISE Gemini Rule 802.

[5] *See* Securities Exchange Act Release No. 76505 (November 23, 2015), 80 FR 74824 (''Notice'').

[6] *See* Securities Exchange Act Release No. 76894, 81 FR 3213 (January 20, 2016).

[7] 15 U.S.C. 78s(b)(2)(B).

[8] *See* Securities Exchange Act Release No. 77247, 81 FR 11309 (March 3, 2016) (''Order Instituting Proceedings'').

[9] 15 U.S.C. 78f(b)(5).

[10] *See* Securities Exchange Act Release No. 77927, 81 FR 35411 (June 2, 2016).

[11] *See* ISE Gemini Rule 804(g)(1) for a description of the parameters. The time period is specified by the market maker.

[12] *See* ISE Gemini Rule 804(g)(2). The time period for a market-wide speed bump is also specified by the market maker.

[13] *Id.*

[14] *See* Notice, *supra* note 5, at 74824.

[15] *See* proposed Rule 804(g)(2).

inform the Exchange directly when its authorization has been given for the market maker to resume trading.[16] In order to ''facilitate a better response time'' from Clearing Members so that a market maker can re-enter the market, the proposal also allows the Exchange staff to notify Clearing Member(s) when a market maker's quotes have been removed pursuant to the market-wide speed bump.[17]

III. Discussion and Commission Findings

Under Section 19(b)(2)(C) of the Act,[18] the Commission shall approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to such organization.[19] The Commission shall disapprove a proposed rule change if it does not make such a finding.[20] Rule 700(b)(3) of the Commission's Rules of Practice states that the ''burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization that proposed the rule change'' and that a ''mere assertion that the proposed rule change is consistent with those requirements . . . is not sufficient.'' [21]

After careful consideration, the Commission does not find 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.[22] In particular, the Commission does not find that the proposed rule change is consistent with Section 6(b)(5) of the Act,[23] which, among other things, requires 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.

The Commission has stated in the past that, because market makers receive favorable treatment from an exchange, they must also be subject to sufficient and commensurate affirmative obligations, including the obligation to hold themselves out as willing to buy and sell options for their own account on a regular or continuous basis.[24] Accordingly, under ISE Gemini's current rules, a market maker must enter continuous quotations for the options classes to which it is appointed.[25] In return, the market maker receives certain benefits, including participation entitlements–[26] and an exception from the prohibition in Section 11(a) of the Act.[27]

The Exchange proposes to require Clearing Member approval before a market maker can resume trading after triggering a market-wide speed bump. The Exchange states in its filing that the Clearing Member should approve a market maker's re-entry into the market after a market-wide speed bump because the Clearing Member guarantees the market maker's trades and bears the ultimate financial risk associated with the transactions.[28] The Exchange notes that, while not all market makers are Clearing Members, all market makers require a Clearing Member's consent to clear transactions on their behalf in order to conduct business on the Exchange.[29] The Exchange asserts that the proposed rule change will permit Clearing Members to better monitor and manage the potential risks assumed by market makers and will provide Clearing Members with greater control and flexibility over their risk tolerance and exposure.[30] The Exchange further contends that, ''[w]hile in some cases [the proposed rule change] may result in a minimal delay for a market maker that wants to reenter the market quickly following a market-wide speed bump, the Exchange believes that Clearing Member approval. . .ensure[s] that the market maker does not prematurely enter the market without adequate safeguards. . .'' [31]

As noted above, on February 26, 2016, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act [32] to determine whether to approve or disapprove the proposed rule change.[33] In the order instituting proceedings, the Commission noted that the Exchange does not address how the proposal would impact the continuous quoting obligations of market makers and provided no basis for its statement that the proposed rule would result in only a ''minimal delay'' for a market maker seeking to resume quoting following a market-wide speed bump. Accordingly, the Commission stated that the proposed rule change raises questions regarding the ability of market makers to meet their quoting obligations, and whether the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act. The Exchange did not respond to the issues raised in the Commission's order instituting proceedings.

The Commission does not believe the Exchange has met its burden to demonstrate that the proposed rule change is consistent with the Act and the rules and regulations issued thereunder. The Exchange proposes to require Clearing Member approval before a market maker can resume trading following a market-wide speed bump so that Clearing Members can better monitor and manage their potential risks. Providing this additional risk management tool to Clearing Members, however, necessarily will delay the resumption of quoting by market makers and the resulting potential market quality benefits to all users of the Exchange. Although the Exchange states that any delay would be minimal, it provides no evidence to support that assertion. The Exchange also has not explained why Clearing

[16] *See id.*

[17] *See id.*

[18] 15 U.S.C. 78s(b)(2)(C).

[19] *See* 15 U.S.C. 78s(b)(2)(C)(i).

[20] *See* 15 U.S.C. 78s(b)(2)(C)(ii); *see also* 17 CFR 201.700(b)(3).

[21] *See* 17 CFR 201.700(b)(3). ''The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding. Any failure of a self-regulatory organization to provide the information elicited by Form 19b–4 may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder that are applicable to the self-regulatory organization.'' *Id.*

[22] In disapproving the proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[23] 15 U.S.C. 78f(b)(5).

[24] *See, e.g.,* Securities Exchange Act Release No. 68341 (December 3, 2012), 77 FR 73065, 73076 (December 7, 2012) (approving the application of Miami International Securities Exchange, LLC for registration as a national securities exchange); Securities Exchange Act Release No. 70050 (July 26, 2013), 78 FR 46622 (August 1, 2013) (approving the application of Topaz Exchange, LLC for registration as a national securities exchange); Securities Exchange Act Release No. 76998 (January 29, 2016), 81 FR 6066 (February 4, 2016) (approving the application of ISE Mercury, LLC for registration as a national securities exchange).

[25] *See* ISE Gemini Rule 804(e).

[26] *See, e.g.,* ISE Gemini Rule 713.

[27] 15 U.S.C. 78k(a).

[28] *See* Notice, *supra* note 5, at 74824.

[29] Each market maker authorized to trade on the Exchange must obtain from a Clearing Member a ''Letter of Guarantee'' wherein the Clearing Member accepts financial responsibility for all Exchange transactions made by the market maker. *See* ISE Gemini Rule 808.

[30] *See* Notice, *supra* note 5, at 74825. Under ISE Gemini's current rules, the Exchange may share any Member-designated risk settings in the trading system with the Clearing Member that clears transactions on behalf of the Member. *See* ISE Gemini Rule 706(a).

[31] *See* Notice, *supra* note 5, at 74825.

[32] 15 U.S.C. 78s(b)(2)(B).

[33] *See* Securities Exchange Act Release No. 77247, 81 FR 11309 (March 3, 2016) (''Order Instituting Proceedings'').

Member risks cannot effectively be addressed through other means, such as bilateral, contractual arrangements between Clearing Members and market makers that do not impede a market maker's ability to promptly resume quoting and enhance the Exchange's market quality.

Accordingly, the Commission does not believe that the Exchange has met its burden to demonstrate that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder. In particular, the Commission does not find that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act, which requires that the rules of an exchange, among other things, be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.[34]

IV. Conclusion

For the foregoing reasons, the Commission does not find that the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, with Section 6(b)(5) of the Act.

IT IS THEREFORE ORDERED, pursuant to Section 19(b)(2) of the Act,[35] that the proposed rule change (SR–ISE Gemini-2015–17) be, hereby is, disapproved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[36]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–18202 Filed 8–1–16; 8:45 am]

BILLING CODE 8011–01–P

[34] 15 U.S.C. 78f(b)(5).

[35] 15 U.S.C. 78s(b)(2).

[36] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78425; File No. SR–NYSEArca–2016–84]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change to List and Trade Shares of the Global Currency Gold Fund Under NYSE Arca Equities Rule 8.201

July 27, 2016.

On June 1, 2016, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the Global Currency Gold Fund under NYSE Arca Equities Rule 8.201. The proposed rule change was published for comment in the **Federal Register** on June 21, 2016.[3]

Section 19(b)(2) of the Act [4] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The Commission is extending this 45-day time period. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change.

Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates September 19, 2016, as the date by which the Commission shall either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change (File Number SR–NYSEArca–2016–84).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–18203 Filed 8–1–16; 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. 78075 (June 15, 2016), 81 FR 40381.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78423; File No. SR–ISE–2015–30]

Self-Regulatory Organizations; International Securities Exchange, LLC; Order Disapproving a Proposed Rule Change To Amend Rule 804(g)

July 27, 2016.

I. Introduction

On November 10, 2015, the International Securities Exchange, LLC (''ISE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to require Clearing Member [3] approval for a market maker [4] to resume trading after the activation of a market-wide speed bump under ISE Rule 804(g). The proposed rule change was published for comment in the **Federal Register** on November 30, 2015.[5]

On January 13, 2016, the Commission extended the time period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change to February 28, 2016.[6] On February 26, 2016, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act [7] to determine whether to approve or disapprove the proposed rule change.[8] Specifically, the Commission instituted proceedings to allow for additional analysis of, and input from commenters with respect to, the proposed rule change's consistency with Section 6(b)(5) of the Act.[9] On May

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A ''Clearing Member'' is a Member that is self-clearing or an Electronic Access Member that clears transactions executed on or through the facilities of the Exchange for other Members of the Exchange. *See* ISE Rule 100(a)(8). An ''Electronic Access Member'' is an Exchange Member that is approved to exercise trading privileges associated with EAM Rights. *See* Article XIII, Section 13.1(l) of the Second Amended and Restated Constitution of ISE.

[4] ISE has two categories of market makers: Primary Market Makers (''PMMs'') and Competitive Market Makers (''CMMs''). A PMM is appointed to each options class traded on the Exchange, but a CMM may or may not be appointed to each such options class. *See* ISE Rule 802.

[5] *See* Securities Exchange Act Release No. 76506 (November 23, 2015), 80 FR 74829 (''Notice'').

[6] *See* Securities Exchange Act Release No. 76893, 81 FR 3217 (January 20, 2016).

[7] 15 U.S.C. 78s(b)(2)(B).

[8] *See* Securities Exchange Act Release No. 77246, 81 FR 11305 (March 3, 2016) (''Order Instituting Proceedings'').

[9] 15 U.S.C. 78f(b)(5).

26, 2016, the Commission extended the time period for Commission action on the proceedings to determine whether to disapprove the proposed rule change.[10] The Commission did not receive any comments on the proposed rule change and the Exchange did not submit a response to the Commission's order instituting proceedings. This order disapproves the proposed rule change.

II. Description of the Proposal

The Exchange has an automated quotation adjustment functionality that is governed by its Rule 804(g)(1) (for regular orders) and Supplementary Material .04 to Rule 722 (for complex orders). Pursuant to these Rules, the Exchange will automatically remove a market maker's quotations in all series of an options class or in all complex order strategies of an options class when, during a specified time period, the market maker exceeds certain execution parameters.[11] All market makers are required by ISE to provide these specific parameters. Additionally, the Exchange will automatically remove a market maker's quotes in *all* classes when, during a specified time period, the total number of quote removal events (''curtailment events'') described in Rule 804(g)(1) and in Supplementary Material .04 to Rule 722 exceed a specified market-wide parameter (''market-wide speed bump'').[12] As with the functionality to remove all option series of an options class or complex order strategies of an options class, all market makers are required by ISE to specify a market-wide parameter. The market-wide speed bump is available for quotes only on ISE or across both ISE and ISE's affiliated exchange, ISE Gemini, LLC.[13] The Exchange states that, after a market-wide speed bump is triggered and the trading system removes all of a market maker's quotes, the market maker may re-enter the market and resume trading upon notification to the Exchange's Market Operations.[14]

Under the proposal, the Exchange seeks to amend the process by which market makers can re-enter the market. Specifically, the proposal requires Clearing Member approval before a market maker can resume trading after triggering a market-wide speed bump.[15] Following a market-wide speed bump, the proposed rule requires: (1) A market maker to notify its Clearing Member(s) when it is ready to resume trading; and (2) each applicable Clearing Member to inform the Exchange directly when its authorization has been given for the market maker to resume trading.[16] In order to ''facilitate a better response time'' from Clearing Members so that a market maker can re-enter the market, the proposal also allows the Exchange staff to notify Clearing Member(s) when a market maker's quotes have been removed pursuant to the market-wide speed bump.[17]

III. Discussion and Commission Findings

Under Section 19(b)(2)(C) of the Act,[18] the Commission shall approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to such organization.[19] The Commission shall disapprove a proposed rule change if it does not make such a finding.[20] Rule 700(b)(3) of the Commission's Rules of Practice states that the ''burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization that proposed the rule change'' and that a ''mere assertion that the proposed rule change is consistent with those requirements . . . is not sufficient.'' [21]

After careful consideration, the Commission does not find 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.[22] In particular, the Commission does not find that the proposed rule change is consistent with Section 6(b)(5) of the Act,[23] which, among other things, requires 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.

The Commission has stated in the past that, because market makers receive favorable treatment from an exchange, they must also be subject to sufficient and commensurate affirmative obligations, including the obligation to hold themselves out as willing to buy and sell options for their own account on a regular or continuous basis.[24] Accordingly, under ISE's current rules, a market maker must enter continuous quotations for the options classes to which it is appointed.[25] In return, the market maker receives certain benefits, including participation entitlements [26] and an exception from the prohibition in Section 11(a) of the Act.[27]

The Exchange proposes to require Clearing Member approval before a market maker can resume trading after triggering a market-wide speed bump. The Exchange states in its filing that the Clearing Member should approve a market maker's re-entry into the market after a market-wide speed bump because the Clearing Member guarantees the market maker's trades and bears the ultimate financial risk associated with the transactions.[28] The Exchange notes that, while not all market makers are Clearing Members, all market makers require a Clearing Member's consent to clear transactions on their behalf in order to conduct business on the Exchange.[29] The Exchange asserts that

[10] *See* Securities Exchange Act Release No. 77928, 81 FR 35409 (June 2, 2016).

[11] *See* ISE Rule 804(g)(1) and Supplementary Material .04 to Rule 722 for a description of the parameters. The time period is specified by the market maker.

[12] *See* ISE Rule 804(g)(2). The time period for a market-wide speed bump is also specified by the market maker.

[13] *Id.*

[14] *See* Notice, *supra* note 5, at 74830.

[15] *See* proposed Rule 804(g)(2).

[16] *See id.*

[17] *See id.*

[18] 15 U.S.C. 78s(b)(2)(C).

[19] *See* 15 U.S.C. 78s(b)(2)(C)(i).

[20] *See* 15 U.S.C. 78s(b)(2)(C)(ii); *see also* 17 CFR 201.700(b)(3).

[21] *See* 17 CFR 201.700(b)(3). ''The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding. Any failure of a self-regulatory organization to provide the information elicited by Form 19b–4 may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder that are applicable to the self-regulatory organization.'' *Id.*

[22] In disapproving the proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[23] 15 U.S.C. 78f(b)(5).

[24] *See, e.g.,* Securities Exchange Act Release No. 68341 (December 3, 2012), 77 FR 73065, 73076 (December 7, 2012) (approving the application of Miami International Securities Exchange, LLC for registration as a national securities exchange); Securities Exchange Act Release No. 70050 (July 26, 2013), 78 FR 46622 (August 1, 2013) (approving the application of Topaz Exchange, LLC for registration as a national securities exchange); Securities Exchange Act Release No. 76998 (January 29, 2016), 81 FR 6066 (February 4, 2016) (approving the application of ISE Mercury, LLC for registration as a national securities exchange).

[25] *See* ISE Rule 804(e).

[26] *See, e.g.,* ISE Rule 713.

[27] 15 U.S.C. 78k(a).

[28] *See* Notice, *supra* note 5, at 74830.

[29] Each market maker authorized to trade on the Exchange must obtain from a Clearing Member a ''Market Maker Letter of Guarantee'' wherein the Clearing Member accepts financial responsibility for all Exchange transactions made by the market maker. *See* ISE Rule 808.

the proposed rule change will permit Clearing Members to better monitor and manage the potential risks assumed by market makers and will provide Clearing Members with greater control and flexibility over their risk tolerance and exposure.[30] The Exchange further contends that, ''[w]hile in some cases [the proposed rule change] may result in a minimal delay for a market maker that wants to reenter the market quickly following a market-wide speed bump, the Exchange believes that Clearing Member approval . . . ensure[s] that the market maker does not prematurely enter the market without adequate safeguards . . . ''[31]

As noted above, on February 26, 2016, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act[32] to determine whether to approve or disapprove the proposed rule change.[33] In the order instituting proceedings, the Commission noted that the Exchange does not address how the proposal would impact the continuous quoting obligations of market makers and provided no basis for its statement that the proposed rule would result in only a ''minimal delay'' for a market maker seeking to resume quoting following a market-wide speed bump. Accordingly, the Commission stated that the proposed rule change raises questions regarding the ability of market makers to meet their quoting obligations, and whether the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act. The Exchange did not respond to the issues raised in the Commission's order instituting proceedings.

The Commission does not believe the Exchange has met its burden to demonstrate that the proposed rule change is consistent with the Act and the rules and regulations issued thereunder. The Exchange proposes to require Clearing Member approval before a market maker can resume trading following a market-wide speed bump so that Clearing Members can better monitor and manage their potential risks. Providing this additional risk management tool to Clearing Members, however, necessarily will delay the resumption of quoting by market makers and the resulting potential market quality benefits to all users of the Exchange. Although the Exchange states that any delay would be minimal, it provides no evidence to support that assertion. The Exchange also has not explained why Clearing Member risks cannot effectively be addressed through other means, such as bilateral, contractual arrangements between Clearing Members and market makers that do not impede a market maker's ability to promptly resume quoting and enhance the Exchange's market quality.

Accordingly, the Commission does not believe that the Exchange has met its burden to demonstrate that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder. In particular, the Commission does not find that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act, which requires that the rules of an exchange, among other things, be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.[34]

IV. Conclusion

For the foregoing reasons, the Commission does not find that the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, with Section 6(b)(5) of the Act.

IT IS THEREFORE ORDERED, pursuant to Section 19(b)(2) of the Act,[35] that the proposed rule change (SR–ISE–2015–30) be, hereby is, disapproved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[36]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–18207 Filed 8–1–16; 8:45 am]

BILLING CODE 8011–01–P

[30] *See* Notice, *supra* note 5, at 74830. Under ISE's current rules, the Exchange may share any Member-designated risk settings in the trading system with the Clearing Member that clears transactions on behalf of the Member. *See* ISE Rule 706(a).

[31] *See* Notice, *supra* note 5, at 74830.

[32] 15 U.S.C. 78s(b)(2)(B).

[33] *See* Securities Exchange Act Release No. 77246, 81 FR 11305 (March 3, 2016) (''Order Instituting Proceedings'').

[34] 15 U.S.C. 78f(b)(5).

[35] 15 U.S.C. 78s(b)(2).

[36] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78428; File No. SR–BOX–2016–36]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule on the BOX Market LLC (''BOX'') Options Facility

July 27, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 25, 2016, BOX Options Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A)(ii) of the Act,[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the Fee Schedule to adjust the fee assessed in Section IV (Eligible Orders Routed to an Away Exchange) on the BOX Market LLC (''BOX'') options facility. While changes to the fee schedule pursuant to this proposal will be effective upon filing, the changes will become operative on August 1, 2016. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's Internet Web site at *http://boxexchange.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the 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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule for trading on BOX to adjust the fee assessed in Section IV (Eligible Orders Routed to an Away Exchange) of the BOX Fee Schedule. Specifically, the Exchange proposes to increase the $0.50 per contract routing fee to $0.60.

Currently, BOX uses third-party broker-dealers to route orders to other exchanges and incurs charges for each order routed to and executed at an away market, in addition to the transaction fees charged by other exchanges. To offset the fees charged to the Exchange for orders routed to other exchanges, the Exchange charges a $0.50 per contract fee for customer accounts. However, the Exchange charges no fee for non-Professional, Public Customer Directed Orders when: (i) Less than 45% of a Participants' monthly executions for such orders are routed to and executed at an Away Exchange; and (ii) 33% or more of a Participants' monthly executions for such orders occur through the PIP. In an effort to continue to offer routing services to its Participants at prices that approximate the cost to the Exchange, the Exchange is proposing to increase the routing fee to $0.60 per contract from $0.50 per contract for customer accounts.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act, in general, and Section 6(b)(4) and 6(b)(5)of the Act,[5] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among BOX Participants and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues or providers of routing services if they deem fee levels to be excessive.

The Exchange generally attempts to approximate the cost of routing to other options exchanges, including other applicable costs to the Exchange for routing. The Exchange believes that the proposed fee change which is based on approximate Routing Costs is a reasonable, equitable and not unfairly discriminatory approach to pricing. Specifically, the Exchange believes that its proposal to moderately increase the routing fee is fair, equitable and reasonable because the fee is generally an approximation of the cost to the Exchange for routing orders to such exchanges. Further, the Exchange believes that the proposed fee is reasonable and appropriate as it is in line with what is currently charged by the industry.[6] Accordingly, the Exchange believes that the proposed increases [sic] are reasonable, equitable and not unfairly discriminatory because they will help the Exchange to avoid subsidizing routing to away options exchanges and to continue providing quality routing services. The Exchange believes that its fee for orders routed to various venues is a reasonable approach to pricing, as it provides certainty with respect to execution fees at away options exchanges. As a general matter, the Exchange believes that the proposed fee will allow it to recoup and cover its costs of providing routing services to away exchanges. The Exchange notes that routing through the Exchange is voluntary. The Exchange also believes that the proposed fee for orders routed to and executed at away options exchanges is fair and equitable and not unreasonably discriminatory in that it applies equally to all Participants.

The Exchange reiterates that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels to be excessive or providers of routing services if they deem fee levels to be excessive. Finally, the Exchange notes that it constantly evaluates its routing fees, including profit and loss attributable to routing and would consider future adjustments to the proposed fee to the extent it was recouping a significant profit or loss from routing to away options exchanges.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. As it relates to the proposes change to the routing fee, the proposes change will assist the Exchange in recouping costs for routing orders to other options exchanges on behalf of its Participants in a manner that is a better approximation of actual costs than is currently in place and that reflects pricing changes by various options exchanges as well as increases to other Routing Costs incurred by the Exchange. The Exchange also notes that Participants may choose to designate their orders as ineligible for routing to avoid incurring routing fees.[7]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Exchange Act[8] and Rule 19b–4(f)(2) thereunder,[9] because it establishes or changes a due, or fee.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BOX–2016–36 on the subject line.

[5] 15 U.S.C. 78f(b)(4) and (5).

[6] *See* Miami International Securities Exchange LLC (''MIAX'') Fee Schedule Section (1)(C) *and* NASDAQ Options Market (''NOM'') Fees and Rebates Section (2)3. On MIAX and NOM, the general range of fees for orders routed to away exchanges is between $0.10 and $0.99, with the $0.99 fee being assessed to Non-Customers.

[7] *See* BOX Rule 15030 (describing the routing process, which requires orders to be designated as eligible for routing).

[8] 15 U.S.C. 78s(b)(3)(A)(ii).

[9] 17 CFR 240.19b–4(f)(2).

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BOX–2016–36. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BOX–2016–36, and should be submitted on or before August 23, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–18206 Filed 8–1–16; 8:45 am]

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[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78426; File No. SR–NYSEArca–2016–101]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change Relating to the Listing and Trading of Shares of SolidX Bitcoin Trust Under NYSE Arca Equities Rule 8.201

July 27, 2016.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 13, 2016, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade shares of the following under NYSE Arca Equities Rule 8.201: SolidX Bitcoin Trust (''Trust''). The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Under NYSE Arca Equities Rule 8.201, the Exchange may propose to list and/or trade pursuant to unlisted trading privileges (''UTP'') ''Commodity-Based Trust Shares''.[4] The Exchange proposes to list and trade shares (''Shares'') of the Trust pursuant to NYSE Arca Equities Rule 8.201.[5]

The sponsor of the Trust is SolidX Management LLC (''Sponsor''), a Delaware limited liability company. The Sponsor is a wholly-owned subsidiary of SolidX Partners Inc. The trustee for the Trust (''Trustee'') serves pursuant to a trust agreement. The Bank of New York Mellon will be the administrator (''Administrator'') and the custodian, with respect to cash, of the Trust (''Custodian'').

The Trust is a grantor trust formed under the laws of the State of New York. The Trust has no fixed termination date.

According to the Registration Statement, each Share will represent a fractional undivided beneficial interest in the Trust's net assets. The Trust's assets will consist of bitcoin [6] held on the Trust's behalf by the Sponsor utilizing a secure process as described below in ''bitcoin Security and Storage for the Trust''. The Trust will not normally hold cash or any other assets, but may hold a very limited amount of cash in connection with the creation and redemption of ''Baskets'' [7] and to pay Trust expenses, as described below.

According to the Registration Statement, the Trust will invest in bitcoin only. The activities of the Trust are limited to: (i) Issuing Baskets in exchange for bitcoin or the cash deposited with the Custodian as consideration; (ii) purchasing bitcoin from various exchanges and in over-the-counter (''OTC'') transactions; (iii) selling bitcoin (or transferring bitcoin, at the Sponsor's discretion) as necessary to cover the Sponsor's management fee,

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] Commodity-Based Trust Shares are securities issued by a trust that represent investors' discrete identifiable and undivided beneficial ownership interest in the commodities deposited into the Trust.

[5] On July 11, 2016, the Trust filed a registration statement (''Registration Statement'') on Form S–1 under the Securities Act of 1933 (15 U.S.C. 77a). The descriptions of the Trust, the Shares and bitcoin contained herein are based, in part, on the Registration Statement.

[6] A ''bitcoin'' is an asset that can be transferred among parties via the Internet, but without the use of a central administrator or clearing agency (''bitcoin''). The asset, bitcoin, is generally written with a lower case ''b''. The asset, bitcoin, is differentiated from the computers and software (or the protocol) involved in the transfer of bitcoin among users, which constitute the ''Bitcoin Network''. The asset, bitcoin, is the intrinsically linked unit of account that exists within the Bitcoin Network. *See* ''bitcoin and the Bitcoin Industry'' below.

[7] The Trust will issue and redeem ''Baskets'', each equal to a block of 10,000 Shares, only to ''Authorized Participants''. *See* ''Creation and Redemption of Shares'' below.

Trust expenses not assumed by the Sponsor and other liabilities; (iv) selling bitcoin as necessary in connection with redemptions; (v) delivering bitcoin or cash in exchange for Baskets surrendered for redemption; and (vi) maintaining insurance coverage for the bitcoin held by the Trust.

According to the Registration Statement, the Trust is neither an investment company registered under the Investment Company Act of 1940, as amended,[8] nor a commodity pool for purposes of the Commodity Exchange Act (''CEA''),[9] and neither the Sponsor nor the Trustee is subject to regulation as a commodity pool operator or a commodity trading adviser in connection with the Shares.

Investment Objective

According to the Registration Statement and as further described below, the Trust will seek to provide investors with exposure to the daily change in the U.S. dollar price of bitcoin, before expenses and liabilities of the Trust, as measured by the TradeBlock XBX Index (''XBX''). The Trust intends to achieve this objective by investing substantially all of its assets in bitcoin traded on various domestic and international bitcoin exchanges and OTC markets depending on liquidity and otherwise at the Sponsor's discretion. The Trust is not actively managed. It does not engage in any activities designed to obtain a profit from, or to ameliorate losses caused by, changes in the price of bitcoin.

Investment in Bitcoin

Subject to certain requirements and conditions described below and in the Registration Statement, the Trust, under normal market conditions,[10] will use available offering proceeds to purchase bitcoin that are traded on various domestic and international exchanges and OTC markets, without being leveraged or exceeding relevant position limits. Generally, the Sponsor will directly place purchase or sale orders for bitcoin on behalf of the Trust on domestic and international exchanges and with OTC participants using delivery-versus-payment (''DVP'') and receive-versus-payment (''RVP'') arrangements.

Bitcoin and the Bitcoin Industry

General

The following is a brief introduction to the global bitcoin market. The data presented below are derived from information released by various third-party sources, including white papers, other published materials, research reports and regulatory guidance.

The Bitcoin Network

A bitcoin is an asset that can be transferred among parties via the Internet, but without the use of a central administrator or clearing agency. The term ''decentralized'' is often used in descriptions of bitcoin, in reference to bitcoin's lack of necessity for administration by a central party. The Bitcoin Network (*i.e.,* the network of computers running the software protocol underlying bitcoin involved in maintaining the database of bitcoin ownership and facilitating the transfer of bitcoin among parties) and the asset, bitcoin, are intrinsically linked and inseparable. Bitcoin was first described in a white paper released in 2008 and published under the name ''Satoshi Nakamoto'', and the protocol underlying bitcoin was subsequently released in 2009 as open source software.

Bitcoin Ownership and the Blockchain

To begin using bitcoin, a user may download specialized software referred to as a ''bitcoin wallet''. A user's bitcoin wallet can run on a computer or smartphone. A bitcoin wallet can be used both to send and to receive bitcoin. Within a bitcoin wallet, a user will be able to generate one or more ''bitcoin addresses'', which are similar in concept to bank account numbers, and each address is unique. Upon generating a bitcoin address, a user can begin to transact in bitcoin by receiving bitcoin at his or her bitcoin address and sending it from his or her address to another user's address. Sending bitcoin from one bitcoin address to another is similar in concept to sending a bank wire from one person's bank account to another person's bank account.

Balances of the quantity of bitcoin associated with each bitcoin address are listed in a database, referred to as the ''blockchain''. Copies of the blockchain exist on thousands of computers on the Bitcoin Network throughout the Internet. A user's bitcoin wallet will either contain a copy of the blockchain or be able to connect with another computer that holds a copy of the blockchain.

When a bitcoin user wishes to transfer bitcoin to another user, the sender must first request a bitcoin address from the recipient. The sender then uses his or her bitcoin wallet software, to create a proposed addition to the blockchain. The proposal would decrement the sender's address and increment the recipient's address by the amount of bitcoin desired to be transferred. The proposal is entirely digital in nature, similar to a file on a computer, and it can be sent to other computers participating in the Bitcoin Network. Such digital proposals are referred to as ''bitcoin transactions''. Bitcoin transactions and the process of one user sending bitcoin to another should not be confused with buying and selling bitcoin, which is a separate process (as discussed below in ''bitcoin Trading On Exchanges'' and ''bitcoin Trading Over-the-Counter'').

A bitcoin transaction is similar in concept to an irreversible digital check. The transaction contains the sender's bitcoin address, the recipient's bitcoin address, the amount of bitcoin to be sent, a confirmation fee and the sender's digital signature. The sender's use of his or her digital signature enables participants on the Bitcoin Network to verify the authenticity of the bitcoin transaction.

A user's digital signature is generated via usage of the user's so-called ''private key'', one of two numbers in a so-called cryptographic ''key pair''. A key pair consists of a ''public key'' and its corresponding private key, both of which are lengthy numerical codes, derived together and possessing a unique relationship.

Public keys are used to create bitcoin addresses. Private keys are used to sign transactions that initiate the transfer of bitcoin from a sender's bitcoin address to a recipient's bitcoin address. Only the holder of the private key associated with a particular bitcoin address can digitally sign a transaction proposing a transfer of bitcoin from that particular bitcoin address.

A user's bitcoin address (which is derived from a public key) may be safely distributed, but a user's private key must remain known solely by its rightful owner. The utilization of a private key is the only mechanism by which a bitcoin user can create a digital signature to transfer bitcoin from him or herself to another user. Additionally, if a malicious third party learns of a user's private key, that third party could forge the user's digital signature and send the user's bitcoin to any arbitrary bitcoin address (*i.e.,* the third party could steal the user's bitcoin).

[8] 15 U.S.C. 80a–1.

[9] 17 U.S.C. 1.

[10] The term ''under normal circumstances'' includes, but is not limited to, the absence of extreme volatility or trading halts in the price of bitcoin or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

When a bitcoin holder sends bitcoin to a destination bitcoin address, the transaction is initially considered unconfirmed. Confirmation of the validity of the transaction involves verifying the signature of the sender, as created by the sender's private key. Confirmation also involves verifying that the sender has not ''double spent'' the bitcoin (*e.g.,* confirming Party A has not attempted to send the same bitcoin both to Party B and to Party C). The confirmation process occurs via a process known as ''bitcoin mining''.

Bitcoin mining utilizes a combination of computer hardware and software to accomplish a dual purpose: (i) To verify the authenticity and validity of bitcoin transactions (*i.e.,* the movement of bitcoin between addresses) and (ii) the creation of new bitcoin. Neither the Sponsor nor the Trust intends to engage in bitcoin mining.

Bitcoin miners do not need permission to participate in verifying transactions. Rather, miners compete to solve a prescribed and complicated mathematical calculation using computers dedicated to the task. Rounds of the competition repeat approximately every ten minutes. In any particular round of the competition, the first miner to find the solution to the mathematical calculation is the miner who gains the privilege of announcing the next block to be added to the blockchain.

A new block that is added to the blockchain serves to take all of the recent-yet-unconfirmed transactions and verify that none are fraudulent. The recent-yet-unconfirmed transactions also generally contain transaction fees that are awarded to the miner who produces the block in which the transactions are inserted, and thereby confirmed. The successful miner also earns the so-called ''block reward'', an amount of newly created bitcoin. Thus, bitcoin miners are financially incentivized to conduct their work. The financial incentives received by bitcoin miners are a vital part of the process by which the Bitcoin Network functions.

Upon successfully winning a round of the competition (winning a round is referred to as mining a new block), the miner then transmits a copy of the newly-formed block to peers on the Bitcoin Network, all of which then update their respective copies of the blockchain by appending the new block, thereby acknowledging the confirmation of the transactions that had previously existed in an unconfirmed state.

A recipient of bitcoin must wait until a new block is formed in order to see the transaction convert from an unconfirmed state to a confirmed state. According to the Registration Statement, with new rounds won approximately every ten minutes, the average wait time for a confirmation is five minutes.

The protocol underlying bitcoin provides the rules by which all users and miners on the Bitcoin Network must operate. A user or miner attempting to operate under a different set of rules will be ignored by other network participants, thus rendering that user's or miner's behavior moot. The protocol also lays out the block reward, the amount of bitcoin that a miner earns upon creating a new block. The initial block reward when Bitcoin was introduced in 2009 was 50 bitcoin per block. That number has and will continue to halve approximately every four years until approximately 2140, when it is estimated that block rewards will go to zero. The next halving is projected for July 2016, which will reduce the block reward to 12.5 bitcoin from its current level of 25.[11] The halving thereafter will occur in another four years and will reduce the block reward to 6.25 bitcoin, and so on. Currently, there are approximately 15 million bitcoin that have been created, a number that will grow with certainty to a maximum of 21 million, estimated to occur by the year 2140. Bitcoin mining should not be confused with buying and selling bitcoin, which, as discussed below, is a separate process.

Use of Bitcoin and the Blockchain

Beyond using bitcoin as a value transfer mechanism, applications related to the blockchain technology underlying bitcoin have become increasingly prominent.[12] Blockchain-focused applications take advantage of certain unique characteristics of the blockchain such as secure time stamping (secure time stamps are on newly created blocks), highly redundant storage (copies of the blockchain are distributed throughout the Internet) and tamper-resistant data secured by secure digital signatures.

According to the Registration Statement, blockchain-focused applications in usage and under development include, but are not limited to, supply chain management, secure cloud storage, identity management, counterfeit and fraud detection systems, database security enhancement, evidence capture, secure document and contract signing, asset title transfer and financial asset settlement. Whether used for value transfer or other blockchain-focused applications, each transaction or use of the blockchain requires a fee, priced and paid in bitcoin. Therefore, the usage of bitcoin, the asset, is inherently involved in blockchain-focused applications, thus linking the growth and adoption of blockchain-focused applications to the growth and adoption of bitcoin.

According to the Registration Statement, as a value transfer mechanism, over 100,000 merchants worldwide currently accept bitcoin as payment for goods and services. Notable merchants accepting bitcoin for certain types of purchases include Microsoft, Dell, Expedia, Overstock.com and Dish Network. Common bitcoin purchases include Web site hosting, home furnishings, gift cards and consumer electronics. Bitcoin is also accepted by a number of non-profit organizations worldwide, including United Way Worldwide, the American Red Cross, Wikipedia and Fidelity Charitable.[13]

Bitcoin Exchanges

Bitcoin exchanges operate Web sites that facilitate the purchase and sale of bitcoin for various government-issued currencies, including the U.S. dollar, the euro or the Chinese yuan. Activity on bitcoin exchanges should not be confused with the process of users sending bitcoin from one bitcoin address to another bitcoin address, the latter being an activity that is wholly within the confines of the Bitcoin Network and the former being an activity that occurs entirely on private Web sites.

Bitcoin exchanges operate in a manner that is unlike the traditional capital markets infrastructure in the U.S. and in other developed nations. Bitcoin exchanges combine the process of order matching, trade clearing, trade settlement and custody into a single entity. For example, a user can send U.S. dollars via wire to a bitcoin exchange and then visit the exchange's Web site to purchase bitcoin. The entirety of the transaction—from trade to clearing to settlement to custody (at least temporary custody)—is accomplished by the bitcoin exchange in a matter of seconds. The user can then withdraw the purchased bitcoin into a wallet to take custody of the bitcoin directly.

According to the Registration Statement, there are currently several

[11] *http://www.bitcoinblockhalf.com/.*

[12] Additional applications based on blockchain technology—both the blockchain underlying bitcoin as well as separate public blockchains incorporating similar characteristics of the blockchain underlying bitcoin—are currently in development by numerous entities, including financial institutions like banks.

[13] Attached as Exhibit 3, Item 1 is a chart setting forth a summary of bitcoin transaction volume (*i.e.,* transfers of bitcoin between parties on the Bitcoin Network, which is different than and should not be confused with bitcoin exchange-traded volume) from January 2009 through January 2016.

U.S.-based regulated entities that facilitate bitcoin trading and that comply with U.S. anti-money laundering (''AML'') and know your customer (''KYC'') regulatory requirements:

- Coinbase, which is based in California, is a bitcoin exchange that maintains money transmitter licenses in over thirty states, the District of Columbia and Puerto Rico (''Coinbase''). Coinbase is subject to the regulations enforced by the various state agencies that issued their respective money transmitter licenses to Coinbase. In New York, Coinbase applied for a BitLicense, a regulatory framework created by the New York Department of Financial Services (''DFS'') that sets forth consumer protection, AML compliance, and cyber security rules tailored for digital currency companies operating and transacting business in New York.
- itBit is a bitcoin exchange that was granted a limited purpose trust company charter by the DFS in May 2015 (''itBit''). Limited purpose trusts, according to the DFS, are permitted to undertake certain activities, such as transfer agency, securities clearance, investment management, and custodial services, but without the power to take deposits or make loans.
- Gemini is a bitcoin exchange that is also regulated by the DFS. In October 2015, the DFS granted Gemini authorization to operate as a limited purpose trust company (''Gemini'').
- SecondMarket, Inc. d/b/a Genesis Global Trading is a FINRA member firm that makes a market in bitcoin by offering two-sided liquidity (''Genesis Global Trading'').

According to the Registration Statement, the majority of bitcoin transactions are executed on public bitcoin exchanges where bitcoin are bought and sold daily for value in U.S. dollar, euro and other government currencies. These bitcoin exchanges provide the most data with respect to prevailing valuations of bitcoin. The exchanges typically publish real-time trade data including last price, bid and ask spread, and trade volume on their respective Web sites and through application programming interfaces. As a result, the prices on bitcoin exchanges are the most accurate expression of the value of bitcoin. The XBX, which the Trust will use to calculate the net asset value of the Shares, accordingly tracks the price of bitcoin across multiple exchanges (*see* ''bitcoin Price Indexes'' below).

The bitcoin marketplace is a 24-hour, 365-day per year market. There currently exist globally over 30 bitcoin exchanges. The Sponsor represents that the exchanges with the most significant bitcoin trading by volume (*i.e.,* Bitfinex,[14] Bitstamp,[15] BTCC,[16] BTC-e,[17] Coinbase, Huobi,[18] itBit, OKCoin Exchange China [19] and OKCoin International [20]) traded approximately 422 million bitcoin at U.S. dollar converted prices ranging between $199 and $706 for a total trade volume of over $154 billion during the period February 2014 through January 2016. The Sponsor represents that average global daily trade volume during this period was approximately $212 million.

The various bitcoin exchanges are generally available to the public through online web portals. Trading information, including pricing, volumes, and order book is available on the exchanges' Web sites, and most such information is publicly available to anyone who visits the site. According to the Sponsor, for those exchanges that comply with applicable KYC requirements, prior to trading bitcoin, users are required to provide the exchange with KYC verifiable identification and other such documentation. Once a user establishes an account with the exchange, the user deposits government currency with the exchange by completing a wire of government currency to the exchange's bank.

Bitcoin are traded with publicly disclosed valuations for each transaction, measured by one or more government currencies such as the U.S. dollar, the euro or the Chinese yuan. Bitcoin exchanges typically report publicly on their site the valuation of each transaction and bid and ask prices for the purchase or sale of bitcoin. Although each bitcoin exchange has its own market price, it is expected that most bitcoin exchanges' market prices should be relatively consistent with the bitcoin exchange market average since market participants can choose the bitcoin exchange on which to buy or sell bitcoin (*i.e.,* exchange shopping). According to the Registration Statement, price differentials across bitcoin exchanges enable arbitrage between bitcoin prices on the various exchanges.

Bitcoin Price Indexes

XBX Index. Launched in July 2014, the XBX represents the value of one bitcoin in U.S. dollars at any point in time and closes as of 4:00 p.m., Eastern time (''E.T.''), each weekday. The intra-day levels of the XBX incorporate the real-time price of bitcoin based on trading activity derived from constituent exchanges throughout each trading day. The closing level of the XBX is calculated using a proprietary methodology utilizing bitcoin trading data from constituent exchanges and is published at or after 4:00 p.m., E.T., each weekday. The XBX is published to two decimal places rounded on the last digit.

Schvey, Inc. d/b/a TradeBlock (''TradeBlock'') is the index sponsor and calculation agent for the XBX. The Sponsor has entered into a licensing agreement with TradeBlock to use the XBX. The Trust is entitled to use the XBX pursuant to a sub-licensing arrangement with the Sponsor.

The XBX is a real-time U.S. dollar-denominated composite reference rate for the price of bitcoin. The XBX calculates the intra-day price of bitcoin every second, including the closing price as of 4:00 p.m., E.T. The intra-day price and closing price are based on a methodology that consists of collecting and cleansing actual trade data from several bitcoin exchanges included within the XBX.

According to the Registration Statement, to ensure that TradeBlock's exchange selection process is impartial, TradeBlock implements a standardized eligibility criteria framework based on periodically-reviewed governance principles that includes elements such as depth of liquidity, compliance with applicable legal and regulatory requirements, data availability and acceptance of U.S. dollar deposits. As of June 30, 2016, the eligible bitcoin exchanges selected by TradeBlock for inclusion in the XBX are Bitfinex, Bitstamp, Coinbase, itBit and OKCoin International. The XBX currently does not include any other bitcoin exchanges, derivative exchanges, dark pools, OTC or other trading venues.

The logic utilized for the derivation of the daily closing index level for the XBX

[14] Bitfinex is a bitcoin exchange that facilitates U.S. dollar-denominated bitcoin trading (''Bitfinex''). It is based in Hong Kong and holds a Money Services Operator license issued by the Customs and Excise Department, Money Services Supervision Bureau.

[15] Bitstamp is a bitcoin exchange that facilitates U.S. dollar-denominated bitcoin trading (''Bitstamp''). It is based in the United Kingdom with offices in London, Luxembourg and New York. The government of Luxembourg granted Bitstamp a license to operate as a regulated bitcoin exchange in the European Union.

[16] BTCC is a bitcoin exchange that is headquartered in Shanghai and facilitates yuan-denominated bitcoin trading (''BTCC'').

[17] BTC-e is a U.S. dollar-denominated bitcoin exchange (''BTC-e'').

[18] Huobi is a bitcoin exchange that is based in Beijing and facilitates yuan-denominated bitcoin trading.

[19] OKCoin Exchange China is located in Beijing and facilitates Chinese yuan-denominated bitcoin trading (''OKCoin Exchange China'').

[20] OKCoin International is located in Singapore and facilitates U.S. dollar-denominated bitcoin trading (''OKCoin International'').

is intended to analyze actual bitcoin transactional data, verify and refine the data set and yield an objective, fair-market value of one bitcoin as of 4:00 p.m., E.T., each weekday, priced in U.S. dollars. As discussed herein, the XBX intra-day price and the XBX closing price are collectively referred to as the XBX price, unless otherwise noted.

The key elements of the algorithm underlying the XBX include:

• Volume/Liquidity Weighting: Exchanges with greater liquidity receive a higher weighting in the XBX, increasing the ability to execute against the XBX in the underlying spot markets. Liquidity weighting also mitigates the impact of volume spikes during off-peak trading hours.

• Price Variance Weighting: The XBX price reflects data points that are discretely weighted in proportion to their variance from contemporaneous pricing reflected on the XBX's constituent exchanges. As the price at a particular exchange diverges from the rest of the data points, its influence on the XBX consequently decreases.

• Inactivity Adjustment: The algorithm penalizes stale ticks on any given exchange. If an exchange does not have recent trading data, its weighting is gradually reduced, until it is de-weighted entirely. Similarly, once activity resumes, the corresponding weighting for that constituent is gradually increased until it reaches the appropriate level.

• Thin Order Books: The XBX minimizes the impact of thin order books and fluctuating prices, which provides a more stable and reliable benchmark for the price of bitcoin.

The XBX index calculation methodology and governance protocol are based on principles established by the International Organization of Securities Commissions for financial benchmarks. TradeBlock conducts a quarterly review of the constituent exchanges and the algorithm used to calculate XBX prices and maintains a history of all updates. In the event of market stress or unresponsive input data from the constituent exchanges, the XBX algorithm will incorporate a minimum of one input to calculate a benchmark value. In the unlikely event of no input data from all constituent values, the XBX will default to the most recent value for which one or more inputs were present.

The Sponsor is not aware of any bitcoin derivatives currently trading based on the XBX.

NYXBT Index. Launched in May 2015, the NYSE Bitcoin Index (''NYXBT'') represents the value of one bitcoin in U.S. dollars at any point in time and closes as of 4:00 p.m., E.T., each weekday.

CoinDesk Bitcoin Price Index. CoinDesk, a digital currency content provider (''Coindesk''), launched a proprietary bitcoin price index, the CoinDesk Bitcoin Price Index (''XBP'') in September 2013. The XBP takes the average of U.S. dollar bitcoin prices from leading exchanges.

Bitcoin Trading on Exchanges

According to the Registration Statement, an individual who wishes to purchase bitcoin on a bitcoin exchange would create an account on the exchange Web site. After creating an account, the buyer would send government issued money to the Web site via traditional payment methods such as ACH and wire transfer. The buyer's account at the bitcoin exchange would be credited with the money sent, and the buyer would then be able to visit the Web site and make a purchase of bitcoin. Directly after the purchase is made, the bitcoin acquired still remains in the custody of the bitcoin exchange (*i.e.,* it remains at a bitcoin address controlled by the exchange). To take custody of the bitcoin, the purchaser would direct the exchange Web site to transfer the bitcoin to a bitcoin address controlled by the purchaser, thereby completing the process of acquiring bitcoin. A sale of bitcoin using a bitcoin exchange involves the same process but in reverse. The seller would transfer bitcoin from an address under his or her control to an address under the bitcoin exchange's control. The seller's account at the bitcoin exchange would be credited with the bitcoin sent, and the seller would be able to commence the sale of the bitcoin via the Web site. Upon completion of the sale, the seller's account would reflect the seller's balance, in government currency, which the seller could then receive by directing the exchange to send the funds via traditional payment methods to the seller's bank account. Bitcoin exchange Web sites generally show users a central limit order book (*i.e.,* a list of all bids and offers for purchases and sales of bitcoin on the exchange).

The Sponsor has trading experience with several U.S. and foreign bitcoin exchanges that generally represent the highest daily U.S. dollar bitcoin trading volume.

The Sponsor may conduct some of its bitcoin trading on behalf of the Trust through a wholly-owned subsidiary, SolidX Management Ltd., an exempted limited company established in the Cayman Islands (''Subsidiary''), to buy and sell bitcoin on behalf of the Trust on certain bitcoin exchanges which are only open to non-U.S. persons or which do not conduct business in New York or with New York residents. The officers of the Sponsor also serve as officers of the Subsidiary. When conducting trading through the Subsidiary, the Sponsor is responsible for the security of the bitcoin to the same extent as if trading bitcoin directly. Bitcoin traded through the Subsidiary will be stored in the same way as bitcoin that is traded directly by the Sponsor, and the Trust's bitcoin insurance on bitcoin traded through the Subsidiary will apply to the same extent as otherwise applicable. Furthermore, the Subsidiary will have the same trading arrangements with the applicable bitcoin exchanges as does the Sponsor itself. Accordingly, references herein to the Sponsor's trading arrangements with bitcoin exchanges on behalf of the Trust include trading conducted by the Sponsor through the Subsidiary, unless otherwise noted.

The Sponsor intends to conduct its bitcoin exchange trading on the following U.S. dollar-denominated bitcoin exchanges: Bitfinex, Bitstamp, Coinbase, Gemini, itBit, Kraken [21] and OKCoin International.[22] The Sponsor represents that all of these exchanges follow AML and KYC regulatory requirements. Because Bitfinex and Kraken do not conduct business in New York or with New York residents, and OKCoin International is only open to non-U.S. persons, the Sponsor intends to conduct its bitcoin trading on these three exchanges through the Subsidiary. As discussed above, the Sponsor does not expect the Trust to experience any differences between bitcoin exchange trades on the Trust's behalf conducted through the Subsidiary versus those conducted by the Sponsor directly.

According to the Registration Statement, during the preceding twelve-month period (June 2015 through May 2016), the aggregate trading volume on the five constituent exchanges comprising the XBX (*i.e.,* Bitfinex, Bitstamp, Coinbase, itBit and OKCoin International) represented approximately 80% of the entire global U.S. dollar-denominated bitcoin exchange market.[23]According to the

[21] Kraken is located in San Francisco (''Kraken''). Although Kraken conducts U.S. dollar bitcoin trading, it is primarily a euro-denominated bitcoin exchange.

[22] The Sponsor intends to trade with OKCoin International, the Singaporean entity, and not with the yuan-denominated OKCoin Exchange China.

[23] In addition to the five constituent exchanges comprising the XBX, the global U.S. dollar-denominated bitcoin exchange market also includes BTC-e, Gemini, LakeBTC (located in Shanghai, China) and Kraken. The Sponsor represents that although BTC-e is a U.S. dollar-denominated

Continued

Registration Statement, during the period April 2015 through April 2016 (including weekends and holidays), average daily bitcoin trading on Bitfinex, Bitstamp, Coinbase, Gemini, itBit and OKCoin International totaled approximately 64,000 bitcoin across all of those exchanges at prices that ranged between $217 and $469. Of that trading, Bitfinex accounted for 38%, Bitstamp accounted for 19%, Coinbase accounted for 13%, Gemini accounted for 1%, itBit accounted for 7% and OKCoin International accounted for 23%. With a Basket (as defined below) size of 1,000 bitcoin, the creation or redemption of one Basket would represent approximately 1.5% of the aggregate daily U.S. dollar-denominated bitcoin trading volume across these exchanges and approximately 1% of the aggregate daily (i) U.S. dollar-denominated bitcoin trading volume on these exchanges plus (ii) global U.S. dollar-denominated OTC bitcoin trading volume.

The Sponsor has established, on behalf of the Trust, DVP and RVP trading arrangements with several of the U.S. dollar-denominated bitcoin exchanges pursuant to which the Trust will be able to minimize exchange counterparty risk. These arrangements are on a trade-by-trade basis and do not bind the Sponsor or the Trust to continue to trade with any exchange. Under these arrangements, the Sponsor, on behalf of the Trust, will receive bitcoin from an exchange that has entered into a DVP/RVP arrangement with the Sponsor without having to deposit U.S. dollars with the exchange prior to trade execution. Once the Sponsor receives the bitcoin it purchased, the Sponsor will within 24 hours wire U.S. dollars to the exchange to settle the trade. When selling bitcoin on behalf of the Trust, an exchange that has entered into a DVP/RVP arrangement with the Sponsor will permit the Sponsor to sell bitcoin on the exchange without the need to deposit bitcoin with the exchange beforehand. The Sponsor will transmit bitcoin to the exchange only after the exchange has wired the U.S. dollar sales proceeds to the Sponsor. These DVP and RVP settlement terms reduce exchange counterparty risks for the Trust.

bitcoin exchange with significant trading volume, BTC-e does not comply with certain of the Sponsor's internal criteria regarding the exchanges on which the Sponsor will trade and, therefore, the Sponsor will not transact with BTC-e. The Sponsor represents that it is also aware of other smaller U.S. dollar-denominated bitcoin exchanges, but the trading volume on these exchanges is insignificant and the Sponsor does not intend to conduct business with these smaller exchanges.

Bitcoin Price Transparency

According to the Registration Statement, bitcoin trading currently occurs globally across over 30 bitcoin exchanges and trades against over 20 government currencies 24-hours per day, 365 days per year. Individual bitcoin exchanges continually publish publicly available price and volume data that is utilized by service providers to create various bitcoin indexes. Bitcoin prices are also available via major market data vendors such as Bloomberg and Thomson Reuters. Real-time and historical price data is available through numerous public web platforms including: *https://tradeblock.com/; http://www.coindesk.com/; https://bitcoinaverage.com;* and others.

Although the trading volumes on BTCC, Huobi and OKCoin Exchange China are significant, trading on these exchanges is limited to Chinese yuan, and the Sponsor therefore does not intend to transact with these exchanges. The Sponsor intends to transact with U.S. dollar-denominated exchanges only. However, the Sponsor represents that the price of bitcoin on BTCC, Huobi and OKCoin Exchange China generally has been consistent with the price of bitcoin on U.S. dollar-denominated bitcoin exchanges, including Bitfinex, Bitstamp, Coinbase, itBit and OKCoin International.

The Sponsor represents that because bitcoin trades on more than 30 exchanges globally on a 24-hour basis, it is difficult for attempted market manipulation on any one exchange to affect the global market price of bitcoin. Any such attempt to manipulate the price would result in an arbitrage opportunity among exchanges, which typically would be acted upon by market participants.

In addition to the price transparency of the bitcoin exchange market itself, the Trust will provide information regarding the Trust's bitcoin holdings as well as additional data regarding the Trust. The Sponsor expects that the dissemination of information on the Trust's Web site, along with quotations for and last-sale prices of transactions in the Shares and the intra-day indicative value (''IIV'') and net asset value (''NAV'') of the Trust will help to reduce the ability of market participants to manipulate the bitcoin market or the price of the Shares and that the Trust's arbitrage mechanism will facilitate the correction of price discrepancies in bitcoin and the Shares. The Sponsor believes that demand from new investors accessing bitcoin through investment in the Shares will broaden the investor base in bitcoin, which could further reduce the possibility of collusion among market participants to manipulate the bitcoin market.

According to the Sponsor, the XBX's price variance weighting, which decreases the influence on the XBX of any particular exchange that diverges from the rest of the data points used by the XBX, reduces the possibility of an attempt to manipulate the price of bitcoin as reflected by the XBX.

Bitcoin Trading Over-the-Counter

OTC trading of bitcoin is generally accomplished via bilateral agreements on a principal-to-principal basis. All risks and issues of credit are between the parties directly involved in the transaction. The OTC market provides a relatively flexible market in terms of quotes, price, size and other factors. The OTC market has no formal structure and no open-outcry meeting place. Parties engaging in OTC transactions will agree upon a price—often via phone or email—and one of the two parties would then initiate the transaction. For example, a seller of bitcoin could initiate the transaction by sending the bitcoin to the buyer's bitcoin address. The buyer would then wire U.S. dollars to the seller's bank account.

Based on its observations and experience in the market, the Sponsor estimates that the U.S. dollar OTC bitcoin trading volume globally represents on average approximately fifty percent of the trading volume of bitcoin traded globally in U.S. dollars on U.S. dollar-denominated bitcoin exchanges.

According to the Registration Statement, transaction costs in the OTC market are negotiable between the parties and therefore vary with some participants willing to offer competitive prices for larger volumes, although this will vary according to market conditions. Cost indicators can be obtained from various information service providers, such as the bitcoin price indexes and bitcoin exchanges. OTC trading tends to be in large blocks of bitcoin and between institutions.

In addition to using Bitfinex, Bitstamp, Coinbase, Gemini, itBit, Kraken and OKCoin International to buy and sell bitcoin, the Trust intends to participate in the OTC bitcoin market when such market opportunities are deemed by the Sponsor to be advantageous for the Trust. The Sponsor currently expects that often it will be more cost efficient to effect large trades (*e.g.,* $500,000 or greater) on behalf of the Trust in the OTC market rather than on a bitcoin exchange. The Sponsor

therefore expects to conduct most of its trading in the OTC bitcoin market.

When deciding whether to buy and sell bitcoin in the OTC market, the Sponsor will consider various market factors, including the total U.S. dollar size of the trade, the volume of bitcoin traded across the various U.S. dollar-denominated bitcoin exchanges during the preceding 24-hour period, available liquidity offered by OTC market participants and the bid and ask quotes offered by OTC market participants. The Sponsor's experience is that the prices at which trades in the OTC market are executed closely correspond to the XBX. The Sponsor expects the price at which it will trade bitcoin in the OTC market will generally track the XBX, and, therefore, should not affect the Trust's ability to track the XBX. The Sponsor also maintains an internal proprietary database, which it does not share with anyone, of potential OTC bitcoin trading counterparties, including hedge funds, family offices, private wealth managers and high-net-worth individuals. All such potential counterparties will be subject to the Sponsor's AML and KYC compliance procedures. The Sponsor will add additional potential counterparties to its internal proprietary database as it becomes aware of additional market participants. The Sponsor will decide whether or not to trade with OTC counterparties based on its ability to fill orders at the best available price amongst OTC market participants and bitcoin exchanges. Generally, the Sponsor will directly place purchase or sale orders for bitcoin on behalf of the Trust with participants in the OTC markets using DVP and RVP style arrangements.

While the Sponsor expects that most of its bitcoin trading with exchanges and OTC counterparties on behalf of the Trust will occur pursuant to DVP and RVP arrangements, the Sponsor may also enter into collateral arrangements with certain bitcoin exchanges and OTC counterparties where DVP and RVP arrangements are not practicable. Such collateral arrangements require the Sponsor, out of its own assets, and the bitcoin exchange or OTC counterparty to open and maintain collateral deposit accounts with a bank or similar financial intermediary for the purpose of collateralizing pending bitcoin transactions effected by the Sponsor on behalf of the Trust and the bitcoin exchange or OTC counterparty. The Trust would not pledge (or receive) collateral pursuant to these arrangements and the Sponsor would bear any exchange counterparty risk. The Sponsor represents that a default of an exchange or OTC counterparty under such arrangement would have no greater impact on the Trust than a default under the DVP and RVP arrangements.

To the extent a Basket creation or redemption order necessitates the buying or selling of a large block of bitcoin (*e.g.,* an amount that if an order were placed on an exchange would potentially move the price of bitcoin), the Sponsor represents that placing such a trade in the OTC market may be advantageous to the Trust. OTC trades help avoid factors such as potential price slippage (causing the price of bitcoin to move as the order is filled on the exchange), while offering speed in trade execution and settlement (an OTC trade can be executed immediately upon agreement of terms between counterparties) and privacy (to avoid other market participants entering trades in advance of a large block order).

OTC bitcoin trading is typically private and not regularly reported. For example, Genesis Global Trading and itBit release periodic reports that discuss their respective OTC trading volumes. The Trust does not intend to report its OTC trading.

Regardless of whether the Sponsor buys bitcoin on an exchange or in the OTC market, the Sponsor expects the Trust to take custody of bitcoin within one business day of receiving an order from an Authorized Participant to create a Basket (as defined in ''Creation and Redemption of Shares'' below).

Historical Chart of the Price of Bitcoin

The price of bitcoin is volatile and fluctuations are expected to have a direct impact on the value of the Shares. However, movements in the price of bitcoin in the past are not a reliable indicator of future movements. Movements may be influenced by various factors, including supply and demand, geo-political uncertainties, economic concerns such as inflation and real or speculative investor interest.[24]

Additional Bitcoin Trading Products

Certain non-U.S. based bitcoin exchanges offer derivative products on bitcoin such as options, swaps and futures.

According to the Registration Statement, BitMex (based in the Republic of Seychelles), CryptoFacilites (based in the United Kingdom), 796 Exchange (based in China) and OKCoin Exchange China all offer futures contracts settled in bitcoin. Coinut, based in Singapore, offers bitcoin binary options and vanilla options based on the Coinut index. Nadex, based in Chicago, offers bitcoin binary options denominated in U.S. dollars using the TeraBit Bitcoin Price Index.[25] IGMarkets (based in the United Kingdom), Avatrade (based in Ireland) and Plus500 (based in Israel) also offer bitcoin derivative products.

The Commodity Futures Trading Commission (''CFTC'') has approved TeraExchange, LLC as a swap execution facility (''TeraExchange'') and LedgerX provisionally as a swap execution facility, where bitcoin swap and non-deliverable forward contracts may be entered into.

The CFTC commissioners have expressed publicly that derivatives based on bitcoin are subject to regulation by the CFTC, including oversight to prevent market manipulation of the price of bitcoin. In addition, the CFTC has stated that bitcoin and other virtual currencies are encompassed in the definition of commodities under the CEA.[26]

In May 2015, the Swedish FSA approved the prospectus for ''Bitcoin Tracker One'', an open-ended exchange-traded note that tracks the price of bitcoin in U.S. dollars. The Bitcoin Tracker One initially traded in Swedish krona on the Nasdaq Nordic in Stockholm, but is now also available to trade in euro. The Bitcoin Tracker One is available to retail investors in the European Union and to those investors in the U.S. who maintain brokerage accounts with Interactive Brokers. Founded in 2013, Bitcoin Investment Trust, a private, open-ended trust available to accredited investors, is another investment vehicle that derives

[24] Attached as Exhibit 3, Item 2 is a chart illustrating the changes in the price of bitcoin during the period July 2010 through March 2016. Attached as Exhibit 3, Item 3 is a chart comparing the trailing calendar month volatility in the price of bitcoin compared to the trailing calendar month volatility in the prices of gold, platinum, copper and oil during the period May 1, 2014 through May 31, 2016 (excluding holidays and weekends). Attached as Exhibit 3, Item 4 is a chart comparing the trailing calendar month volatility in the price of bitcoin compared to the trailing calendar month volatility in the prices of gold, platinum, copper and oil during the period March 1, 2016 through May 31, 2016 (excluding holidays and weekends).

[25] The TeraBit Bitcoin Price Index is disseminated by TeraExchange.

[26] *See* ''In the Matter of Coinflip, Inc.'' (CFTC Docket 15–29 (September 17, 2015)) (order instituting proceedings pursuant to Sections 6(c) and 6(d) of the CEA, making findings and imposing remedial sanctions), in which the CFTC stated the following:

''Section 1a(9) of the CEA defines 'commodity' to include, among other things, 'all services, rights, and interests in which contracts for future delivery are presently or in the future dealt in.' 7 U.S.C. 1a(9). The definition of a 'commodity' is broad. *See, e.g.,* Board of Trade of City of Chicago v. SEC, 677 F. 2d 1137, 1142 (7th Cir. 1982). Bitcoin and other virtual currencies are encompassed in the definition and properly defined as commodities.''

its value from the price of bitcoin. Eligible shares of the Bitcoin Investment Trust are quoted on the OTCQX marketplace under the symbol ''GBTC''.

Bitcoin Security and Storage for the Trust

According to the Sponsor, given the novelty and unique digital characteristics (as set forth above) of bitcoin as an innovative asset class, traditional custodians who normally custody assets do not currently offer custodial services for bitcoin. Accordingly, the Sponsor will secure the bitcoin held by the Trust using multi-signature ''cold storage wallets'', an industry best practice. A cold storage wallet is created and stored on a computer with no access to a network, *i.e.,* an ''air-gapped'' computer with no ability to access the Internet. Such a computer is isolated from any network, including local or Internet connections. A multi-signature address is an address associated with more than one private key. For example, a ''2 of 3'' address requires two signatures (out of three) from two separate private keys (out of three) to move bitcoin from a sender address to a receiver address.

The Sponsor will utilize bitcoin private keys that are generated and stored on air-gapped computers. The movement of bitcoin will require physical access to the air-gapped computers and use of multiple authorized signers. For backup and disaster recovery purposes, the Sponsor will maintain cold wallet backups in locations geographically distributed throughout the United States, including in the Northeast and Midwest.

In addition to the Sponsor's security system, the Sponsor has arranged for the Trust to maintain comprehensive insurance coverage underwritten by various insurance carriers. The purpose of the insurance is to protect investors against loss or theft of the Trust's bitcoin. The insurance will cover loss of bitcoin by, among other things, theft, destruction, bitcoin in transit, computer fraud (*i.e.,* hacking attack) and other loss of the private keys that are necessary to access the bitcoin held by the Trust. The coverage is subject to certain terms, conditions and exclusions, as discussed in the Registration Statement. The insurance policy will carry initial limits of $25 million in primary coverage and $100 million in excess coverage, with the ability to increase coverage depending on the value of the bitcoin held by the Trust.

The Sponsor expects that the Trust's auditor will verify the existence of bitcoin held in custody by the Trust. In addition, the Trust's insurance carriers will have inspection rights associated with the bitcoin held in custody by the Trust.

Bitcoin Market Price

In the ordinary course of business, the Administrator will value the bitcoin held by the Trust based on the price set by the XBX as of 4:00 p.m., E.T., on the valuation date on any day that the NYSE Arca is open for regular trading. For further detail, *see* (i) below. If the procedures described in (i) fail and the Administrator is unable to value the Trust's bitcoin using the procedures described in (i), the Administrator will value the Trust's bitcoin using the cascading set of rules set forth in (ii) through (iv) below; the methodology used to established the value of the bitcoin held by the Trust will be the ''bitcoin Market Price''. For the avoidance of doubt, the Administrator will employ the below rules sequentially and in the order as presented, should the Sponsor determine that one or more specific rule(s) fails. The Sponsor may determine that a rule has failed if the pricing source is unavailable or, in the judgment of the Sponsor, is deemed unreliable. To the extent the Administrator uses any of the cascading set of rules, the Sponsor will make public on the Trust's Web site the rule being used.

(i) bitcoin Market Price = The price set by the XBX as of 4:00 p.m., E.T., on the valuation date. The XBX is a real-time U.S. dollar-denominated composite reference rate for the price of bitcoin. The XBX calculates the intra-day price of bitcoin every second, including the closing price as of 4:00 p.m., E.T. The intra-day price and closing price are based on a methodology that consists of collecting and cleansing actual trade data from several bitcoin exchanges included within the XBX. TradeBlock uses standardized eligibility criteria based on periodically-reviewed governance principles to select trading venues for inclusion in the XBX. As of June 30, 2016, the eligible bitcoin exchanges selected by TradeBlock for inclusion in the XBX are Bitfinex, Bitstamp, Coinbase, itBit and OKCoin International. The logic utilized for the derivation of the daily closing index level is intended to analyze actual bitcoin transactional data, verify and refine the data set and yield an objective, fair-market value of one bitcoin as of 4:00 p.m., E.T., each weekday, priced in U.S. dollars.

(ii) bitcoin Market Price = The price set by the CoinDesk Bitcoin Price Index XBP as of 4:00 p.m., E.T., on the valuation date. The XBP is a U.S. dollar-denominated composite reference rate for the price of bitcoin based on the volume-weighted price at trading venues selected by CoinDesk. Trading venues used to calculate the XBP may include bitcoin exchanges, OTC markets or derivative platforms. CoinDesk uses its discretion to select trading venues that will be included in the XBP based on guidelines, including depth of liquidity, compliance with applicable legal and regulatory requirements, data availability, domicile in the United States and acceptance of U.S. dollar deposits. To calculate the reference rate, trade data is cleansed and compiled in such a manner as to algorithmically reduce the impact of anomalistic or manipulative trading. This is accomplished by adjusting the weight of each data input based on price deviation relative to the observable set of data for the relevant trading venue, as well as recent and long-term trading volume at each venue relative to the observable set for the relevant trading venues. To calculate volume-weighted price, the weighting algorithm is applied to the price and volume of all inputs for the immediately preceding 24-hour period at 4:00 p.m., E.T., on the valuation date.

(iii) bitcoin Market Price = The volume-weighted average bitcoin price for the immediately preceding 24-hour period at 4:00 p.m., E.T., on the valuation date as published by an alternative third party's public data feed that the Sponsor determines is reasonably reliable, subject to the requirement that such data is calculated based upon a volume-weighted average bitcoin price obtained from the major U.S. dollar-denominated bitcoin exchanges (''Second Source''). Subject to the next sentence, if the Second Source becomes unavailable (*e.g.,* data sources from the Second Source for bitcoin prices become unavailable, unwieldy or otherwise impractical for use), or if the Sponsor determines in good faith that the Second Source does not reflect an accurate bitcoin price, then the Sponsor will, on a best efforts basis, contact the Second Source in an attempt to obtain the relevant data. If after such contact the Second Source remains unavailable or the Sponsor continues to believe in good faith that the Second Source does not reflect an accurate bitcoin price, then the Administrator will employ the next rule to determine the bitcoin Market Price.

(iv) bitcoin Market Price = The Sponsor will use its best judgment to determine a good faith estimate of the bitcoin Market Price.

The Trust

According to the Registration Statement, the Trust will invest in bitcoin only. The Trust will cause the Sponsor to either (i) receive bitcoin from the Trust in such quantity as may be necessary to pay the Sponsor's management fee and other Trust expenses and liabilities not assumed by the Sponsor or (ii) sell bitcoin in such quantity as may be necessary to permit payment in cash of the Sponsor's management fee and other Trust expenses and liabilities not assumed by the Sponsor. As a result, the amount of bitcoin sold will vary from time to time depending on the level of the Trust's expenses and the market price of bitcoin.

The Trust will pay the Sponsor a management fee as compensation for services performed on behalf of the Trust and for services performed in connection with maintaining the Trust. The Sponsor's fee will be payable monthly in arrears and will be accrued daily.

The Sponsor will be responsible for paying all of the routine operational, administrative and other ordinary expenses of the Trust, including, but not limited to, the fees and expenses of the Trustee and Administrator, custody fees, transfer agency fees, distribution and marketing fees, up to $100,000 per annum in legal fees, audit and accounting fees and expenses, filing fees, exchange listing fees and printing, mailing and duplication costs. The Sponsor will also be responsible for paying the premiums associated with the insurance coverage of the bitcoin held by the Trust. The Trust will be responsible for paying, or for reimbursing the Sponsor or its affiliates for paying, all the extraordinary fees and expenses, if any, of the Trust. The management fee to be paid to the Sponsor is expected to be the only ordinary recurring operating expense of the Trust.

Net Asset Value

The NAV for the Trust will equal the market value of the Trust's total assets, including bitcoin and cash, less liabilities of the Trust, which include estimated accrued but unpaid fees, expenses and other liabilities. Under the Trust's proposed operational procedures, the Administrator will calculate the NAV on each business day that the NYSE Arca is open for regular trading, as promptly as practicable after 4:00 p.m., E.T. To calculate the NAV, the Administrator will use the bitcoin Market Price. The Administrator will also determine the NAV per Share by dividing the NAV of the Trust by the number of the Shares outstanding as of the close of trading on the NYSE Arca Core Trading Session, *i.e.,* 9:30 a.m. to 4:00 p.m., E.T. (which includes the net number of any Shares deemed created or redeemed on such day).

According to the Registration Statement, Authorized Participants (as defined in ''Creation and Redemption of Shares'' below), or their clients or customers, may have an opportunity to realize a riskless profit if they can create a Basket (as defined in ''Creation and Redemption of Shares'' below) at a discount to the public trading price of the Shares or can redeem a Basket at a premium over the public trading price of the Shares. The Sponsor expects that the exploitation of such arbitrage opportunities by Authorized Participants and their clients and customers will tend to cause the public trading price to track NAV per Share closely over time. Such arbitrage opportunities will not be available to holders of Shares who are not Authorized Participants.

The Sponsor represents that bitcoin is a bearer asset, so unlike most financial assets within the modern financial system, Authorized Participants seeking to acquire quantities of bitcoin will require specialized knowledge to source and secure the bitcoin. Such potential holders of bitcoin without sufficient technological knowledge will encounter both counterparty and custodial issues that will effectively lock them out of accessing the bitcoin market. Therefore, although there is nothing preventing Authorized Participants from participating directly in the bitcoin market, the Sponsor believes, based on the current state of the bitcoin market and its participants, many probably will not until such time as the bitcoin market matures so that the technological, counterparty and custodial issues evolve to become similar to those of traditional financial instruments. Notwithstanding the foregoing, the Sponsor believes, based on conversations with market participants, that one or more Authorized Participants and/or market makers may be interested in participating directly in the bitcoin market and creating or redeeming Baskets in-kind.

According to the Sponsor, whether creating and redeeming baskets in-kind or for cash, Authorized Participants and market makers can hedge their exposure to bitcoin using non-deliverable forward contracts (''NDFs'') and swap contracts that will create synthetic long and short exposure to bitcoin. NDFs will be offered by several participants in the bitcoin marketplace, including bitcoin exchanges, bitcoin OTC market participants and the Sponsor itself, operating on a principal basis. Such arrangements make it possible for Authorized Participants that lack the trading infrastructure to transact in bitcoin to be able to hedge their exposure by entering into an NDF or swap contract. Accordingly, an Authorized Participant may hedge its exposure to bitcoin without the need to custody bitcoin, or to engage a third party to custody bitcoin. In addition, to the extent requested by Authorized Participants and market makers, the Sponsor will act as agent by buying and selling bitcoin on behalf of the Authorized Participants and market makers, including short sale orders for hedging purposes.

The NDF and swap contracts that the Sponsor will enter into as agent on behalf of the Authorized Participants and market makers will be bespoke, OTC and cash settled. The terms of the NDF and swap contracts will be negotiated between the counterparties to the NDF and swap contracts. The NDF and swap contracts may be traded electronically on at least one swap execution facility. Generally, the NDF and swap contract strike prices will be based on the bitcoin spot price, as determined by the XBX, or other pricing source as agreed to between the NDF and swap contract counterparties, when the contract is entered into. The NDF termination price will be based on the NAV of the Trust determined as of 4:00 p.m., E.T. The terms of the NDF and swap contracts will be governed by International Swaps and Derivatives Associations, Inc. (''ISDA'') agreements. The ISDA terms, including to the extent necessary any collateral arrangements, will be negotiated between the counterparties to the NDF and swap contracts.

While the Trust's investment objective is to seek to provide shareholders with exposure to the daily change in the U.S. dollar price of bitcoin, before expenses and liabilities of the Trust, as measured by the XBX, the Shares may trade in the secondary market at prices that are lower or higher relative to their NAV per Share.

The NAV per Share may fluctuate with changes in the market value of the bitcoin held by the Trust. The value of the Shares may be influenced by non-concurrent trading hours between NYSE Arca and the various bitcoin exchanges comprising the XBX, all of which constituent bitcoin exchanges operate 24 hours per day, 365 days per year. As a result, there will be periods when the NYSE Arca is closed and such bitcoin exchanges continue to trade. Significant

changes in the price of bitcoin on such exchanges could result in a difference in performance between the value of bitcoin as measured by the XBX and the most recent NAV per Share or closing trading price. The non-concurrent trading hours also may result in trading spreads and the resulting premium or discount on the Shares widening, increasing the difference between the price of the Shares and the NAV of such Shares.

The price difference may also be due to the fact that supply and demand forces at work in the secondary trading market for Shares are closely related, but not identical, to the same forces influencing the XBX spot price. Consequently, an Authorized Participant may be able to create or redeem a Basket of Shares at a discount or a premium to the public trading price per Share.

Impact on Arbitrage

Investors and market participants are able throughout the trading day to compare the market price of the Shares and the Share's IIV. According to the Sponsor, if the market price of the Shares diverges significantly from the IIV, Authorized Participants will have an incentive to execute arbitrage trades. Because of the potential for arbitrage inherent in the structure of the Trust, the Sponsor believes that the Shares will not trade at a material discount or premium to the underlying bitcoin held by the Trust. The arbitrage process, which in general provides investors the opportunity to profit from differences in prices of assets, increases the efficiency of the markets, serves to prevent potentially manipulative efforts, and can be expected to operate efficiently in the case of the Shares and bitcoin.

For example, if the Shares appear to be trading at a discount compared to the IIV, an Authorized Participant could buy the Shares on the NYSE Arca and simultaneously hedge their exposure to the price of the Shares by entering into an NDF or swap contract—in a dollar amount equal to the aggregate price of the Shares bought—that would provide the Authorized Participant with synthetic short exposure to bitcoin. The Authorized Participant then could redeem a Basket at NAV and realize a profit. Conversely, if the Shares appear to be trading at a premium compared to the IIV, an Authorized Participant could sell short the Shares on the NYSE Arca and simultaneously hedge their exposure to the short sale by entering into an NDF or swap contract—in a dollar amount equal to the aggregate price of the Shares sold—that would provide the Authorized Participant with synthetic long exposure to bitcoin. The Authorized Participant then could create a Basket at NAV, use those newly created Shares to cover the short sale and realize a profit. Such arbitrage trades can tighten the tracking between the market price of the Shares and the IIV and thus can be beneficial to all market participants.

Creation and Redemption of Shares

According to the Registration Statement, the Trust will issue and redeem ''Baskets'', each equal to a block of 10,000 Shares, only to ''Authorized Participants'' (as described below). The size of a Basket is subject to change. The creation and redemption of Baskets will principally be made in exchange for the delivery to the Trust or the distribution by the Trust of the amount of cash or bitcoin represented by the combined NAV of the Baskets being created or redeemed, the amount of which will be based on the combined bitcoin represented by the number of Shares included in the Baskets being created or redeemed determined on the day the order to create or redeem Baskets is properly received.

Orders to create and redeem Baskets may be placed only by Authorized Participants.[27] A transaction fee will be assessed on all creation and redemption transactions effected in-kind. In addition, a variable transaction fee will be charged to the Authorized Participants for creations and redemptions effected in cash to cover the Trust's expenses related to purchasing and selling bitcoin on bitcoin exchanges or in OTC transactions. Such expenses may vary, but the Trust currently expects such expenses to constitute 1% or less of the value of a Basket.

Creation Procedures

On any business day, an Authorized Participant may place an order with the Administrator to create one or more Baskets. For purposes of processing both purchase and redemption orders, a ''business day'' means any day other than a day when the NYSE Arca is closed for regular trading. Purchase orders must be placed by 1:00 p.m., E.T. The day on which the Administrator receives a valid purchase order is the ''purchase order date''. Purchase orders are irrevocable. By placing a purchase order, and prior to delivery of such Baskets, an Authorized Participant's DTC account will be charged the non-refundable transaction fee due for the purchase order.

Determination of Required Payment

The total payment required to create each Basket is determined by calculating the NAV of 10,000 Shares of the Trust as of the closing time of the NYSE Arca Core Trading Session on the purchase order date. Baskets are issued as of 9:30 a.m., E.T., on the business day immediately following the purchase order date at the applicable NAV as of the closing time of the NYSE Arca Core Trading Session on the purchase order date, but only if the required payment has been timely received.

Orders to purchase Baskets must be placed no later than 1:00 p.m., E.T., but the total payment required to create a Basket will not be determined until 4:00 p.m., E.T., on the date the purchase order is received. Authorized Participants therefore will not know the total amount of the payment required to create a Basket at the time they submit an irrevocable purchase order for the Basket. Valid orders to purchase Baskets received after 1:00 p.m., E.T., are considered received on the following business day. The NAV of the Trust and the total amount of the payment required to create a Basket could rise or fall substantially between the time an irrevocable purchase order is submitted and the time the amount of the purchase price in respect thereof is determined.

The payment required to create a Basket typically will be made in cash, but it may also be made partially or wholly in-kind at the discretion of the Sponsor if the Authorized Participant requests to convey bitcoin directly to the Trust. To the extent the Authorized Participant places an in-kind order to create, the Authorized Participant must deliver bitcoin directly to the Sponsor (*i.e.,* to the security system that holds the Trust's bitcoin) and an amount of cash referred to as the ''Cash Component'', computed as described below, each no later than 1:00 p.m., E.T., on the date the purchase order is received. The amount of bitcoin delivered by the Authorized Participant must be in an amount equal to the number of bitcoin necessary to create a Basket as of 4:00 p.m., E.T., on the date the purchase order is received. Upon delivery of the bitcoin to the Sponsor's security system and the Cash

[27] An Authorized Participant must: (1) Be a registered broker-dealer or other securities market participant, such as a bank or other financial institution, which, but for an exclusion from registration, would be required to register as a broker-dealer to engage in securities transactions and (2) be a participant in Depository Trust Company (''DTC''). To become an Authorized Participant, a person must enter into an ''Authorized Participant Agreement'' with the Sponsor and the Administrator. The Authorized Participant Agreement provides the procedures for the creation and redemption of Baskets and for the delivery of the cash (and, potentially, bitcoin in-kind) required for such creations and redemptions.

Component to the Custodian, the Administrator will cause the Trust to issue a Basket to the Authorized Participant. Expenses relating to purchasing bitcoin in assembling an in-kind creation Basket, such as bitcoin exchange-related fees and transaction fees, will be borne by Authorized Participants. With respect to creations in cash, Authorized Participants will be charged a variable transaction fee to cover expenses as set forth above.

The Cash Component is an amount equal to the difference between the NAV of the Shares (per Basket) and the ''Deposit Amount'', which is an amount equal to the market value of bitcoin (per Basket) which, for this purpose, is calculated in the same manner as the Trust values its bitcoin as set forth in ''bitcoin Market Price'' above. The Cash Component serves to compensate for any difference between the NAV per Basket and the Deposit Amount. Payment of any tax or other fees and expenses payable upon transfer of bitcoin shall be the sole responsibility of the Authorized Participant purchasing a Basket.

The Sponsor makes available through the National Securities Clearing Corporation (''NSCC'') on each business day, prior to the opening of business on the NYSE Arca, the amount of bitcoin required for an in-kind creation of a Basket. This amount is applicable in order to effect in-kind purchases of Baskets until such time as the next-announced amount is made available.

Rejection of Purchase Orders

The Administrator may reject a purchase order if: (i) It determines that the purchase order is not in proper form; (ii) the Administrator or the Sponsor believes the purchase order would have adverse tax consequences to the Trust or the shareholders; or (iii) circumstances outside the control of the Sponsor make it, for all practical purposes, not feasible to process creations of Baskets. The Administrator may reject a purchase order if the Sponsor thinks it is necessary or advisable for any reason, which the Sponsor determines is in the best interests of the Trust or shareholders.

Redemption Procedures

The procedures by which an Authorized Participant can redeem one or more Baskets mirror the procedures for the creation of Baskets. On any business day, an Authorized Participant may place an order with the Administrator to redeem one or more Baskets. Redemption orders must be placed no later than 1:00 p.m., E.T. The day on which the Administrator receives a valid redemption order is the ''redemption order date''. Redemption orders are irrevocable. The redemption procedures allow only Authorized Participants to redeem Baskets.

By placing a redemption order, an Authorized Participant agrees to deliver the Baskets to be redeemed through DTC's book-entry system to the Trust not later than 1:00 p.m., E.T., on the business day immediately following the redemption order date. By placing a redemption order, and prior to receipt of the redemption proceeds, an Authorized Participant's DTC account will be charged the non-refundable transaction fee due for the redemption order.

Determination of Redemption Proceeds

The redemption proceeds from the Trust consist of the ''cash redemption amount'' and, if making an in-kind redemption, bitcoin. The cash redemption amount is equal to the combined NAV of the number of Baskets of the Trust requested in the Authorized Participant's redemption order as of the closing time of the NYSE Arca Core Trading Session on the redemption order date. The Administrator will distribute the cash redemption amount at 4:00 p.m., E.T., on the business day immediately following the redemption order date through DTC to the account of the Authorized Participant as recorded on DTC's book-entry system. At the discretion of the Sponsor and if the Authorized Participant requests to receive bitcoin directly, some or all of the redemption proceeds may be distributed to the Authorized Participant in-kind.

Orders to redeem Baskets must be placed no later than 1:00 p.m., E.T., but the total amount of redemption proceeds typically will not be determined until after 4:00 p.m., E.T., on the date the redemption order is received. Authorized Participants therefore will not know the total amount of the redemption proceeds at the time they submit an irrevocable redemption order.

Delivery of Redemption Proceeds

The redemption proceeds due from the Trust are delivered to the Authorized Participant at 4:00 p.m., E.T., on the business day immediately following the redemption order date if, by such time on such business day immediately following the redemption order date, the Trust's DTC account has been credited with the Baskets to be redeemed. If the Trust's DTC account has not been credited with all of the Baskets to be redeemed by such time, the redemption distribution is delivered to the extent of whole Baskets received. Any remainder of the redemption distribution is delivered on the next business day to the extent of remaining whole Baskets received if the Sponsor receives the fee applicable to the extension of the redemption distribution date which the Sponsor may, from time to time, determine and the remaining Baskets to be redeemed are credited to the Trust's DTC account by 4:00 p.m., E.T., on such next business day. Any further outstanding amount of the redemption order shall be cancelled. The Sponsor will also be authorized to deliver the redemption distribution notwithstanding that the Baskets to be redeemed are not credited to the Trust's DTC account by 4:00 p.m., E.T., on the business day immediately following the redemption order date if the Authorized Participant has collateralized its obligation to deliver the Baskets through DTC's book-entry system on such terms as the Sponsor may determine from time to time.

In the case of in-kind redemptions, the Sponsor makes available through the NSCC, prior to the opening of business on the NYSE Arca on each business day, the amount of bitcoin per Basket that will be applicable to redemption requests received in proper form.

To the extent the Authorized Participant places an in-kind order to redeem a Basket, the Sponsor will deliver, on the business day immediately following the day the redemption order is received, bitcoin to the Authorized Participant in an amount equal to the number of bitcoin necessary to redeem a Basket as of 4:00 p.m., E.T. Expenses relating to transferring bitcoin to an Authorized Participant in a redemption Basket will be borne by Authorized Participants via the redemption transaction fee. With respect to redemptions in cash, Authorized Participants will be charged a variable transaction fee to cover expenses as set forth above.

Suspension or Rejection of Redemption Orders

The Administrator may, in its discretion, suspend the right of redemption or postpone the redemption settlement date (1) for any period during which an emergency exists as a result of which the redemption distribution is not reasonably practicable or (2) for such other period as the Sponsor determines to be necessary for the protection of the shareholders. None of the Sponsor, the Administrator or the Custodian will be liable to any person or in any way for any loss or damages that may result from any such suspension or postponement.

The Administrator will reject a redemption order if the order is not in proper form as described in the Authorized Participant Agreement or if the fulfillment of the order, in the opinion of its counsel, might be unlawful.

Availability of Information

The Trust's Web site will provide an intra-day indicative value (''IIV'') per Share updated every 15 seconds, as calculated by the Exchange or a third party financial data provider during the Exchange's Core Trading Session. The IIV will be calculated by using the prior day's closing NAV per Share as a base and updating that value during the NYSE Arca Core Trading Session to reflect changes in the value of the Trust's bitcoin holdings during the trading day.

The IIV disseminated during the NYSE Arca Core Trading Session should not be viewed as an actual real-time update of the NAV, which will be calculated only once at the end of each trading day. The IIV will be widely disseminated on a per Share basis every 15 seconds during the NYSE Arca Core Trading Session by one or more major market data vendors. In addition, the IIV will be published on the NYSE Global Index Feed and will be available through on-line information services such as Bloomberg and Reuters.

The Web site for the Trust, which will be publicly accessible at no charge, will contain the following information: (a) The current NAV per Share daily and the prior business day's NAV and the reported closing price; (b) the mid-point of the bid-ask price [28] in relation to the NAV as of the time the NAV is calculated (''Bid-Ask Price'') and a calculation of the premium or discount of such price against such NAV; (c) data in chart form displaying the frequency distribution of discounts and premiums of the Bid-Ask Price against the NAV, within appropriate ranges for each of the four previous calendar quarters (or for the life of the Trust, if shorter); (d) the prospectus; and (e) other applicable quantitative information. The Trust will also disseminate the Trust's holdings on a daily basis on the Trust's Web site. The price of bitcoin will be made available by one or more major market data vendors, updated at least every 15 seconds during the Exchange's Core Trading Session. Information about the XBX, including key elements of how the XBX algorithm is calculated, is publicly available at *https://tradeblock.com/markets/index/.*

The NAV for the Trust will be calculated by the Administrator once a day and will be disseminated daily to all market participants at the same time. The Exchange will also make available on its Web site daily trading volume of the Shares, closing prices of the Shares and the corresponding NAV for the Trust. In addition, bitcoin prices are available from automated quotation systems, published or other public sources or on-line information services such as Bloomberg or Reuters. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the Consolidated Tape Association (''CTA'').

Quotation and last sale information for bitcoin will be widely disseminated through a variety of major market data vendors, including Bloomberg and Reuters. In addition, the complete real-time price (and volume) data for bitcoin is available by subscription from Reuters and Bloomberg. The spot price of bitcoin is available on a 24-hour basis from major market data vendors, including Bloomberg and Reuters. Information relating to trading, including price and volume information, in bitcoin will be available from major market data vendors and from the exchanges on which bitcoin are traded. The normal trading hours for bitcoin exchanges are 24-hours per day, 365-days per year.

The Trust will provide Web site disclosure of its bitcoin holdings daily. The Web site disclosure of the Trust's portfolio composition will occur at the same time as the disclosure by the Sponsor of the portfolio composition to Authorized Participants so that all market participants are provided portfolio composition information at the same time. Therefore, the same portfolio information will be provided on the public Web site as well as in electronic files provided to Authorized Participants. Accordingly, each investor will have access to the current portfolio composition of the Trust through the Trust's Web site.

Trading Rules

The Trust will be subject to the criteria in NYSE Arca Equities Rule 8.201, including 8.201(e), for initial and continued listing of the Shares. A minimum of 100,000 Shares will be required to be outstanding at the start of trading. With respect to application of Rule 10A–3 under the Act, the Trust will rely on the exception contained in Rule 10A–3(c)(7). The Exchange believes that the anticipated minimum number of Shares outstanding at the start of trading is sufficient to provide adequate market liquidity.

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Trading in the Shares on the Exchange will occur in accordance with NYSE Arca Equities Rule 7.34(a). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Equities Rule 7.6, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00 for which the MPV for order entry is $0.0001.

Further, NYSE Arca Equities Rule 8.201 sets forth certain restrictions on Equity Trading Permit Holders (''ETP Holders'') acting as registered Market Makers in the Shares to facilitate surveillance. Pursuant to NYSE Arca Equities Rule 8.201(g), an ETP Holder acting as a registered Market Maker in the Shares is required to provide the Exchange with information relating to its trading in the underlying bitcoin, related futures or options on futures or any other related derivatives. Commentary .04 of NYSE Arca Equities Rule 6.3 requires an ETP Holder acting as a registered Market Maker, and its affiliates, in the Shares to establish, maintain and enforce written policies and procedures reasonably designed to prevent the misuse of any material nonpublic information with respect to such products, any components of the related products, any physical asset or commodity underlying the product, applicable currencies, underlying indexes, related futures or options on futures and any related derivative instruments (including the Shares).

As a general matter, the Exchange has regulatory jurisdiction over its ETP Holders and their associated persons, which include any person or entity controlling an ETP Holder. A subsidiary or affiliate of an ETP Holder that does business only in commodities or futures contracts would not be subject to Exchange jurisdiction, but the Exchange could obtain information regarding the activities of such subsidiary or affiliate through surveillance sharing agreements with regulatory organizations of which such subsidiary or affiliate is a member.

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares. Trading on the Exchange in the Shares may be halted because of market

[28] The bid-ask price of the Trust is determined using the highest bid and lowest offer on the Consolidated Tape as of the time of calculation of the closing day NAV.

conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which conditions in the underlying bitcoin markets have caused disruptions and/or lack of trading or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. In addition, trading in Shares will be subject to trading halts caused by extraordinary market volatility pursuant to the Exchange's ''circuit breaker'' rule.[29]

The Exchange will halt trading in the Shares if the NAV of the Trust is not calculated or disseminated daily. The Exchange may halt trading during the day in which an interruption occurs to the dissemination of the IIV or to the dissemination of bitcoin pricing data by one or more bitcoin Market Price sources. If the interruption to the dissemination of the IIV or the value of bitcoin persists past the trading day in which it occurs, the Exchange will halt trading no later than the beginning of the trading day following the interruption.[30] In addition, if the Exchange becomes aware that the NAV with respect to the Shares is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants.

Surveillance

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by the Financial Industry Regulatory Authority (''FINRA'') on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[31] The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares with other markets and other entities that are members of the Intermarket Surveillance Group (''ISG''), and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement (''CSSA'').[32]

Also, pursuant to NYSE Arca Equities Rule 8.201(g), the Exchange is able to obtain information regarding trading in the Shares and the underlying bitcoin or any bitcoin derivative through ETP Holders acting as registered Market Makers, in connection with such ETP Holders' proprietary or customer trades through ETP Holders which they effect on any relevant market.

The Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

All statements and representations made in this filing regarding (i) the description of the portfolio, (ii) limitations on portfolio holdings or reference assets or (iii) the applicability of Exchange rules and surveillance procedures shall constitute continued listing requirements for listing the Shares on the Exchange.

The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Equities Rule 5.5(m).

Information Bulletin

Prior to the commencement of trading, the Exchange will inform its ETP Holders in an ''Information Bulletin'' of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (1) The procedures for purchases and redemptions of Shares in Baskets (including noting that the Shares are not individually redeemable); (2) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) how information regarding how the Index and the IIV are disseminated; (4) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; (5) the possibility that trading spreads and the resulting premium or discount on the Shares may widen during the Opening and Late Trading Sessions, when an updated IIV will not be calculated or publicly disseminated; and (6) trading information. For example, the Information Bulletin will advise ETP Holders, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Trust. The Exchange notes that investors purchasing Shares directly from the Trust will receive a prospectus. ETP Holders purchasing Shares from the Trust for resale to investors will deliver a prospectus to such investors.

In addition, the Information Bulletin will reference that the Trust is subject to various fees and expenses as described in the Registration Statement. The Information Bulletin will disclose that information about the Shares of the Trust is publicly available on the Trust's Web site.

The Information Bulletin will also discuss any relief, if granted, by the Commission or the staff from any rules under the Act.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)[33] that an exchange have rules that are 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, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange

[29] *See* NYSE Arca Equities Rule 7.12.

[30] The Exchange notes that the Exchange may halt trading during the day in which an interruption to the dissemination of the IIV or the value of bitcoin occurs.

[31] FINRA conducts cross market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[32] For the list of current members of ISG, *see https://www.isgportal.org/home.html.*

[33] 15 U.S.C. 78f(b)(5).

pursuant to the initial and continued listing criteria in NYSE Arca Equities Rule 8.201. The Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares with other markets that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares from such markets. In addition, the Exchange may obtain information regarding trading in the Shares from markets that are members of ISG or with which the Exchange has in place a CSSA. Also, pursuant to NYSE Arca Equities Rule 8.201(g), the Exchange is able to obtain information regarding trading in the Shares and the underlying bitcoin or any bitcoin derivative through ETP Holders acting as registered Market Makers, in connection with such ETP Holders' proprietary or customer trades through ETP Holders which they effect on any relevant market.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that there is a considerable amount of bitcoin price and bitcoin market information available on public Web sites and through professional and subscription services. Investors may obtain on a 24-hour basis bitcoin pricing information based on the spot price for bitcoin from various financial information service providers. The closing price and settlement prices of bitcoin are readily available from the bitcoin exchanges and other publicly available Web sites. In addition, such prices are published in public sources or on-line information services such as Bloomberg and Reuters. The Trust will provide Web site disclosure of its bitcoin holdings daily. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA. The IIV will be widely disseminated on a per Share basis every 15 seconds during the NYSE Arca Core Trading Session by one or more major market data vendors. In addition, the IIV will be published on the NYSE Global Index Feed and will be available through on-line information services such as Bloomberg and Reuters. The Exchange represents that the Exchange may halt trading during the day in which an interruption to the dissemination of the IIV or the value of bitcoin occurs. If the interruption to the dissemination of the IIV or the value of bitcoin persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption. In addition, if the Exchange becomes aware that the NAV with respect to the Shares is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants. The NAV per Share will be calculated daily and made available to all market participants at the same time. One or more major market data vendors will disseminate for the Trust on a daily basis information with respect to the recent NAV per Share and Shares outstanding.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a CSSA. In addition, as noted above, investors will have ready access to information regarding the Trust's bitcoin holdings, IIV and quotation and last sale information for the Shares.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that the proposed rule change will facilitate the listing and trading of an additional type of exchange-traded product, and the first such product based on bitcoin, which will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will: (a) By order approve or disapprove such proposed rule change; or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2016–101 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–NYSEArca–2016–101. 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 the

filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2016–101 and should be submitted on or before August 23, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–18204 Filed 8–1–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78427; File No. SR–BOX–2016–34]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule on the BOX Market LLC (''BOX'') Options Facility

July 27, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 18, 2016, BOX Options Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A)(ii) of the Act,[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the Fee Schedule to on the BOX Market LLC (''BOX'') options facility. While changes to the fee schedule pursuant to this proposal will be effective upon filing, the changes will become operative on August 1, 2016. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's Internet Web site at *http://boxexchange.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to make a number of changes to the BOX Fee Schedule.

Exchange Fees

PIP and COPIP Transactions

The Exchange proposes to remodel the current fee structure for PIP and COPIP Transactions. Currently, PIP and COPIP transactions are assessed fees based upon the account type of the Participant and whether the order is a: (i) PIP or COPIP Order; (ii) Improvement Order in PIP or COPIP; or (iii) Primary Improvement Order. The current PIP and COPIP Transactions fee structure is as follows:

	Account type			
	Public customer	Professional customer	Broker dealer	Market maker
PIP Order or COPIP Order[5]	$0.00	$0.15	$0.15	$0.15.
Improvement Order in PIP or COPIP[6]	$0.15	$0.37	$0.37	$0.30.
Primary Improvement Order[7]	See Section I. B.1	See Section I. B.1	See Section I. B.1	See Section I. B.1.

First, the Exchange proposes to restructure the PIP and COPIP Transactions fee schedule to differentiate between fees assessed in Penny and Non-Penny Pilot Classes. Next, the Exchange proposes to adjust the Improvement Order fees assessed for Broker Dealers, Professional Customers and Market Makers. Specifically, the Exchange proposes to establish a fee of $0.12 for Broker Dealers, Professional Customer and Market Maker Improvement Orders in Penny Pilot Classes. For Improvement Orders in Non-Penny Pilot Classes, the Exchange proposes to establish a fee of $0.38 for Market Makers, Broker Dealers and Professional Customers. Public Customer Improvement Order fees will remain the same, as well as the PIP and COPIP Order fees for all Participants.

The proposed PIP and COPIP fee structure will be as follows:

[34] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] A PIP Order or COPIP Order is a Customer Order (an agency order for the account of either a customer or a broker-dealer) designated for the PIP or COPIP, respectively.

[6] An Improvement Order is a response to a PIP or COPIP auction.

[7] A Primary Improvement Order is the matching contra order submitted to the PIP or COPIP on the opposite side of the PIP or COPIP order.

Account type	PIP and COPIP orders [8]		Improvement orders [9]	
	Penny pilot classes	Non-penny pilot classes	Penny pilot classes	Non-penny pilot classes
Public Customer	$0.00	$0.00	$0.15	$0.15
Professional Customer or Broker Dealer	0.15	0.15	0.12	0.38
Market Maker	0.15	0.15	0.12	0.38

The Exchange is also proposing to remove the Primary Improvement Order row in the schedule which references the Tiered Fee Schedule for Initiating Participants in Section 1.B.1 as well as amend the footnotes in the PIP and COPIP Transactions subsection to reflect to revised fee structure.

Tiered Fee Schedule for Initiating Participants

The Exchange proposes to rename Section I.B.1 from ''Tiered Fee Schedule for Initiating Participants'' to ''Primary Improvement Order'' to clarify that this section reflects the per contract execution fees for Primary Improvement Orders. The Exchange is also proposing to amend the footnotes in proposed Section I.B.1 to include the definition of a Primary Improvement Order.

BOX Volume Rebate

The Exchange proposes to amend the BOX Volume Rebate (''BVR'') in Section I.B.2 of the Fee Schedule.

Under the current BVR, the Exchange offers a tiered per contract rebate for all PIP Orders and COPIP Orders of 100 contracts and under. PIP and COPIP executions of 100 contracts and under are awarded a per contract rebate calculated on a monthly basis by totaling the Participant's PIP and COPIP volume submitted to BOX, relative to the total national Customer volume in multiply-listed options classes. The current per contract rebate for Participants in PIP and COPIP Transactions under the BVR is:

Tier	Percentage thresholds of national customer volume in multiply-listed options classes (monthly)	Per contract rebate (all account types)	
		PIP	*COPIP*
1	0.000% to 0.159%	($0.00)	($0.00)
2	0.160% to 0.339%	($0.04)	($0.02)
3	0.340% to 0.999%	($0.11)	($0.04)
4	1.000% to 1.249%	($0.14)	($0.06)
5	1.250% and Above	($0.18)	($0.06)

First, the Exchange is proposing to lower the per contract rebate for PIP and COPIP Orders of 100 and under that trade solely with their contra order. Specifically, the Exchange is proposing to lower the rebate to $0.03 per contract from $0.05 per contract. Next, the Exchange proposes to lower the per contract rebates associated with each volume tier in PIP transactions. The per contract rebates associated with COPIP Orders remain unchanged. The new BVR set forth in Section I.B.2 of the BOX Fee Schedule will be as follows:

Tier	Percentage thresholds of national customer volume in multiply-listed options classes (monthly)	Per contract rebate (all account types)	
		PIP	*COPIP*
1	0.000% to 0.159%	($0.00)	($0.00)
2	0.160% to 0.339%	($0.02)	($0.02)
3	0.340% to 0.999%	($0.04)	($0.04)
4	1.000% to 1.249%	($0.07)	($0.06)
5	1.250% and Above	($0.10)	($0.06)

Liquidity Fees and Credits

The Exchange then proposes to amend Section II.A. of the BOX Fee Schedule, liquidity fees and credits for PIP and COPIP transactions. Specifically, the Exchange proposes to increase the fees and credits for PIP and COPIP transactions in Penny and Non-Penny Pilot Classes. The Exchange proposes to raise the fees for adding liquidity in PIP and COPIP Transactions to $0.77 from $0.75 in Non-Penny Pilot Classes, and to $0.38 from $0.35 in Penny Pilot Classes. The Exchange also proposes to increase the credits for removing liquidity in PIP and COPIP Transactions. Specifically, the Exchange proposes to increase the credit to $0.77 from $0.75 in Non-Penny Pilot Classes, and to $0.38 from $0.35 in Penny Pilot Classes.

Lastly, the Exchange also proposes to make non-substantive technical chances

[8] A PIP Order or COPIP Order is a Customer Order (an agency order for the account of either a customer or a broker-dealer) designated for the PIP or COPIP, respectively.

[9] An Improvement Order is a response to a PIP or COPIP auction.

[sic] to renumber the footnotes within the BOX Fee Schedule.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act, in general, and Section 6(b)(4) and 6(b)(5)of the Act,[10] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among BOX Participants and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

Exchange Fees

PIP and COPIP Transactions

The Exchange believes that remodeling the fee structure for PIP and COPIP Transactions is reasonable, equitable, and not unfairly discriminatory. In particular, the proposed revisions will allow the Exchange to apply separate fees for transactions in Penny and Non-Penny Pilot Classes, a distinction that is made in many other section [sic] of the BOX Fee Schedule, including Section I.A (Non-Auction Transactions) and Section III.A (All Complex Orders).

The Exchange also believes the proposed fees for Broker Dealers, Professional Customer and Market Makers submitting Improvement Orders in Penny and Non-Penny Pilot classes are reasonable equitable and not unfairly discriminatory. Professional Customers and Broker Dealers are currently charged a flat fee of $0.37 for Improvement Orders, while Market Makers are charged a flat fee of $0.30. The proposal lowers the Improvement Order fees for these Participants to $0.12 for Penny Pilot Classes, while slightly raising the fee for Non-Penny Pilot Classes to $0.38. The Exchange believes these fees are reasonable as they are in line with other exchanges in the industry.[11]

Tiered Fee Schedule for Initiating Participants

The Exchange believes that the proposal to rename sections [sic] I.B.1 to ''Primary Improvement Order is reasonable equitable and not unfairly discriminatory, as it will provide further clarity to the fee schedule and will eliminate any potential investor confusion.

BOX Volume Rebate

The Exchange believes the proposed changes to the BVR are reasonable, equitable and non-discriminatory. The BVR was adopted to attract Public Customer order flow to the Exchange by offering these Participants incentives to submit their PIP and COPIP Orders to the Exchange. The Exchange believes providing a rebate to Participants that reach a certain volume threshold is equitable and non-discriminatory as the rebate will apply to all Participants uniformly.

The Exchange believes it is reasonable, equitable and non-discriminatory to reduce the flat rebate in the BVR for PIP Orders and COPIP Orders of 100 and under contracts that trade solely with their contra order. The Exchange recently amended the BVR to introduce the flat $0.05 rebate, regardless of tier.[12] The Exchange now believes it is reasonable to lower the flat rebate to $0.03 per contract, regardless of tier. The BVR is intended to incentivize Participants to direct Customer order flow to the Exchange, and while the Exchange believes that the potentially higher BVR rebate tiers are not necessary for internalized PIP Orders that only trade against their contra order, a flat $0.03 rebate will continue to be the appropriate incentive for these orders. The Exchange also believes that the proposed flat $0.03 rebate for internalized COPIP Orders that only trade against their contra order will continue to be a reasonable incentive.

The Exchange believes that lowering the rebates associated with each volume tier for PIP transactions is reasonable. Once the volume threshold is met the Exchange will continue to pay rebates on applicable PIP Orders. The Exchange also believes the proposed rebates are equitable and not unfairly discriminatory because Participants are eligible to receive the rebate provided they meet the volume and order type requirements. The Exchange believes that applying the rebate to PIP Orders will continue to provide these Participants with an added incentive to transact a greater number of Public Customer Orders on the Exchange to the benefit of all market participants.

Liquidity Fees and Credits

BOX believes that the changes to PIP and COPIP transaction liquidity fees and credits are equitable and not unfairly discriminatory in that they apply to all categories of participants and across all account types. The Exchange notes that liquidity fees and credits on BOX are meant to offset one another in any particular transaction. The liquidity fees and credits do not directly result in revenue to BOX, but simply allow BOX to provide incentives to Participants to attract order flow. The Exchange also believes the liquidity fees and credits are reasonable and competitive when compared to similar fees at competing venues.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposed fee changes are reasonably designed to enhance competition in BOX transactions, particularly auction transactions.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Exchange Act[13] and Rule 19b–4(f)(2) thereunder,[14] because it establishes or changes a due, or fee.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further 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:

[10] 15 U.S.C. 78f(b)(4) and (5).

[11] *See* NASDAQ OMX PHLX, (''PHLX'') Pricing Schedule, where Responders to the PIXL are charged $0.25.

[12] *See* Securities Exchange Release No. 77694 (April 22, 2016), 81 FR 25460 (April 28, 2016) (Notice of Filing and Immediate Effectiveness SR–BOX–2016–17).

[13] 15 U.S.C. 78s(b)(3)(A)(ii).

[14] 17 CFR 240.19b–4(f)(2).

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BOX–2016–34 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BOX–2016–34. 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–BOX–2016–34, and should be submitted on or before August 23, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–18205 Filed 8–1–16; 8:45 am]

BILLING CODE 8011–01–P

[15] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 14784 and # 14785]

North Carolina Disaster # NC–00075

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of North Carolina dated 07/26/2016.

Incident: High Winds, Flooding and Severe Storms.

Incident Period: 07/16/2016.

DATES: *Effective Date:* 07/26/2016.

Physical Loan Application Deadline Date: 09/26/2016.

Economic Injury (EIDL) Loan Application Deadline Date: 04/26/2017.

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: Durham.

Contiguous Counties:

North Carolina: Chatham, Granville, Orange, Person, Wake.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.250
Homeowners Without Credit Available Elsewhere	1.625
Businesses With Credit Available Elsewhere	6.250
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 14784 B and for economic injury is 14785 0.

The States which received an EIDL Declaration # are NORTH CAROLINA.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: July 26, 2016.

Maria Contreras-Sweet,

Administrator.

[FR Doc. 2016–18274 Filed 8–1–16; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Announcement of Funding Pool Size for the Growth Accelerator Fund Competition

AGENCY: U.S. Small Business Administration

ACTION: Notice.

SUMMARY: On May 4, 2016, the U.S. Small Business Administration (SBA) published a notice in the **Federal Register** (81 FR 26861) to announce the 2016 Growth Accelerator Fund Competition, pursuant to the America Competes Act (15 U.S.C. 3719), to identify the nation's most innovative accelerators and similar organizations and award them cash prizes they may use to fund their operations costs and allow them to bring startup companies to scale and new ideas to life, including providing assistance to small businesses submitting proposals through the Small Business Innovation Research and/or Small Business Technology Transfer Programs (SBIR/STTR). In partnership with several U.S. agencies, SBA will be awarding prizes to winners from a total funding pool size of up to $3.4 million. The $50,000 prize to each winner will be paid from the total funding pool, including SBA's appropriated funds, and will be provided to each winner via check. This notice serves as an update to the original notice affecting only the funding pool size of prizes to be awarded to competition winners. All rules and requirements outlined in the May 4, 2016, **Federal Register** notice will remain in effect.

Competition Details

- *Prizes for Winners:* SBA is partnering with the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Department of Education (DoED) to create a total funding pool size of up to $3.4 million to provide additional prizes to accelerators that assist entrepreneurs in submitting SBIR/STTR proposals. Special consideration will be given to

accelerator models that support women-owned or minority-owned small businesses and/or that assist entrepreneurs with submitting SBIR/STTR proposals. SBA's Office of Investment and Innovation (OII) will also be partnering with the Office of Native American Affairs (ONAA) and the Office of Veterans Business Development (OVBD) to award additional prizes to accelerators assisting the Native American and U.S. Veterans start-up community. SBA anticipates awarding up to 68 market stimulation cash prizes of $50,000 each to the highest-rated contestants that also represent the greatest degree of achieving national geographic distribution in both urban and rural areas, including at minimum: 14 accelerator models focused in Native American populations (American Indian, Alaska Native or Native Hawaiian); 2 accelerator models focused on the Veterans community and Veteran entrepreneurship; 20 accelerator models focused on life-sciences (medical); 10 accelerator models focused on science and engineering (non-medical), and 2 accelerator models focused on education research technology. SBA is also partnering with the Inter-American Development Bank (IDB) to provide a prize directly from IDB to 1 accelerator model focused on assisting the African descendant start-up community in Latin America and the Caribbean. Prizes will be paid in lump sum via the Automated Clearing House (ACH). Winners will be required to create an account in the System for Award Management (SAM) in order to receive an award.

Authority: Pub. L. 111–358 (2011).

Dated: July 27, 2016.

Mark Walsh,

Associate Administrator, Office of Investment and Innovation.

[FR Doc. 2016–18244 Filed 8–1–16; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14752 and #14753]

California Disaster #CA–00248

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 07/26/2016.

INCIDENT: Erskine Fire.

INCIDENT PERIOD: 06/23/2016 through 07/06/2016.

EFFECTIVE DATE: 07/26/2016.

PHYSICAL LOAN APPLICATION DEADLINE DATE: 09/26/2016.

ECONOMIC INJURY (EIDL) LOAN APPLICATION DEADLINE DATE: 04/26/2017.

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: Kern

Contiguous Counties:

California: Inyo, Kings, Los Angeles, San Bernardino, San Luis Obispo Santa Barbara, Tulare, Ventura

The Interest Rates are:

For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.250
Homeowners Without Credit Available Elsewhere	1.625
Businesses With Credit Available Elsewhere	6.250
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 14752 5 and for economic injury is 14753 0.

The State which received an EIDL Declaration # is CALIFORNIA

(Catalog of Federal Domestic Assistance Number 59008)

Dated; July 26, 2016.

Maria Contreras-Sweet,

Administrator.

[FR Doc. 2016–18233 Filed 8–1–16; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 14765 and # 14766]

Texas Disaster Number TX–00474

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Texas (FEMA–4272–DR), dated 07/08/2016.

Incident: Severe Storms and Flooding.

Incident Period: 05/26/2016 through 06/24/2016.

EFFECTIVE DATE: 07/25/2016.

Physical Loan Application Deadline Date: 09/06/2016.

Economic Injury (EIDL) Loan Application Deadline Date: 04/10/2017.

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: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of TEXAS, dated 07/08/2016, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Austin, Bosque, Brazoria, Brazos, Burleson, Callahan, Coleman, Comanche, Erath, Falls, Fisher, Hardin, Lee, Leon, Liberty, Madison, Montgomery, Navarro, Palo Pinto, Somervell, Stephens, Throckmorton, Trinity, Tyler, Walker, Waller.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2016–18275 Filed 8–1–16; 8:45 am]

BILLING CODE 8025–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 728]

Policy Statement on Implementing Intercity Passenger Train On-Time Performance and Preference Provisions of 49 U.S.C. 24308(c) and (f)

AGENCY: Surface Transportation Board.

ACTION: Withdrawal of proposed statement of board policy.

SUMMARY: The Surface Transportation Board (Board) is withdrawing the proposed Policy Statement (80 FR 80878) previously issued in this docket regarding complaint proceedings under 49 U.S.C. 24308(f) and related issues under 49 U.S.C. 24308(c).

FOR FURTHER INFORMATION CONTACT: Scott M. Zimmerman, (202) 245–0386. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision. Board decisions and notices are available on our Web site at ''*WWW.STB.DOT.GOV.*''

Decided: July 28, 2016.

By the Board, Chairman Elliott, Vice Chairman Miller, and Commissioner Begeman.

Tia Delano,

Clearance Clerk.

[FR Doc. 2016–18241 Filed 8–1–16; 8:45 am]

BILLING CODE 4915–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Rescinded for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the approved by rule projects rescinded by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: June 1–30, 2016.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, being rescinded for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22(e) and § 806.22(f) for the time period specified above:

Rescinded ABR Issued

1. Seneca Resources Corporation, Pad ID: Gamble Pad C, ABR–201506006, Gamble Township, Lycoming County, Pa.; Rescind Date: June 15, 2016.

2. Atlas Resources, LLC, Pad ID: Perry Well Pad, ABR–201201019, Mill Creek Township, Lycoming County, Pa.; Rescind Date: June 15, 2016.

3. Atlas Resources, LLC, Pad ID: Stubler Pad B, ABR–201307006, Gamble Township, Lycoming County, Pa.; Rescind Date: June 15, 2016.

4. EOG Resources, Inc., Pad ID: GHFC Pad A, ABR–201110030, Lawrence Township, Clearfield County, Pa.; Rescind Date: June 15, 2016.

5. EOG Resources, Inc., Pad ID: GHFC Pad B, ABR–201110029, Lawrence Township, Clearfield County, Pa.; Rescind Date: June 15, 2016.

6. EOG Resources, Inc., Pad ID: GHFC Pad D, ABR–201203009, Goshen Township, Clearfield County, Pa.; Rescind Date: June 15, 2016.

7. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 244 #1000H, ABR–20090927.R1, Rush Township, Centre County, Pa.; Rescind Date: June 16, 2016.

8. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 244 #1001H & #1002H, ABR–20090928.R1, Rush Township, Centre County, Pa.; Rescind Date: June 16, 2016.

9. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 342 D, ABR–20100349.R1, Beech Creek Township, Clinton County, Pa.; Rescind Date: June 16, 2016.

10. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 344 Pad B, ABR–201008019.R1, Grugan Township, Clinton County, Pa.; Rescind Date: June 16, 2016.

11. Anadarko E&P Onshore, LLC, Pad ID: Tx Gulf B #2H & #3H, ABR–20090823.R1, Beech Creek Township, Clinton County, Pa.; Rescind Date: June 16, 2016.

12. Anadarko E&P Onshore, LLC, Pad ID: Williams S. Kieser Pad A, ABR–201011046.R1, Cogan House Township, Lycoming County, Pa.; Rescind Date: June 16, 2016.

13. American Energy—Marcellus, LLC, Pad ID: Sooner Magic 1, ABR–201412001, Union Township, Huntingdon County, Pa.; Rescind Date: June 29, 2016.

14. SWN Production Company, LLC, Pad ID: WY 03 LUMBER PAD, ABR–201401005, Tunkhannock Township, Wyoming County, Pa.; Rescind Date: June 29, 2016.

15. SWN Production Company, LLC, Pad ID: WY 05 DZIUBA BENJAMIN PAD, ABR–201402003, Eaton Township, Wyoming County, Pa.; Rescind Date: June 29, 2016.

16. SWN Production Company, LLC, Pad ID: FRIES Pad, ABR–201112033, Lenox Township, Susquehanna County, Pa.; Rescind Date: June 29, 2016.

17. SWN Production Company, LLC, Pad ID: WY 02 HARDING PAD, ABR–201402007, Tunkhannock Township, Wyoming County, Pa.; Rescind Date: June 29, 2016.

18. SWN Production Company, LLC, Pad ID: Malling Well Pad, ABR–201208017, Silver Lake Township, Susquehanna County, Pa.; Rescind Date: June 29, 2016.

19. SWN Production Company, LLC, Pad ID: Nota Well Pad, ABR–201210019, Franklin Township, Susquehanna County, Pa.; Rescind Date: June 29, 2016.

20. SWN Production Company, LLC, Pad ID: TI–03 Porter Dennis—Pad, ABR–201403001, Union Township, Tioga County, Pa.; Rescind Date: June 29, 2016.

21. SWN Production Company, LLC, Pad ID: WHENGREEN, ABR–201111033, Lenox Township, Susquehanna County, Pa.; Rescind Date: June 29, 2016.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.*, 18 CFR parts 806, 807, and 808.

Dated: July 28, 2016.

Stephanie L. Richardson,

Secretary to the Commission.

[FR Doc. 2016–18268 Filed 8–1–16; 8:45 am]

BILLING CODE 7040–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the projects approved by rule by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: June 1–30, 2016.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, receiving approval for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22(e) and (f) for the time period specified above:

Approvals By Rule Issued Under 18 CFR 806.22(e):

1. The Hershey Company, West Hershey Plant, ABR–201606003, Derry Township, Dauphin County, Pa.; Consumptive Use of Up to 0.499 mgd; Approval Date: June 17, 2016.

Approvals By Rule Issued Under 18 CFR 806.22(f):

1. Chesapeake Appalachia, LLC, Pad ID: Gestewitz, ABR–201111002.R1, North Towanda Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: June 2, 2016.

2. Chesapeake Appalachia, LLC, Pad ID: Coyle, ABR–201111009.R1, Albany Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: June 2, 2016.

3. Chesapeake Appalachia, LLC, Pad ID: Bartholomew, ABR–201111012.R1, Franklin Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: June 2, 2016.

4. Chesapeake Appalachia, LLC, Pad ID: Dulcey, ABR–201111020.R1, Wilmot Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: June 2, 2016.

5. Chesapeake Appalachia, LLC, Pad ID: Gregerson, ABR–201111025.R1, Auburn Township, Susquehanna County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: June 2, 2016.

6. SWEPI LP, Pad ID: Weiner 882, ABR–201103045.R1, Farmington Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: June 2, 2016.

7. SWEPI LP, Pad ID: Swan 1122, ABR–201104031.R1, Farmington Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: June 2, 2016.

8. Anadarko E&P Onshore LLC, Pad ID: COP Tract 027B Pad A, ABR–201107030.R1, McHenry Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: June 3, 2016.

9. Anadarko E&P Onshore LLC, Pad ID: COP Tract 356 Pad G, ABR–201108017.R1, Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: June 3, 2016.

10. Chief Oil & Gas LLC, Pad ID: Bouse Drilling Pad #1, ABR–201110008.R1, Monroe Township, Bradford County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: June 3, 2016.

11. Chief Oil & Gas LLC, Pad ID: Nelson Drilling Pad #1, ABR–201111031.R1, Forks Township, Sullivan County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: June 3, 2016.

12. Seneca Resources Corporation, Pad ID: Gamble Pad R, ABR–201606001, Eldred Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: June 3, 2016.

13. Seneca Resources Corporation, Pad ID: DCNR 100 Pad G, ABR–201108032.R1, McIntyre Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: June 3, 2016.

14. Chief Oil & Gas LLC, Pad ID: Beirne Green Hills Farms A Drilling Pad #1, ABR–201111024.R1, Asylum and Monroe Townships, Bradford County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: June 8, 2016.

15. EXCO Resources (PA), LLC, Pad ID: Cadwalader Pad, ABR–201103039.R1, Cogan House Township, Lycoming County, Pa.; Consumptive Use of Up to 8.0000 mgd; Approval Date: June 8, 2016.

16. Chesapeake Appalachia, LLC, Pad ID: Hess, ABR–201105004.R1, Rome Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: June 10, 2016.

17. Chief Oil & Gas LLC, Pad ID: Madigan Farms A Drilling Pad #1, ABR–201111016.R1, Burlington Township, Bradford County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: June 10, 2016.

18. EOG Resources, Inc., Pad ID: HOLCOMBE 1H Pad, ABR–201107022.R1, Smithfield Township, Bradford County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: June 10, 2016.

19. EOG Resources, Inc., Pad ID: STAHL 1H Pad, ABR–201107021.R1, Smithfield Township, Bradford County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: June 10, 2016.

20. Chesapeake Appalachia, LLC, Pad ID: LW, ABR–201111027.R1, Cherry Township, Sullivan County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: June 13, 2016.

21. Endless Mountain Energy Partners, LLC, Pad ID: Sturgis-B, ABR–201105019.R1, Gallagher Township, Clinton County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: June 13, 2016.

22. Energy Corporation of America, Pad ID: Coldstream Affiliates B, ABR–201110019.R1, Goshen Township, Clearfield County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: June 13, 2016.

23. SWEPI LP, Pad ID: Showalter 822, ABR–201105018.R1, Chatham Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: June 13, 2016.

24. Range Resources—Appalachia, LLC, Pad ID: Mohawk South Unit Well Pad, ABR–201606002, Gallagher Township, Clinton County, Pa.; Consumptive Use of Up to 1.0000 mgd; Approval Date: June 14, 2016.

25. Chesapeake Appalachia, LLC, Pad ID: Robbins, ABR–201111018.R1, Ulster Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: June 21, 2016.

26. Chief Oil & Gas LLC, Pad ID: Squier B Drilling Pad #1, ABR–201110007.R1, Springville Township, Susquehanna County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: June 21, 2016.

27. Talisman Energy USA Inc., Pad ID: 07 185 Camp Comfort, ABR–201106025.R1, Middletown Township, Susquehanna County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: June 21, 2016.

28. SWN Production Company, LLC, Pad ID: Zeffer Pad, ABR–201108029.R1, New Milford Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.9900 mgd; Approval Date: June 23, 2016.

29. SWN Production Company, LLC, Pad ID: Scott Pad, ABR–201108030.R1, New Milford Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.9900 mgd; Approval Date: June 23, 2016.

30. Clean Energy E&P, LLC, Pad ID: Whispering Pines Pad 1, ABR–201606004, Delmar Township, Tioga County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: June 24, 2016.

31. Seneca Resources Corporation, Pad ID: DCNR 595 Pad L, ABR–201108033.R1, Bloss Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: June 24, 2016.

32. SWEPI LP, Pad ID: Sanchis 1129, ABR–201105017.R1, Farmington Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: June 24, 2016.

33. SWEPI LP, Pad ID: Drake 274, ABR–201106003.R1, Lawrence Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: June 24, 2016.

34. SWEPI LP, Pad ID: Fuller 826, ABR–201606005, Middlebury Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: June 24, 2016.

35. Talisman Energy USA Inc., Pad ID: 02 011 DCNR 587, ABR–201106029.R1, Ward Township, Tioga County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: June 24, 2016.

36. Talisman Energy USA Inc., Pad ID: 03–086 Everts P, ABR–201606006, Columbia Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: June 24, 2016.

37. Chesapeake Appalachia, LLC, Pad ID: Lines, ABR–201111017.R1, Monroe Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: June 28, 2016.

38. Chesapeake Appalachia, LLC, Pad ID: Knapp, ABR–201111003.R1, Burlington and Ulster Townships, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: June 28, 2016.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: July 28, 2016.

Stephanie L. Richardson,

Secretary to the Commission.

[FR Doc. 2016–18267 Filed 8–1–16; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Industry Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting.

SUMMARY: The Federal Aviation Administration (FAA) is hosting a public meeting to conclude the Aircraft Access to System Wide Information Management (AAtS) Demonstration project. The meeting will inform flight operations stakeholders and information service providers on the demonstrated concept, prototype applications developed, and results collected throughout the project. This meeting is not a precursor to a request for proposal (RFP) or request for offer (RFO). The FAA is not seeking or accepting unsolicited proposals.

DATES: The public meeting will be held on August 16, 2016, from 8:00 a.m. to 4:30 p.m.

ADDRESSES: The public meeting will be held at Florida NextGen Test Bed, 557 Innovation Way, Daytona Beach, FL 32114.

FOR FURTHER INFORMATION CONTACT: Kelly Mulholland, ANG–C52, Technology Development and Prototyping, Federal Aviation Administration, 800 Independence Ave. SW., Washington, DC 20591; telephone (202) 267–7970; email: *9-ANG-AAtS@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA's System Wide Information Management (SWIM) program is one of the transformational programs of the NextGen portfolio. SWIM utilizes a Service Oriented Architecture (SOA) to exchange aviation data and services without the restrictive, time consuming and expensive process of developing unique interfaces for the numerous systems and equipment used by the National Airspace System (NAS).

On November 17, 2014, the FAA hosted a public meeting for the Aircraft Access to System Wide Information Management (AAtS) Phase 2 Working Group to discuss the operational needs for a capability such as AAtS. AAtS is a technology agnostic concept demonstration effort conducted by the FAA to improve collaborative decision making by establishing the airborne component of the ground based SWIM. AAtS leverages rapidly growing air/ground third party service providers' infrastructure and technologies such as inflight Internet Protocol (IP) Data Link and Electronic Flight Bags (EFB) to exchange non-command and control/safety critical information between pilots and other NAS users without new equipage mandates.

To demonstrate feasibility and highlight the future potential of connecting aircraft to SWIM, the FAA developed prototype systems and applications in collaboration with industry partners and conducted live operational demonstrations with airline and business aircraft operators. The concept demonstrated by AAtS will help create a shared NAS picture and is expected to contribute to increased predictability, flexibility, and efficiency through collaborative decision making. The FAA will summarize the demonstrations at the August 16, 2016, meeting to conclude the AAtS Demonstration project.

Registration

To attend the meeting, participants must register via email by close of business day Tuesday, August 9, 2016. In accordance with security procedures, participants must provide the following information to *9-ANG-AAtS@faa.gov:* Full Name, Company, Phone Number, and U.S. Citizen (Y/N).

Issued in Washington, DC, on July 20, 2016.

John Maffei,

Director (A), NextGen Portfolio Management and Technology Development.

[FR Doc. 2016–18219 Filed 8–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2016–84]

Petition for Exemption; Summary of Petition Received; Diamond Aircraft Industries GmbH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before August 22, 2016.

ADDRESSES: Send comments identified by docket number FAA–2016–7399 using any of the following methods:

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

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records

notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

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

FOR FURTHER INFORMATION CONTACT: Paul Pellicano (404) 474–5558, Small Airplane Directorate, Regulations and Policy, ACE–111, 901 Locust, Kansas City, KS 64106.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on July 8, 2016.

Dale Bouffiou,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2016–7399.

Petitioner: Diamond Aircraft Industries GmbH.

Section(s) of 14 CFR Affected: 23.1419(a).

Description of Relief Sought: This exemption, if granted, would exempt the Diamond Aircraft Industries, model DA 62 airplane from the 61-knot maximum landing configuration stall speed requirement with ice accretions and will also have a landing configuration stall speed, without ice accretions, above 61 knots.

[FR Doc. 2016–18232 Filed 8–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Buy America Waiver Notification

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice provides information regarding FHWA's finding that a Buy America waiver is appropriate for the obligation of Federal-aid funds for 49 State projects involving the acquisition of vehicles and equipment on the condition that they be assembled in the U.S.

DATES: The effective date of the waiver is August 3, 2016.

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Mr. Gerald Yakowenko, FHWA Office of Program Administration, 202–366–1562, or via email at *gerald.yakowenko@dot.gov*. For legal questions, please contact Mr. William Winne, FHWA Office of the Chief Counsel, 202–366–1397, or via email at *William.Winne@dot.gov*. Office hours for the FHWA are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded from the **Federal Register**'s home page at *http://www.archives.gov* and the Government Printing Office's database at *http://www.access.gpo.gov/nara.*

Background

This notice provides information regarding FHWA's finding that a Buy America waiver is appropriate for the obligation of Federal-aid funds for 49 State projects involving the acquisition of vehicles (including sedans, vans, pickups, trucks, buses, and street sweepers) and equipment (such as trail grooming equipment) on the condition that they be assembled in the U.S. The waiver would apply to approximately 196 vehicles and equipment acquisitions. The requests for the first quarter of calendar year 2016, available at *http://www.fhwa.dot.gov/construction/contracts/cmaq160517.cfm*, are incorporated by reference into this notice. These projects are being undertaken to implement air quality improvement, safety, and mobility goals under FHWA's Congestion Mitigation and Air Quality Improvement Program and the Recreational Trails Program.

Title 23, Code of Federal Regulations, section 635.410 requires that steel or iron materials (including protective coatings) that will be permanently incorporated in a Federal-aid project must be manufactured in the U.S. For FHWA, this means that all the processes that modified the chemical content, physical shape or size, or final finish of the material (from initial melting and mixing, continuing through the bending and coating) occurred in the U.S. The statute and regulations create a process for granting waivers from the Buy America requirements when its application would be inconsistent with the public interest or when satisfactory quality domestic steel and iron products are not sufficiently available. In 1983, FHWA determined that it was both in the public interest and consistent with the legislative intent to waive Buy America for manufactured products other than steel manufactured products. However, FHWA's national waiver for manufactured products does not apply to the requests in this notice because they involve predominately steel and iron manufactured products. The FHWA's Buy America requirements do not have special provisions for applying Buy America to ''rolling stock'' such as vehicles or vehicle components (see 49 U.S.C. 5323(j)(2)(C), 49 CFR 661.11, and 49 U.S.C. 24405(a)(2)(C) for examples of Buy America rolling stock provisions for other DOT agencies).

Based on all the information available to the agency, FHWA concludes that there are no domestic manufacturers that produce the vehicles and vehicle components identified in this notice in such a way that their steel and iron elements are manufactured domestically. The FHWA's Buy America requirements were tailored to the types of products that are typically used in highway construction, which generally meet the requirement that steel and iron materials be manufactured domestically. In today's global industry, vehicles are assembled with iron and steel components that are manufactured all over the world. The FHWA is not aware of any domestically produced vehicle on the market that meets FHWA's Buy America requirement to have all its iron and steel be manufactured exclusively in the U.S. For example, the Chevrolet Volt, which was identified by many commenters in a November 21, 2011, **Federal Register** Notice (76 FR 72027) as a car that is made in the U.S., is comprised of only 45 percent of U.S. and Canadian content according to the National Highway Traffic Safety Administration's Part 583 American Automobile Labeling Act Report Web page (*http://www.nhtsa.gov/Laws+&+Regulations/Part+583+American+Automobile+Labeling+Act+(AALA)+Reports*). Moreover, there is no indication of how much of this 45 percent content is U.S.-manufactured (from initial melting and mixing) iron and steel content.

In accordance with Division K, section 122 of the ''Consolidated and Further Continuing Appropriations Act, 2015'' (Pub. L. 113–235), FHWA published a notice of intent to issue a waiver on its Web site at *http://www.fhwa.dot.gov/construction/contracts/waivers.cfm?id=126* on May 17. The FHWA received no comments in response to the publication.

Based on FHWA's conclusion that there are no domestic manufacturers that can produce the vehicles and equipment identified in this notice in such a way that steel and iron materials are manufactured domestically, and after consideration of the comments received, FHWA finds that application of FHWA's Buy America requirements

to these products is inconsistent with the public interest (23 U.S.C. 313(b)(1) and 23 CFR 635.410(c)(2)(i)). However, FHWA believes that it is in the public interest and consistent with the Buy America requirements to impose the condition that the vehicles and the vehicle components be assembled in the U.S. Requiring final assembly to be performed in the U.S. is consistent with past guidance to FHWA Division Offices on manufactured products (see Memorandum on Buy America Policy Response, Dec. 22, 1997, *http://www.fhwa.dot.gov/programadmin/contracts/122297.cfm*). A waiver of the Buy America requirement without any regard to where the vehicle is assembled would diminish the purpose of the Buy America requirement. Moreover, in today's economic environment, the Buy America requirement is especially significant in that it will ensure that Federal Highway Trust Fund dollars are used to support and create jobs in the U.S. This approach is similar to the conditional waivers previously given for various vehicle projects. Thus, so long as the final assembly of the 49 State projects occurs in the U.S., applicants to this waiver request may proceed to purchase these vehicles and equipment consistent with the Buy America requirement.

In accordance with the provisions of section 117 of the ''Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users, Technical Corrections Act of 2008'' (P.L. 110–244), FHWA is providing this notice of its finding that a public interest waiver of Buy America requirements is appropriate on the condition that the vehicles and equipment identified in the notice be assembled in the U.S. The FHWA invites public comment on this finding for an additional 15 days following the effective date of the finding. Comments may be submitted to FHWA's Web site via the link provided to the waiver page noted above.

Authority: 23 U.S.C. 313; P.L. 110–161, 23 CFR 635.410

Issued on: July 22, 2016.

Gregory G. Nadeau,

Administrator, Federal Highway Administration.

[FR Doc. 2016–18270 Filed 8–1–16; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA–2016–0027]

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Requirements (ICRs) abstracted below have been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICRs describes the nature of the information collection and the expected burdens.

FOR FURTHER INFORMATION CONTACT: Tia Swain, Office of Administration, Office of Management Planning, (202) 366–0354.

SUPPLEMENTARY INFORMATION:

Title: 49 U.S.C. Sections 5310 and 5311—Capital Assistance Program for Elderly Persons and Persons with Disabilities and Non-Urbanized Area Formula Program: (OMB Number 2132–0500)

Abstract: 49 U.S.C. 5310—Capital Assistance Program for Elderly Persons And Persons with Disabilities provides financial assistance for the specialized transportation service needs of elderly persons and persons with disabilities in large urban, small urban and rural areas. Formula funding is apportioned to direct recipients: States for rural (under 50,000 population) and small urban (areas (50,000–200,000); and designated recipients chosen by the Governor of the State for large urban areas (populations or 200,000 or more); or a State or local governmental entity that operates a public transit service. Section 3006(b) of Fixing America's Surface Transportation Act (FAST Act), Pub. L. 114–94 authorizes a pilot program for innovative coordinated access and mobility. 49 U.S.C. 5311—Formula Grants for Rural Areas provides financial assistance for the provision of public transportation services in rural areas. This program is administered by States. The Public Transportation on Indian Reservations Program or Tribal Transit Program (TTP), is authorized as 49 U.S.C. 5311(j). The TTP is a set-aside from the Rural Area Formula Program (Section 5311), and consists of a $30 million formula program and a $5 million discretionary grant program. These funds are apportioned directly to Indian tribes. Eligible recipients of TTP program funds include federally recognized Indian tribes, or Alaska Native villages, groups, or communities as identified by the Bureau of Indian Affairs. The **Federal Register** notice with a 60-day comment period soliciting comments for the 49 U.S.C. Sections 5310 and 5311—Capital Assistance Program for Elderly Persons and Persons with Disabilities and Non-urbanized Area Formula Program was published on April 5, 2016 (Vol. 81, No. 65) pages 19709–19710). No comments were received from that notice.

DATES: Comments must be submitted before September 1, 2016. a comment to OMB is most effective, if OMB receives it within 30 days of publication.

Estimated Total Burden: 45,087 hours.

ADDRESSES: All written comments must refer to the docket number that appears at the top of this document and be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention: FTA Desk Officer.

Comments are Invited On: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

William Hyre,

Deputy Associate Administrator for Administration.

[FR Doc. 2016–18224 Filed 8–1–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA–2016–0023]

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Requirements (ICRs) abstracted below have been forwarded

to the Office of Management and Budget (OMB) for review and comment. The ICRs describes the nature of the information collection and the expected burdens.

Public Transportation Emergency Relief Program

The Moving Ahead for Progress in the 21st Century Act (MAP–21, Pub. L. 112–141) authorized the Emergency Relief Program at 49 U.S.C. 5324. FTA's Emergency Relief program enables FTA to provide assistance to public transit operators in the aftermath of an emergency or major disaster. This program helps States and public transportation systems pay for protecting, repairing, and/or replacing equipment and facilities that may suffer or have suffered serious damage as a result of an emergency, including natural disasters such as floods, hurricanes, and tornadoes. The program can fund capital projects to protect, repair, or replace facilities or equipment that are in danger of suffering serious damage, or have suffered serious damage as a result of an emergency. The program can also fund the operating costs of evacuation, rescue operations, temporary public transportation service, or reestablishing, expanding, or relocating service before, during or after an emergency.

The **Federal Register** notice with a 60-day comment period soliciting comments for the Public Transportation Emergency Relief Program was published on April 5, 2016 (Citation 81 FR 19711). No comments were received from that notice.

DATES: Comments must be submitted before September 1, 2016. A comment to OMB is most effective, if OMB receives it within 30 days of publication.

FOR FURTHER INFORMATION CONTACT: Tia Swain, Office of Administration, Office of Management Planning, (202) 366–0354.

SUPPLEMENTARY INFORMATION:

Title: Public Transportation Emergency Relief Program (*OMB Number: 2132–0575*).

Abstract: As a result of Hurricane Sandy, President Obama declared a major disaster in late 2012 for areas of 12 States and the District of Columbia affected by Hurricane Sandy. Public transportation agencies in the counties specified in the disaster declaration were eligible for financial assistance under FTA's Public Transportation Emergency Relief Program. Under the Disaster Relief Appropriations Act (Pub. L. 113–2), Congress provided $10.9 billion for FTA's Emergency Relief Program for recovery, relief and resilience efforts in areas affected by Hurricane Sandy. Approximately $10.2 billion remained available after implementation of the Balanced Budget and Emergency Deficit Control Act of 2011 (Pub. L. 112–25) and after intergovernmental transfers to other bureaus and offices within DOT. FTA allocated approximately $9.27 billion in multiple tiers for response, recovery and rebuilding, for locally prioritized resilience projects, and for competitively selected resilience projects. In addition, FTA has reserved approximately $817 million for remaining unfunded recovery expenses.

Estimated Total Burden: 3,600 hours.

ADDRESSES: All written comments must refer to the docket number that appears at the top of this document and be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention: FTA Desk Officer.

Comments are Invited On: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

William Hyre,

Deputy Associate Administrator for Administration.

[FR Doc. 2016–18225 Filed 8–1–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA–2016–0026]

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Requirements (ICRs) abstracted below have been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICRs describes the nature of the information collection and the expected burdens.

FOR FURTHER INFORMATION CONTACT: Tia Swain, Office of Administration, Office of Management Planning, (202) 366–0354.

SUPPLEMENTARY INFORMATION:

49 U.S.C. Section 5317—New Freedom Program (OMB Number 2132–0565)

Abstract: The purpose of the New Freedom program was to make grants available to assist states and designated recipients to reduce barriers to transportation services and expand the transportation mobility options available to people with disabilities beyond the requirements of the Americans with Disabilities Act (ADA) of 1990. The New Freedom program was repealed in 2012 with the enactment of the Moving Ahead for Progress in the 21st Century Act (MAP–21). However, funds previously authorized for programs repealed by MAP–21 remain available for their originally authorized purposes until the period of availability expires, the funds are fully expended, the funds are rescinded by Congress, or the funds are otherwise reallocated. To meet program oversight responsibilities, FTA must continue to collect information until the period of availability expires, the funds are fully expended, the funds are rescinded by Congress, or the funds are otherwise reallocated. Grant recipients are required to make information available to the public and to publish a program of projects which identifies the sub-recipients and projects for which the State or designated recipient is applying for financial assistance. FTA uses the information to monitor the grantees' progress in implementing and completing project activities. FTA collects performance information annually from designated recipients in rural areas, small urbanized areas, other direct recipients for small urbanized areas, and designated recipients in urbanized areas of 200,000 persons or greater. FTA collects milestone and financial status reports from designated recipients in large urbanized areas on a quarterly basis. The information submitted ensures FTA's compliance with applicable federal laws and OMB Uniform Administrative Requirements (Super Circular). The **Federal Register** notice with a 60-day comment period soliciting comments for the 49 U.S.C. Sections 5317—New Freedom Program was published on April 5, 2016 (Vol. 81, No. 65) pages 19710–1971). No comments were received from that notice.

Estimated Total Burden: 14,640 hours.

ADDRESSES: All written comments must refer to the docket number that appears at the top of this document and be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street NW., Washington, DC 20503, Attention: FTA Desk Officer.

Comments are Invited On: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

William Hyre,

Deputy Associate Administrator for Administration.

[FR Doc. 2016–18226 Filed 8–1–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2016–0059; Notice 1]

Notice of Receipt of Petition for Decision That Nonconforming Model Year 2014 Bentley Flying Spur Saloon/ Continental Passenger Cars Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Receipt of petition.

SUMMARY: This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that model year (MY) 2014 Bentley Flying Spur 4-door (Saloon) and 2-Door (Continental) passenger cars (PC's) that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards (FMVSS), are eligible for importation into the United States because they are substantially similar to vehicles that were originally manufactured for sale in the United States and that were certified by their manufacturer as complying with the safety standards (the U.S.-certified version of the 2014 Bentley Flying Spur Saloon/Continental PC's) and they are capable of being readily altered to conform to the standards.

DATES: The closing date for comments on the petition is September 1, 2016.

ADDRESSES: Comments should refer to the docket and notice numbers above and be submitted by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online 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 or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251

Instructions: Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

How to Read Comments submitted to the Docket: You may read the comments received by Docket Management at the address and times given above. You may also view the documents from the Internet at *http://www.regulations.gov.* Follow the online instructions for accessing the dockets. The docket ID number and title of this notice are shown at the heading of this document notice. Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically search the Docket for new material.

FOR FURTHER INFORMATION CONTACT: George Stevens, Office of Vehicle Safety Compliance, NHTSA (202–366–5308).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable FMVSS shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable FMVSS.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

J. K. Technologies, LLC (JK), Inc. of Baltimore, Maryland (Registered Importer R–90–006) has petitioned NHTSA to decide whether nonconforming MY 2014 Bentley Flying Spur PC's are eligible for importation into the United States. The vehicles which JK believes are substantially similar are MY 2014 Bentley Flying Spur PC's sold in the United States and certified by their manufacturer as conforming to all applicable FMVSS.

The petitioner claims that it compared the subject non-U.S. certified MY 2014 Bentley Flying Spur PC's to their U.S.-certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most FMVSS.

JK submitted information with its petition intended to demonstrate that the subject non-U.S. certified MY 2014 Bentley Flying Spur PC's, as originally manufactured, conform to many applicable FMVSS in the same manner as their U.S.-certified counterparts, or are capable of being readily altered to conform to those standards. Specifically, the petitioner claims that the subject non U.S.-certified MY 2014 Bentley Flying Spur PC's, as originally manufactured, conform to: Standard

Nos. 102 *Transmission Shift Lever Sequence, Starter Interlock, and Transmission Braking Effect,* 103 *Windshield Defrosting and Defogging Systems,* 104 *Windshield Wiping and Washing Systems,* 135 *Light Vehicle Brake Systems,* 106 *Brake Hoses,* 113 *Hood Latch System,* 114 *Theft Protection,* 116 *Motor Vehicle Brake Fluids,* 118 *Power-Operated Window, Partition, and Roof panel System,* 124 *Accelerator Control Systems,* 126 *Electronic Stability Control Systems,* 138 *Tire Pressure Monitoring Systems, 139 New Pneumatic Radial Tires for Light Vehicles,* 201 *Occupant Protection in Interior Impact,* 202a *Head Restraints,* 204 *Steering Control Rearward Displacement,* 205 *Glazing Materials,* 206 *Door Locks and Door Retention Components,* 207 *Seating Systems,* 209 *Seat Belt Assemblies,* 210 *Seat Belt Assembly Anchorages,* 212 *Windshield Mounting,* 214 *Side Impact Protection,* 216 *Roof Crush Resistance,* 219 *Windshield Zone Intrusion,* 225 *Child Restraint Anchorage Systems,* and 302 *Flammability of Interior Materials.*

The petitioner also contends that the subject non-U.S certified vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays:* Replacement of the speedometer with U.S. model components and addition of the brake warning indicator to fully comply with the standard.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment:* replacement of the taillamps, headlamps, and front and rear side marker lamps with U.S.-conforming components.

Standard No. 110 *Tire Selection and Rims and Motor Home/Recreation Vehicle Trailer Load Carrying Capacity Information for Motor Vehicles with a GVWR of 4,536 Kilograms (10,000 Pounds) or Less:* Installation of the required tire information placard.

Standard No. 111 *Rearview Mirrors:* Inscription of the required warning statement on the face of the passenger side rearview mirror or replacement of mirror with the U.S. model component.

Standard No. 208 *Occupant Crash Protection:* Replacement of the knee air bags (and associated hardware), passenger seat cushion weight sensor, software, warning labels, warning lights and owner manuals that are not identical to the U.S. model components with U.S. model components as detailed in the petition and its attachments.

After all new components are installed and wired, the diagnostic programming/coding tool must be used to ensure that the latest U.S. model code packs are installed and that all vehicle control modules associated with the occupant protection system function as required for the vehicles to conform to the standard.

Standard No. *301 Fuel System Integrity:* Replacement of the fuel filler cap, leak diagnostics pump, vent pipe, and hose with U.S. model components as detailed in the petition and its attachments.

After all new components are installed and wired, the diagnostic programming/coding tool must be used to ensure that the latest U.S. model code packs are installed and that all vehicle control modules associated with the fuel system function as required for the vehicles to conform to the standard.

Standard No. 401 *Interior Trunk Release:* Installation of a U.S. model interior trunk release system as detailed in the petition and its attachments.

The petitioner additionally states that a vehicle identification plate must be affixed to the vehicle near the left windshield pillar to meet the requirements of 49 CFR part 565.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above addresses both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141(a)(1)(A), (a)(1)(B), and (b)(1); 49 CFR 593.7; delegation of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2016–18227 Filed 8–1–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2016–0131]

Privacy Act of 1974; Department of Transportation, Federal Aviation Administration, DOT/FAA854 Requests for Waivers and Authorizations Under 14 CFR Part 107 System of Records Notice

AGENCY: Office of the Departmental Chief Information Officer, Office of the Secretary of Transportation, DOT.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the United States Department of Transportation proposes to issue a Department of Transportation system of records titled, ''Department of Transportation Federal Aviation Administration; DOT/FAA854 Requests for Waivers and Authorizations Under 14 CFR part 107.'' On June 28, 2016 the FAA issued a Final Rule setting forth standards for operation and certification of small unmanned aircraft systems (hereinafter, ''small UAS''). RIN 2120–AJ60.

Small UAS operators may request waivers of operational rules applicable to small UAS, requirements such as the requirement to maintain visual line of sight and yield right of way to manned aircraft, as well as prohibitions on operations over people and in certain airspace. Small UAS operators who determine to seek a waiver or authorization must request such by electronically completing a form on the FAA Web site or by mailing a completed paper form to the FAA. The forms will contain: aircraft operator name; aircraft owner name; name of person requesting a waiver or authorization; contact information for person applying for waiver or authorization: mailing address, telephone number, and email address of person submitting application for waiver or authorization; responses to inquiries concerning the applicant's previous and current waivers; remote pilot in command name; contact information for remote pilot in command: address and telephone number; remote pilot in command certificate number; aircraft manufacturer name and model; aircraft registration number; regulations subject to waiver or authorization; requested date and time operations will commence and conclude under waiver or authorization; requested altitude applicable to the waiver or authorization; description of proposed operations. In addition to the entries on the completed form, the applicant may provide additional information, such as maps, illustrations, specifications, or other items the applicant would like the FAA to consider. After reviewing the information the applicant provides, the FAA will determine whether it can assure safety in the national airspace when granting the waiver; often, such grants will include provisions to which the requester must adhere, to mitigate the risk associated with the waiver.

The final rule prohibits operation of small UAS in Class B, Class C, or Class D airspace, as well as operation within the lateral boundaries of the surface area of Class E airspace designated for an airport unless the person has prior

authorization from Air Traffic Control. To obtain this authorization, operators may complete and submit an electronic form available on the FAA's Web site. This system will consist of records (1) relevant to waivers of certain provisions of 14 CFR part 107 and (2) airspace authorization requests.

DATES: Written comments should be submitted on or before September 1, 2016. The Department may publish an amended Systems of Records Notice in light of any comments received. This new system will be effective September 1, 2016.

ADDRESSES: You may submit comments, identified by docket number DOT–OST–2016–0131 by any of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal Holidays.
- *Fax:* (202) 493–2251.

Instructions: You must include the agency name and docket number DOT–OST–2016–0131. 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 all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Department of Transportation's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://DocketsInfo.dot.gov.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or to the street address listed above. Follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: For questions, please contact: Claire W. Barrett, Departmental Chief Privacy Officer, Privacy Office, Department of Transportation, Washington, DC 20590; *privacy@dot.gov;* or 202.527.3284.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Transportation (DOT)/Federal Aviation Administration (FAA) proposes to issue a DOT system of records titled, ''DOT/FAA854 Requests for Waivers and Authorizations Under 14 CFR part 107.'' This SORN results from the FAA's recent decision issue a final rule to integrate small UAS operations into the national airspace, setting forth standards for operations and certification of small UAS operations. 81 FR 42063 (June 28, 2016).

A. Description of Records

The FAA's rule governing operation of small UAS permits operators to apply for certificates of waiver to allow a small UAS operation to deviate from certain provisions of 14 CFR part 107 if the Administrator finds the operator can conduct safely the proposed operation under the terms of a certificate of waiver. The rule also permits operators to request authorizations to enter controlled airspace (Class B, Class C, or Class D airspace, as well as the lateral boundaries of the surface area of Class E airspace designated for an airport). The process of the FAA issuing certificates of waiver will allow the FAA to assess case-specific information concerning a small UAS operation that takes place in a unique operating environment and consider allowing additional operating flexibility that recognizes safety mitigations provided by the specific operating environment. Accordingly, this SORN covers documents relevant to both waivers of certain provisions of part 107 as well as airspace authorizations, as described in 14 CFR 107.41.

1. Waivers

To obtain a certificate of waiver, an applicant must submit a request containing a complete description of the proposed operation and a justification, including supporting data and documentation as necessary, to establish the proposed operation can safely be conducted under the terms of the requested certificate of waiver. As stated in the preamble describing the FAA's final rule provisions, the FAA expects the amount of data and analysis required as part of the application will be proportional to the specific relief that is requested. Similarly, the FAA anticipates that the time required for it to make a determination regarding waiver requests will vary based on the complexity of the request. For example, a request for a major deviation from part 107 for an operation that takes place in a congested metropolitan area with heavy air traffic will likely require significantly more data and analysis than a request for a minor deviation for an operation that takes place in a sparsely populated area with minimal air traffic. If a certificate of waiver is granted, that certificate may include additional conditions and limitations designed to ensure that the small UAS operation can be conducted safely.

The certificate-of-waiver process will allow the FAA to assess case-specific information concerning a small UAS operation that takes place in a unique operating environment and consider allowing additional operating flexibility that recognizes safety mitigations provided by the specific operating environment. The FAA anticipates that this process will also serve as a bridging mechanism for new and emerging technologies; allowing the FAA to permit testing and use of those technologies, as appropriate, before the pertinent future rulemaking is complete.

2. Airspace Authorizations

This SORN covers two methods by which a remote pilot in command may request FAA authorization for a small unmanned aircraft to operate in Class B, C, D, and the lateral boundaries of the surface area of Class E airspace designated for an airport. First, a remote pilot in command may seek approval from air traffic control (ATC). The second, alternative method allows a remote pilot to request a waiver from this provision in order to operate in Class B through E airspace. The appropriate ATC facility has the best understanding of local airspace, its usage, and traffic patterns and is in the best position to ascertain whether the proposed small UAS operation would pose a hazard to other users or the efficiency of the airspace, and procedures to implement to mitigate such hazards. The ATC facility has the authority to approve or deny aircraft operations based on traffic density, controller workload, communications issues, or any other type of operational issues that could potentially impact the safe and efficient flow of air traffic in that airspace. If necessary to approve a small UAS operation, ATC may require mitigations such as altitude constraints and direct communication. ATC may deny requests that pose an unacceptable risk to the national airspace system (NAS) and cannot be mitigated.

B. System of Records

As described below in the Routine Uses section of this notice, all records the FAA maintains in connection with waivers (approvals and denials) may be made available to the public, except email addresses and personal telephone numbers. Such availability is compatible with the purposes of this

system because this system is intended, in part, to educate small UAS operators who seek to apply for a waiver, as operators will be able to review prior grants of waivers and the accompanying special provisions in their efforts to replicate successful waiver applications. The FAA, however, does not plan to post records relevant to airspace authorizations on its Web site because airspace authorizations are unique to each operation. Each airspace authorization is specific to the location and time of the planned operation; therefore, posting of airspace authorizations would not prove advantageous to prospective applicants who seek to operate in airspace listed as prohibited in 14 CFR 107.41.

In addition, the FAA may share records with law enforcement as necessary to ensure safe operations in the NAS. To provide for safety of the NAS, the FAA may consider enforcement action against a person who violates FAA regulations; such action could involve disclosing information from this system of records, or derived from this system of records, to law enforcement. In addition, the FAA may disclose information to law enforcement as needed for purposes of accident/incident investigations. Overall, the FAA will correspond with law enforcement as needed to ensure operators do not endanger the NAS; such collaboration may entail the sharing of information in this system of records.

II. Privacy Act

The Privacy Act (5 U.S.C. 552a) governs the means by which the Federal Government collects, maintains, and uses personally identifiable information (PII) in a System of Records. A ''System of Records'' is a group of any records under the control of a Federal agency from which information about individuals is retrieved by name or other personal identifier. The Privacy Act requires each agency to publish in the **Federal Register** a System of Records notice (SORN) identifying and describing each System of Records the agency maintains, including the purposes for which the agency uses PII in the system, the routine uses for which the agency discloses such information outside the agency, and how individuals to whom a Privacy Act record pertains can exercise their rights under the Privacy Act (*e.g.,* to determine if the system contains information about them and to contest inaccurate information).

In accordance with 5 U.S.C. 552a(r), DOT has provided a report of this system of records to the Office of Management and Budget and to Congress.

SYSTEM OF RECORDS:

DOT/FAA—854 Requests for Waivers and Authorizations Under 14 CFR part 107.

SYSTEM NAME:

DOT/FAA—854 Requests for Waivers and Authorizations Under 14 CFR part 107.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

For waivers, the system will be located in the Commercial Operations Branch, Flight Standards Service (AFS–820), Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20024.

For airspace authorizations, the system will be located in the Emerging Technologies Team (AJV–115), Air Traffic Organization, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20024.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Aircraft operators, aircraft owners, persons requesting a waiver or authorization.

CATEGORIES OF RECORDS IN THE SYSTEM:

Aircraft operator name; Aircraft owner name; Name of person requesting a waiver or authorization; Contact information for person applying for waiver or authorization: mailing address, telephone number, and email address of person submitting application for waiver or authorization; Responses to inquiries concerning the applicant's previous and current waivers; Remote pilot in command name; Airmen Certification Number (in those individuals certificated under another program prior to 2013 and have not requested a change of certificate number the airmen certificate number may be the individual's Social Security Number); Contact information for remote pilot in command: address and telephone number; Remote pilot in command certificate number; Aircraft manufacturer name and model; Aircraft registration number; Regulations subject to waiver or authorization; Requested date and time operations will commence and conclude under waiver or authorization; Requested altitude applicable to the waiver or authorization; Description of proposed operations.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

i. 49 U.S.C. 106(g), Duties and powers of Administrator

ii. 49 U.S.C. 40101, Policy

iii. 49 U.S.C. 40103, Sovereignty and use of airspace

iv. 49 U.S.C. 40106, Emergency powers

v. 49 U.S.C. 40113, Administrative

vi. 49 U.S.C. 44701, General requirements

vii. FAA Modernization and Reform Act of 2012, Pub. L. 112–95 (''FMRA'') § 333, Special Rules for Certain Unmanned Aircraft Systems

viii. 14 CFR part 107, subpart D, ''Waivers''

ix. 14 CFR 107.41, ''Operation in certain airspace''

PURPOSE(S):

The purpose of this system is to receive, evaluate, and respond to requests for authorization to operate a small UAS, pursuant to 14 CFR part 107, in Class B, C, or D airspace or within the lateral boundaries of the surface area of Class E airspace designated for an airport, and evaluate requests for a certificate of waiver to deviate safely from one or more small UAS operational requirements specified in part 107. The FAA also will use this system to support FAA safety programs and agency management, including safety studies and assessments. The FAA may use contact information provided with requests for waiver or authorization to provide small UAS owners and operators information about potential unsafe conditions and educate small UAS owners and operators regarding safety requirements for operation. The FAA also will use this system to maintain oversight of FAA-issued waiver or authorizations and records from this system may be used by FAA for enforcement purposes.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to other disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DOT as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To the public, waiver and airspace authorization applications and decisions, including any history of previous, pending, existing, or denied requests for waivers and authorizations applicable to the small UAS at issue for purposes of the waiver, and special provisions applicable to the small UAS operation that is the subject of the request. Email addresses and telephone numbers will not be disclosed pursuant to this Routine Use. Airspace

authorizations the FAA issues pursuant to 14 CFR 107.41 also will not be disclosed pursuant to this Routine Use, except to the extent that an airspace authorization is listed or summarized in the terms of a waiver.

2. To law enforcement, when necessary and relevant to a FAA enforcement activity.

3. The Department has also published general routine uses applicable to all DOT Privacy Act systems of records, including this system. These routine uses are published in the **Federal Register** at 75 FR 82132, December 29, 2010, and 77 FR 42796, July 20, 2012, under ''Prefatory Statement of General Routine Uses'' (available at *http://www.transportation.gov/privacy/privacyactnotices*).

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Individual records relevant to both waivers and airspace authorizations under 14 CFR part 107 are maintained in an electronic database system.

RETRIEVABILITY:

Records of applications for waivers and authorizations in the electronic database system may be retrieved by small UAS registration number, the manufacturer's name and model, the name of the current registered owner and/or organization, the name of the remote pilot in command, the airmen certification number, the name of the applicant and/or organization that submitted the request for waiver or authorization, the special provisions (if any) to which the FAA and the applicant agreed for purposes of the waiver or authorization, and the location and altitude, class of airspace and area of operations that is the subject of the request. Records may also be sorted by regulation section that is the subject of the request for waiver or authorization.

SAFEGUARDS:

Records in this system for waivers and airspace authorizations under 14 CFR part 107 are safeguarded in accordance with applicable rules and policies, including all applicable DOT automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RETENTION AND DISPOSAL:

The FAA will retain records in this system of records, which covers both waivers and airspace authorizations under 14 CFR part 107, as permanent government records until it receives record disposition authority from the National Archives and Records Administration (NARA), pursuant to 36 CFR 1225.16 and 1225.18. The FAA has requested from NARA authority to dispose of waiver and authorization records after two years following the expiration of the waiver or authorization.

SYSTEM MANAGER(S) AND ADDRESS:

For waivers: Manager, Commercial Operations Branch, Flight Standards Service (AFS–820), Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20024.

For airspace authorizations: Manager, UAS Tactical Operations Section, Air Traffic Organization, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20024.

NOTIFICATION PROCEDURE:

Individuals seeking notification of whether this system of records contains information about them may contact the System Manager at the address provided in the section ''System manager.''

When seeking records about yourself from this system of records or any other Departmental system of records your request must conform with the Privacy Act regulations set forth in 49 CFR part 10. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records in this system of records should follow the same procedures described in the section ''Notification Procedure,'' above.

CONTESTING RECORD PROCEDURES:

Individuals seeking amendment to records in this system of records should follow the same procedures described in the section ''Notification Procedure,'' above.

RECORD SOURCE CATEGORIES:

Records are obtained from individuals, manufacturers of aircraft, maintenance inspectors, mechanics, and FAA officials.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Claire W. Barrett,

Departmental Chief Privacy Officer.

[FR Doc. 2016–18208 Filed 8–1–16; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

United States Mint

Pricing for the 2016 American Liberty Silver Medals

AGENCY: United States Mint, Department of the Treasury.

ACTION: Notice.

SUMMARY: The United States Mint is announcing the price of the 2016 American Liberty Silver Medals. Each medal will be priced at $34.95. Two silver medals will be offered—one from the United States Mint at West Point and one from the United States Mint at San Francisco.

FOR FURTHER INFORMATION CONTACT: Cathy Olson (Laperle), Marketing Specialist; Numismatic and Bullion Directorate; United States Mint; 801 9th Street NW.; Washington, DC 20220; or call 202–354–7519.

Authority: 31 U.S.C. 5111(a)(2).

Dated: July 29, 2016.

Richard A. Peterson,

Deputy Director for Manufacturing and Quality, United States Mint.

[FR Doc. 2016–18277 Filed 8–1–16; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 510 and 512

Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR); Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 510 and 512

[CMS–5519–P]

RIN 0938–AS90

Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule proposes to implement three new Medicare Parts A and B episode payment models under section 1115A of the Social Security Act. Acute care hospitals in certain selected geographic areas will participate in retrospective episode payment models targeting care for Medicare fee-for-service beneficiaries receiving services during acute myocardial infarction, coronary artery bypass graft, and surgical hip/femur fracture treatment episodes. All related care within 90 days of hospital discharge 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 receiving care for these common clinical conditions and procedures. This proposed rule also includes several proposed modifications to the Comprehensive Care for Joint Replacement model.

DATES: *Comment period:* To be assured consideration, comments on this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EDT on October 3, 2016.

ADDRESSES: In commenting, please refer to file code CMS–5519–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5519–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5519–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

For questions related to the proposed EPMs: *NEPMRULE@cms.hhs.gov*.

For questions related to the CJR model: *CJR@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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 proposed rule, we are listing the acronyms, abbreviations and short forms used and their corresponding terms in alphabetical order.

ACE Acute-care episode
ACO Accountable Care Organization
ALOS Average length of stay
AMA American Medical Association
AMI Acute Myocardial Infarction
APM Alternative Payment Model
ASC QRP Ambulatory Surgical Center Quality Reporting Program
ASC Ambulatory Surgical Center
ASPE Assistant Secretary for Planning and Evaluation
BPCI Bundled Payments for Care Improvement
CABG Coronary Artery Bypass Graft
CAD Coronary artery disease
CAH Critical access hospital
CBSA Core-Based Statistical Area
CC Complication or comorbidity
CCDA Consolidated clinical document architecture
CCDE Core clinical data elements
CCN CMS Certification Number
CEC Comprehensive ESRD Care Initiative
CEHRT Certified Electronic Health Record Technology
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
CoP Condition of Participation
CPC Comprehensive Primary Care Initiative
CPT Current Procedural Terminology
CR Cardiac rehabilitation
CSA Combined Statistical Area
CVICU Cardiovascular intensive care units
CY Calendar year
DME Durable medical equipment
DMEPOS Durable medical equipment, prosthetics, orthotics, and supplies
DSH Disproportionate Share Hospital
ECQM Electronic Clinical Quality Measures
EFT Electronic funds transfer
EHR Electronic health record
E/M Evaluation and management
EPM Episode payment model
ESCO ESRD Seamless Care Organization
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
HHS U.S. Department of Health and Human Services
HH QRP Home Health Quality Reporting Program
HICN Health Insurance Claim Number
HIPPA Health Insurance Portability and Accountability Act
HIQR Hospital Inpatient Quality Reporting
Health IT Health Information Technology
HLMR HCAHPS Linear Mean Roll Up
HOOS Hip Dysfunction and Osteoarthritis Outcome Score
HOPD Hospital outpatient department
HRRP Hospital Readmissions Reductions Program
HRR Hospital Referral Region
HVBP Hospital Value-Based Purchasing Program
HIV Human Immunodeficiency Virus
ICD–9–CM International Classification of Diseases, 9th Revision, Clinical Modification
IRFQRICD–10–CM International Classification of Diseases, 10th Revision, Clinical Modification
ICR Intensive Cardiac Rehabilitation
IME Indirect medical education
IPPS Inpatient Prospective Payment System
IPF Inpatient psychiatric facility
IRF QRP Inpatient Rehabilitation Facility Quality Reporting Program
IPF QRP Inpatient Psychiatric Facility Quality Reporting Program
IRF Inpatient rehabilitation facility
KOOS Knee Injury and Osteoarthritis Outcome Score
LEJR Lower-extremity joint replacement
LIP Low-income percentage
LOS Length-of-stay
LTCH QRP Long-Term Care Hospital Quality Reporting Program
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
MAT Measure Authoring Tool
MCC Major complications or comorbidities
MCCM Medicare Care Choices Model
MDC Major diagnostic category
MDH Medicare-Dependent Hospital
MedPAC Medicare Payment Advisory Commission
MIPS Merit-based Incentive Payment System
MP Malpractice
MSA Metropolitan Statistical Area
MS–DRG Medical Severity Diagnosis–Related Group
NPI National Provider Identifier
NPRA Net Payment Reconciliation Amount
NQF National Quality Forum
OCM Oncology Care Model
OIG Department of Health and Human Services' Office of the Inspector General
OPPS Outpatient Prospective Payment System
OQR Outpatient Quality Reporting
PBPM Per-beneficiary per-month
PCI Percutaneous Coronary Intervention
PCMH Primary Care Medical Homes
PE Practice Expense
PFS Physician Fee Schedule
PGP Physician group practice
PQRS Physician Quality Reporting System
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
PTCA Percutaneous transluminal coronary angioplasty
PY Performance year
QIO Quality Improvement Organization
RAC Recovery Audit Contractor
RRC Rural Referral Center
RSCR Risk-Standardized Complication Rate
RSRR Risk-Standardized Readmission Rate
RSMR Risk-Standardized Mortality Rate
RVU Relative Value Unit
SCH Sole Community Hospital
SHFFT Surgical hip/femur fracture treatment
SILS2 Single Item Health Literacy Screening
SNF QRP Skilled Nursing Facility Quality Reporting Program
SNF Skilled nursing facility
THA Total hip arthroplasty
TIN Taxpayer identification number
TKA Total knee arthroplasty
TP Target price
UHDDS Uniform Hospital Discharge Data Set
VR–12 Veterans Rand 12 Item Health Survey

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I. Executive Summary

A. Purpose

The purpose of this proposed rule—Advancing Care Coordination through Episode Payment Models, is to propose the creation and testing of three new episode payment models (EPMs) and a Cardiac Rehabilitation (CR) incentive payment model under the authority of the Center for Medicare and Medicaid Innovation (CMMI or ''the Innovation Center''). Section 1115A of the Social Security Act (''the Act'') authorizes the Innovation Center to test innovative payment and service-delivery models to reduce Medicare, Medicaid, and Children's Health Insurance Program expenditures while preserving or enhancing the quality of care furnished to such programs' beneficiaries. Under the fee-for-service (FFS) program, 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. The goal for the proposed EPMs is to improve the quality of care provided to beneficiaries in an applicable episode while reducing episode spending through financial accountability.[1] The proposed EPMs would include models for episodes of care surrounding an acute myocardial infarction (AMI), coronary artery bypass graft (CABG), and surgical hip/femur fracture treatment excluding lower extremity joint replacement (SHFFT). Under the proposed rule, the Centers for Medicare & Medicaid Services (CMS) will test whether an EPM for AMI, CABG, and SHFFT episodes of care will reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate the proposed models would benefit Medicare beneficiaries by improving the

[1] In this proposed rule, we use the terms ''AMI episode,'' ''CABG episode,'' and ''SHFFT episode'' to refer to episodes of care as described in section III.C. of this proposed rule.

coordination and transition of care, improving the coordination of items and services paid for through FFS Medicare, 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 spectrum. We propose to test the proposed EPMs for 5 performance years, beginning July 1, 2017, and ending December 31, 2021.

Within this proposed rule, we propose three distinct EPMs focused on episodes of care for AMI, CABG, and SHFFT episodes. We chose these episodes for the proposed models because, as discussed in depth in section III.A. of this proposed rule, we believe hospitals would have significant opportunity to redesign care and improve quality of care furnished during the applicable episode. In addition, significant variation in spending occurs during these high-expenditure, common episodes. The proposed EPMs would enable hospitals to consider the most appropriate strategies for care redesign, including: (1) increasing post-hospitalization follow-up and medical management for patients; (2) coordinating across the inpatient and post-acute care spectrum; (3) conducting appropriate discharge planning; (4) improving adherence to treatment or drug regimens; (5) reducing readmissions and complications during the post-discharge period; (6) managing chronic diseases and conditions that may be related to the proposed EPMs' episodes; (7) choosing the most appropriate post-acute care setting; and (8) coordinating between providers and suppliers such as hospitals, physicians, and post-acute care providers. The proposed EPMs would offer hospitals the opportunity to examine and better understand their own care processes and patterns with regard to patients in AMI, CABG, and SHFFT episodes, as well as the processes of post-acute care providers and physicians.

We previously have used our statutory authority under section 1115A of the Act to test other episode payment models such as the Bundled Payments for Care Improvement (BPCI) initiative and Comprehensive Care for Joint Replacement (CJR) model. Bundled payments for multiple services in an episode of care hold participating organizations financially accountable for that episode of care. Such models also allow participants to receive payments based in part on the reduction in Medicare expenditures that arise from such participants' care redesign efforts. This payment can be used for investments in care redesign strategies and infrastructure, as well as to incentivize collaboration with other providers and suppliers furnishing services to beneficiaries included in the models.

We believe the proposed EPMs would further the Innovation Center's mission and the Administration's goal of increasingly paying for value and outcomes, rather than for volume alone,[2] by promoting the alignment of financial and other incentives for all health care providers caring for beneficiaries during SHFFT, CABG, or AMI episodes. The acute care hospital where an eligible beneficiary has an initial hospitalization for one of the procedures or clinical conditions included in these proposed EPMs would be held accountable for spending during the episode of care. EPM participants could earn reconciliation payments by appropriately reducing expenditures and meeting certain quality metrics. EPM participants also would gain access to data and educational resources to better understand care patterns during the inpatient hospitalization and post-acute periods, as well as associated spending. Payment approaches that reward providers for assuming financial and performance accountability for a particular episode of care create incentives for the implementation and coordination of care redesign between participants and other providers and suppliers such as physicians and post-acute care providers.

The proposal for the AMI, CABG, and SHFFT models would require the participation of hospitals in multiple geographic areas that might not otherwise participate in testing episode payment for the proposed episodes of care. CMS is testing other episode payment models with the BPCI initiative and the CJR model. The BPCI initiative is voluntary; providers applied to participate and chose from 48 clinical episodes. BPCI participants entered the at-risk phase between 2013 and 2015 and have the option to continue participating in the initiative through FY 2018. In the CJR model, acute care hospitals in selected geographic areas are required to participate in the CJR model for all eligible lower-extremity joint replacement (LEJR) episodes that initiate at a CJR participant hospital. The CJR model began its first of 5 performance years on April 1, 2016. Realizing the full potential of new EPMs will require the engagement of an even broader set of providers than have participated to date in our episode payment models such as the BPCI initiative and the CJR model. As such, we are interested in testing and evaluating the impact of episode payment for the three proposed EPMs in a variety of circumstances, including those hospitals that may not otherwise participate in such a test.

While we note that testing of the CJR model that began in April 2016 will allow CMS to gain experience with requiring hospitals to participate in an episode payment model, the clinical circumstances of the episodes we are proposing (AMI, CABG, and SHFFT) differ in important ways from the LEJR episodes included in the CJR model. LEJR procedures are common among the Medicare population, and the majority of such procedures are elective. In contrast, under the three proposed EPMs, CMS would test episode payment for certain cardiac conditions and procedures, as well as SHFFT. We expect the patient population included in these episodes would be substantially different from the patient population in CJR episodes, due to the clinical nature of the cardiac and SHFFT episodes. Beneficiaries in these episodes commonly have chronic conditions that contribute to the initiation of the episodes, and need both planned and unplanned care throughout the EPM episode following discharge from the initial hospitalization that begins the episode. Both AMI and CABG model episodes primarily include beneficiaries with cardiovascular disease, a chronic condition which likely contributed to the acute events or procedures that initiate the episodes. About half the average AMI model historical episode spending was for the initial hospitalization, with the majority of spending following discharge from the initial hospitalization due to hospital readmissions, while there was relatively less spending on SNF services, Part B professional services, and hospital outpatient services. In CABG model historical episodes, about three-quarters of episode spending was for the initial hospitalization, with the remaining episode spending relatively evenly divided between Part B professional services and hospital readmissions, and a lesser percentage on SNF services. Similar to AMI episodes, post-acute care provider use was relatively uncommon in CABG model historical episodes, while hospital readmissions during CABG model historical episodes were relatively common. SHFFT model historical episodes also were accompanied by substantial spending

[2] Episodes for AMI, CABG, and SHFFT beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that end in CY 2014.

for hospital readmissions, and post-acute care provider use in these episodes also was high. The number of affected beneficiaries and potential impact of the models on quality and Medicare spending present an important opportunity to further the Administration's goal of shifting health care payments to support the quality of care over the quantity of services by promoting better coordination among health care providers and suppliers and greater efficiency in the care of beneficiaries in these models, while reducing Medicare expenditures.[3] Pay-for-performance episode payment models such as the three EPMs proposed in this rulemaking financially incentivize improved quality of care and reduced cost by aligning the financial incentives of all providers and suppliers caring for model beneficiaries with these goals. This alignment leads to a heightened focus on care coordination and management throughout the episode that prioritizes the provision of those items and services which improve beneficiary outcomes and experience at the lowest cost. A more detailed discussion of the evidence supporting the episode selection for these models can be found in section III.A.1. of the proposed rule.

The proposed models would also allow CMS to gain additional experience with episode-payment approaches for hospitals with variance in (1) historic care and utilization patterns; (2) patient populations and care patterns; (3) roles within their local markets; (4) volumes of services; (5) levels of access to financial, community, or other resources; and (6) levels of population and health-care-provider density, including local variations in the availability and use of different categories of post-acute care providers. We believe that participation in the proposed EPMs by a large number of hospitals with diverse characteristics would result in a robust data set for evaluating this payment approach and would stimulate the rapid development of new evidence-based knowledge. Testing the proposed EPMs in this manner would also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize quality improvement for beneficiaries receiving services in AMI, CABG, and SHFFT episodes. This knowledge potentially could inform future Medicare payment policies.

[3] 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-msarter-spending-healthier-people.html* (January 26, 2015).

We propose the CR incentive payment model to test the effects on quality of care and Medicare expenditures of providing financial incentives to hospitals for beneficiaries hospitalized for treatment of AMI or CABG to encourage care coordination and greater utilization of medically necessary CR and intensive cardiac rehabilitation (ICR) services for 90 days post-hospital discharge where the beneficiary's overall care is paid under either an EPM or the Medicare FFS program. Despite the evidence from multiple studies that CR services improve health outcomes, the literature also indicates that these services are underutilized, estimating that only about 35 percent of AMI patients older than 50 receive this indicated treatment.[4] [5] [6] Recent analysis confirms a similar pattern of underutilization for Medicare beneficiaries who are eligible for and could benefit from CR.

Considering the evidence demonstrating that CR/ICR services improve long-term patient outcomes, the room for improvement in CR/ICR service utilization for beneficiaries eligible for this benefit, and the need for ongoing, chronic treatment for underlying coronary artery disease (CAD) among beneficiaries that have had an AMI or a CABG, we believe that there is a need for improved long-term care management and care coordination for beneficiaries that have had an AMI or a CABG and that incentivizing the use of CR/ICR services is an important component of meeting this need. We want to reduce barriers to high-value care by testing a financial incentive for hospitals that encourages the management of beneficiaries that have had an AMI or a CABG in ways that may contribute to long-term improvements in quality and reductions in Medicare spending. We seek public comment on the proposals contained in this proposed rule, and also on any alternatives considered.

B. Summary of the Major Provisions

1. Model Overview—EPM Episodes of Care

Under the proposed EPMs, as described further in section III.B.2. of this proposed rule, an AMI, CABG, or SHFFT model episode would begin with an inpatient admission to an anchor hospital assigned to one of the following MS–DRGs upon beneficiary discharge. Acute care hospital services furnished to beneficiaries in AMI, CABG, and SHFFT episodes currently are paid under the Inpatient Prospective Payment System (IPPS) through several Medicare Severity-Diagnosis Related Groups (MS–DRGs): for AMI episodes, AMI MS–DRGs (280–282) and those Percutaneous Coronary Intervention (PCI) MS–DRGs (246–251) representing IPPS admissions for AMI that are treated with PCIs; CABG MS–DRGs (231–236); and SHFFT MS–DRGs (480–482). Episodes would end 90 days after the date of discharge from the anchor hospital, as defined under § 512.2. Defining EPMs' episodes of care in such a manner offers operational simplicity for both providers and CMS. The proposed EPMs' episodes would include the inpatient stays and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, post-acute care, and physician services.

2. Model Scope

Consistent with the CJR model, we propose that acute care hospitals would be the episode initiators and bear financial risk under the proposed AMI, CABG and SHFFT models. In comparison to other health care facilities, hospitals are more likely to have resources that would allow them to appropriately coordinate and manage care throughout an episode, and hospital staff members already are involved in hospital-discharge planning and post-acute care recommendations for recovery, key dimensions of high-quality and efficient care. We propose to require all hospitals that are paid under the IPPS, have a CMS Certification Number (CCN), and have an address located in selected geographic areas to participate in the EPMs, with limited exceptions. An eligible beneficiary who receives care at such a hospital will automatically be included in the applicable EPM. We propose to select geographic areas through a random sampling methodology.

Under the CR incentive payment model, we propose to provide a CR incentive payment specifically to selected hospitals with financial responsibility for AMI or CABG model episodes (hereinafter EPM–CR participants) because they are already engaged in managing the AMI or CABG model beneficiary's overall care for a period of time following hospital discharge. Similarly, we believe there are opportunities to test the same financial incentives for hospitals where the beneficiary's overall care is paid under the Medicare FFS program. Thus,

[5] Anderson L et al. Exercise-based cardiac rehabilitation for coronary heart disease. Cochrane Database Syst Rev. 2016 Jan 5;1:CD001800.

[6] Receipt of outpatient cardiac rehabilitation among heart attack survivors—United States, 2005. MMWR Morbidity and mortality weekly report. 2008 Feb 1:57(4):89–94.

we also propose to provide a CR incentive payment specifically to selected hospitals that are not AMI or CABG model participants (hereinafter FFS–CR participants).

Our proposed geographic-area selection process is detailed further in section III.B.4. of this proposed rule.

3. Payment

We propose to test the AMI, CABG, and SHFFT EPMs for 5 performance years. The first performance year will begin July 1, 2017. During these performance years we propose to 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, would be combined to calculate an actual episode payment. The actual episode payment would then be reconciled against an established EPM quality-adjusted target price. The amount of this calculation, if positive, would be paid to the participant. This would be called a reconciliation payment. If negative, we would require repayment from the participant hospital beginning with episodes ending in the second quarter of performance year 2 of the EPMs. EPM participants' quality performance also would be assessed at reconciliation; each participant would receive a composite quality score and a corresponding quality category. EPM participants that achieve a quality category of ''acceptable'' or higher would be eligible for a reconciliation payment. We also propose to phase in the requirement that participants whose actual episode payments exceed the quality-adjusted target price pay the difference back to Medicare beginning for performance year 2. Under this proposal, Medicare would not require repayment from hospitals for performance year 1 for actual episode payments that exceed their target price in performance year 1, and an applicable discount factor would be used for calculating repayment amounts for performance years 2 and 3, consistent with our final policies for the CJR model. In contrast to the CJR model, due to the clinical characteristics and common patterns of care in AMI episodes, we propose payment adjustments in the cases of certain transfers and readmissions of beneficiaries to inpatient hospitals for these episodes. These payment adjustments are discussed in detail in section III.D.4.b.(1). of this proposed rule. We also propose to limit how much a hospital can gain or lose based on its actual episode payments relative to quality-adjusted target prices. Finally, we propose additional policies to further limit the risk of high payment cases for all participants and for special categories of participants as described in section III.D. of this proposed rule.

In addition to the EPMs, we propose to test a CR incentive payment model to encourage the utilization of CR/ICR services for beneficiaries hospitalized for treatment of AMI or CABG. To determine the CR incentive payment, we propose to count the number of CR/ICR services for the relevant time periods under the Outpatient Prospective Payment System (OPPS) and PFS on the basis of the presence of paid claims of the HCPCS codes that report CR/ICR services and the units of service billed. The initial level of the per-service CR incentive amount would be $25 per CR/ICR service for each of the first 11 CR/ICR services paid for by Medicare during an AMI or CABG model episode or AMI or CABG care period. After 11 CR/ICR services are paid for by Medicare for a beneficiary, the level of the per-service CR incentive amount would increase to $175 per CR/ICR service for each additional CR/ICR service paid for by Medicare during the AMI or CABG model episode or AMI care period or CABG care period. A more detailed discussion of the CR incentive payment is located in section VI.E.1 of this proposed rule. The CR performance years would be the same as the performance years proposed for the EPMs in section III.D.2.a. of this proposed rule. Further details about the payment structure and design of the CR incentive payment model can be found in section VI. of this proposed rule.

4. Similar, Previous, and Concurrent Models

The proposed EPMs are informed by other models and demonstrations currently and previously conducted by CMS, and would explore additional ways to use episode payment to enhance coordination of care and improve the quality of care.

We recently announced practices that will participate in the Oncology Care Model (OCM), an episode payment model for physician practices administering chemotherapy. Under OCM, practices will enter into payment arrangements that include both financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients. We will coordinate with other payers to align with OCM in order to facilitate enhanced services and care at participating practices.[7]

CMMI previously tested innovative episode payment approaches in the Medicare Acute Care Episode (ACE) demonstration,[8] and, as described in this proposed rule, currently is testing additional approaches under the BPCI initiative and the CJR model. The ACE demonstration tested a bundled payment approach for cardiac and orthopedic inpatient surgical services and procedures. All Medicare Part A and Part B services pertaining to the inpatient stay were included in the ACE demonstration episodes of care. Evaluations of the ACE demonstration found that while there was not strong quantitative evidence indicating improvements in quality, there was qualitative evidence that hospitals worked to improve processes and outcomes as a result of their participation in the demonstration.

We currently are testing the BPCI initiative, which is composed of four related payment models that link payments for multiple services that a Medicare beneficiary receives 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) post-acute care 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. Participating organizations chose from 48 clinical episodes, including hip and femur procedures except major joint, acute myocardial infarction, percutaneous coronary intervention, and coronary artery bypass graft surgery. BPCI Model 2 is an episode payment model in which a qualifying acute care hospitalization initiates a 30-, 60-, or 90-day episode of care. The episode includes the inpatient stay in an acute care hospital and all related services covered under Medicare Parts A and B during the episode, including post-acute care services.[9] Our experience testing BPCI Model 2 informed the design of the three

[7] More information on the OCM can be found on the Innovation Center's Web site at *http://innovation.cms.gov/initiatives/Oncology-Care/*.

[8] Information on the ACE Demonstration can be found on the Innovation Center's Web site at *http://innovation.cms.gov/initiatives/ACE/*.

[9] More information on BPCI Model 2 can be found on the Innovation Center's Web site at *http://innovation.cms.gov/initiatives/BPCI-Model-2/*.

proposed EPMs. Although some interim evaluation results from the BPCI models are available, final evaluation results for the models within the BPCI initiative are not yet available. However, we believe that CMS' experiences with BPCI support the design of the proposed EPMs. Stakeholders both directly and indirectly involved in testing BPCI models have conveyed that they perceive the initiative to be an effective mechanism for advancing better, more accountable care and aligning providers along the care continuum. This message has been reinforced through CMS site visits to participating entities, the Bundled Payments summit in Washington, in-person meetings with Awardees at CMS, and Awardee-led Affinity Group discussions. The BPCI initiative incorporates 48 clinical episodes, including cardiac and orthopedic episodes similar to those proposed for the AMI, CABG, and SHFFT models. These clinical episodes are being tested by over 1200 Medicare providers, including acute care hospitals, physician group practices, skilled nursing facilities, and home health agencies. Cardiac and orthopedic clinical episodes are among the most popular episodes in BPCI, indicating that BPCI awardees participating in BPCI believe they can reduce cost and improve quality for beneficiaries in these episodes of care.

Our design and implementation of the CJR model, which is an episode payment model for LEJR episodes, also informed the design of the proposed AMI, CABG, and SHFFT EPMs. After releasing a proposed rule in July 2015 and receiving nearly 400 comments from the public, in November 2015 we released final regulations implementing the CJR model. Approximately 800 acute care hospitals (approximately 23 percent of all IPPS hospitals) now participate in the CJR model. The first CJR performance year began on April 1, 2016. The CJR model will continue for 5 performance years, ending on December 31, 2020. The proposed AMI, CABG, and SHFFT models build upon our experience designing and implementing the CJR model, including feedback from providers and other public stakeholders during the CJR model's rulemaking and implementation processes.

Further information of why specific elements of the models and initiatives were incorporated into the EPMs' designs is discussed later in this proposed rule.

5. Overlap With Ongoing CMS Efforts

We propose to exclude from participation in the AMI, CABG, and SHFFT models certain acute care hospitals participating in BPCI Models 2 and 4 for the hip and femur procedures except major joint or for all three of the BPCI cardiac episodes (AMI, PCI, and CABG). We propose to exclude beneficiaries in the proposed EPMs' episodes from being included in certain Innovation Center ACO models, the Next Generation ACO Model and Comprehensive ESRD Care. Other CMS programs, such as the Medicare Shared Savings Program and other accountable care organization (ACO) or total cost of care initiatives will remain eligible for EPM episode initiation. We propose to account for overlap, that is, where EPM beneficiaries also are included in other models and programs to ensure the financial policies of the models are maintained and results and spending reductions are attributed to one model or program. More detail on our proposed policies for accounting for provider- and beneficiary-level overlap is discussed in section III.D.6. of this proposed rule.

The amendments made by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015) created two paths for eligible clinicians to link quality to payments: The Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs). These two paths create a flexible payment system called the Quality Payment Program as proposed by CMS in the Quality Payment Program proposed rule (81 FR 28161 through 28586). The MIPS streamlines and improves on three current programs—the Physician Quality Reporting System (PQRS), the Physician Value-based Payment Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program—and continues the focus on quality and value in one cohesive program. Through participation in Advanced APMs, eligible clinicians can become Qualifying APM Participants (QPs) for a year beginning with CY 2019 and receive an APM Incentive Payment (or, in later years, a more favorable payment update under the PFS) for the year.

So that the EPMs may be able to meet the criteria to be Advanced APMs based on the requirements proposed in the Quality Payment Program proposed rule, we propose to require EPM participants to use Certified Electronic Health Record Technology (CEHRT) (as defined in section 1848(o)(4) of the Act) in Track 1 of each EPM. We propose that EPM participants in these tracks must use certified health information technology (IT) functions, in accordance with the definition of CEHRT under our regulation at 42 CFR 414.1305, to document and communicate clinical care with patients and other health care professionals as described in the Quality Payment Program proposed rule (81 FR 28161 and 28299). We also make similar proposals with respect to CJR.

We propose to implement two different tracks within the EPMs whereby EPM participants that meet proposed requirements for use of CEHRT and financial risk would be in Track 1 (an Advanced APM track) and EPM participants that do not meet these requirements would be in Track 2 (a non-Advanced APM track). The different tracks would not change how EPM participants operate within the EPM itself, beyond the requirements associated with selecting to meet CEHRT use requirements. The only distinction between the two tracks is that only Track 1 EPMs could be considered an Advanced APM for purposes of the Quality Payment Program based on the proposed criteria in the Quality Payment Program proposed rule. We make similar proposals with respect to CJR. We would consider modifying requirements proposed in this rule as necessary to reconcile them with policies adopted in the Quality Payment Program final rule. A more detailed discussion of the proposals for how EPMs and CJR could qualify as Advanced APMs, and how eligible clinicians participating in the EPMs and CJR would be identified and affected, can be found in sections III.A.2 and V.O. of this proposed rule.

6. Quality Measures and Reporting Requirements

Similar to the quality measures selected for the CJR model, we propose to use established measures used in other CMS quality-reporting programs for the proposed EPMs' episodes. We propose to use these measures to test EPMs' success in achieving its goals under section 1115A of the Act and to monitor for beneficiary safety. For the SHFFT model, we propose applying the same quality measures selected for the CJR model.

The following proposed quality measures for SHFFT episodes are:

- THA/TKA Complications: Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (National Quality Forum [NQF] #1550)
- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAPHS) Survey (NQF #0166)
- Successful Voluntary Reporting of Patient-Reported Outcomes

We propose the following measures for the AMI model:

- MORT–30–AMI: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230).
- AMI Excess Days: Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (acute care days include emergency department, observation, and inpatient readmission days)
- HCAPHS Survey (NQF #0166), linear mean roll-up (HLMR) scores like CJR

We propose the following measures for the CABG model:

- MORT–30–CABG: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft Surgery (NQF #2558)
- HCAPHS Survey (NQF #0166), HLMR scores like CJR

Finally, we are proposing and requesting public feedback on options for including successful implementation testing of the Hybrid AMI measure as a quality measure for the AMI episode. The Hybrid AMI measure will assess a hospital's 30-day risk-standardized acute myocardial infarction mortality rate and will incorporate a combination of claims data and EHR data submitted by hospitals.

Additionally, similar to the CJR model, we propose to adopt a pay-for-performance methodology for EPMs that relies upon a composite quality score to assign respective EPM participants to four quality categories. These quality categories will determine an EPM participant's eligibility for a reconciliation payment should such EPM participant achieve spending below the quality-adjusted target price, as well as the effective discount percentage at reconciliation. Points for quality performance and improvement (as applicable) will be awarded for each episode measure and then summed to develop a composite quality score that will determine the EPM participant's quality category for the episode. Quality performance will make up the majority of available points in the composite quality score, with improvement points available as ''bonus'' points for the measure. This approach resembles the CJR model methodology.

7. Beneficiary Protections

As with the CJR model, Medicare beneficiaries in the proposed models will retain the right to obtain health services from any individual or organization qualified to participate in the Medicare program. Eligible beneficiaries who receive services from model participants would not have the option to opt out of inclusion in the applicable model. We propose to require participants to supply beneficiaries with written information regarding the design and implications of these models as well as the beneficiaries' rights under Medicare, including their right to use their providers of choice. We would make a robust effort to reach out to beneficiaries and their advocates to help them understand the models. We also propose to 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.G. of this proposed rule.

8. Financial Arrangements

We propose to use the same general framework finalized in the CJR model to hold participants financially responsible for AMI, CABG and SHFFT model episodes as discussed in section III.I. of this proposed rule. Specifically, only the EPM participants would be directly subject to the requirements of this proposed rule for the proposed EPMs. EPM participants would be responsible for ensuring that other providers and suppliers collaborating with the EPM participants on care redesign for the applicable EPM episodes are in compliance with the applicable EPM's terms and conditions.

We propose adding hospitals to the list of providers and suppliers eligible for gainsharing as EPM collaborators due to the expected participation of multiple hospitals in the episode care for some beneficiaries in AMI and CABG episodes. We further propose adding ACOs to be eligible for gainsharing as EPM collaborators due to the interest of ACOs in gainsharing during the CJR model rulemaking and the ongoing challenges of addressing overlap between episode payment models and ACOs. We also propose provisions that allow for certain gainsharing within ACOs, detailed further in section III.I. of this proposed rule.

In contrast, the CR incentive payment model is specifically tied to increased utilization of CR/ICR services within AMI and CABG model episodes and, therefore, is designed to reward increased referral of AMI and CABG model beneficiaries to CR/ICR programs, as well as supporting beneficiary adherence to the referral and participation in CR/ICR services, rather than the quality and efficiency of EPM episodes themselves. Thus, we do not propose to allow CR incentive payments to be included in sharing arrangements, and the CR incentive payments may be shared with other individual and entities only under circumstances which comply with all existing laws and regulations, including fraud and abuse laws. Financial arrangements are discussed in further detail in section VI.E. of the proposed rule.

9. Data Sharing

Based on our experience with various Medicare programs and models, including the BPCI initiative, the CJR model, the Shared Savings Program, and the Pioneer ACO model, we believe that providing certain beneficiary claims data to model participants will be essential to their success. We propose to share data with participants upon request throughout the performance period of the models to the extent permitted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and other applicable law. We propose to share upon request both raw claims-level data and claims summary data with participants. This approach would allow participants without prior experience analyzing claims to use summary data for analysis of care and spending patterns, while allowing those participants who prefer raw claims-level data the opportunity to analyze claims. We propose to provide participants with up to 3 years of retrospective claims data upon request that will be used to develop their quality-adjusted target price. In accordance with the HIPAA Privacy Rule, we would limit the content of this data to the minimum data necessary for the participant to conduct quality assessment and improvement activities and effectively coordinate care.

10. Program Waivers

Section 1115A of the Act authorizes the Secretary to waive Medicare program requirements as necessary to implement provisions for testing models. Under the CJR model, CMS waived certain program rules regarding the direct supervision requirement for certain post-discharge home visits, telehealth services, and the skilled nursing facility (SNF) 3-day rule. CMS finalized these waivers to offer providers and suppliers more flexibility so that they may increase coordination of care and management of beneficiaries in model episodes. Adopting the CJR waivers for the proposed EPMs required further examination to determine if such adoption would increase financial vulnerability to the Medicare program or would create inappropriate incentives to reduce the quality of

beneficiary care. As discussed in section III.J. of this proposed rule, we propose to do the following:

- Adopt waivers of the telehealth originating site and geographic site requirement and to allow in-home telehealth visits for all three proposed EPMs, as well as the general waiver to allow post-discharge nursing visits in the home;
- Provide model-specific limits to the number of post-discharge nursing visits and make model-specific decisions about offering the SNF 3-day stay waiver; and
- Adopt a waiver for furnishing cardiac and intensive cardiac rehabilitation services to allow a Nurse Practitioner, Clinical Nurse Specialist, or Physician Assistant, in addition to a physician, to perform specific physician functions.

C. Summary of Economic Effects

As shown in our impact analysis, we expect the EPMs to result in savings to Medicare of $170 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 $12 million, as hospitals will not be subject to downside risk in the first year and the first quarter of the second performance year of the model. As we introduce downside risk beginning in the second quarter of performance year 2 of the model, we estimate Medicare savings of approximately $13 million. In performance year 3 of the model, we estimate Medicare savings of $30 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, and we estimate Medicare savings of $61 million and $79 million, respectively.

As a result, we estimate the net savings to Medicare to be $170 million over the 5 performance years of the model. We anticipate there will be a broader focus on care coordination and quality improvement for EPMs 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.

Additionally, the CR incentive model estimates that the impact on the Medicare program may range from up to $27 million of additional spending to $32 million of savings between 2017 and 2024, depending on the change in utilization of CR/ICR services based on the proposed incentive structure.

Finally, the change in the estimated net financial impact to the Medicare program from the CJR model modifications in this proposed rule is $22 million in spending, and the updated assumptions regarding the number of hospitals that will report quality data result in an increase of $14 million dollars in spending. The total estimated net financial impact to the Medicare program from both the modifications in the proposed rule and revised assumptions are $35 million in spending.

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.

II. Background

This proposed rule proposes the implementation of three new EPMs and a CR incentive payment model under the authority of section 1115A of the Act. Under the AMI, CABG, and SHFFT EPMs, acute care hospitals in certain selected geographic areas will be financially accountable for quality performance and spending for applicable episodes of care. We propose to retrospectively apply through a reconciliation process the episode payment methodology; hospitals and other providers and suppliers would continue to submit claims and receive payment via the usual Medicare FFS payment systems throughout the proposed EPMs' performance years. Hospitals participating in the proposed EPMs would receive target prices, which reflect expected spending for care during an episode as well as a discount to reflect savings to Medicare, on a prospective basis, prior to the beginning of a performance year. All related care covered under Medicare Parts A and B and furnished within 90 days after the date of hospital discharge from the anchor hospitalization which initiated the applicable EPM episode would be included in the episode of care. We believe the proposed models will further our goals of improving the efficiency and quality of care for Medicare beneficiaries for these medical conditions and procedures.

III. Provisions of the Proposed Regulations

A. Selection of Episodes, Advanced Alternative Payment Model Considerations, and Future Directions

1. Selection of Episodes for Episode Payment Models in This Rulemaking

a. Overview

CMS has been engaged since 2013 in testing various approaches to episode payment for Medicare FFS beneficiaries for 48 clinical episodes in the BPCI initiative. As of April 1, 2016, the BPCI initiative has 1,522 participants in the risk-bearing phase, comprised of 321 Awardees and 1,201 Episode Initiators. The breakdown of BPCI participants by provider type is as follows: Acute care hospitals (385); skilled nursing facilities (681); physician group practices (283); home health agencies (99); inpatient rehabilitation facilities (9); and long-term care hospitals (1).[10] In BPCI Models 2 and 3, there is participation across all 48 clinical episodes, and in Model 4 there is participation in 19 clinical episodes. The 10 clinical episodes with the most participation are: major joint replacement of the lower extremity; simple pneumonia and respiratory infections; congestive heart failure; chronic obstructive pulmonary disease; bronchitis; asthma; hip and femur procedures except major joint; sepsis; urinary tract infection; acute myocardial infarction (medical management only); medical non-infectious orthopedic; and other respiratory.[11]

In November 2015, CMS released the Final Rule for the Comprehensive Care for Joint Replacement (CJR) model (80 FR 73274 through 73554), the first test of episode payment for Medicare FFS beneficiaries in which providers are required to participate. The CJR model, which began on April 1, 2016, focuses on the episode-of-care for lower-extremity joint replacement (LEJR) procedures. As discussed in the Final Rule (80 FR 73277), LEJR episodes were chosen for the CJR model because they represent one of the most common high-expenditure, high-utilization procedures furnished to Medicare beneficiaries and have significant variation in episode spending. We believe this high volume, coupled with substantial variation in utilization and spending across individual providers and geographic

[10] *https://innovation.cms.gov/initiatives/bundled-payments/.*

[11] *https://innovation.cms.gov/Files/x/bpcianalyticfile.xlsx.*

regions, created a significant opportunity to test whether an episode payment model focused on a defined set of procedures could improve the quality and coordination of care, as well as result in savings to Medicare. Notably, both BPCI and the CJR model are focused on care that is related to an inpatient hospitalization, with CJR and BPCI Model 2 episodes beginning with an inpatient hospitalization (anchor hospitalization) and extending up to 90 days post-hospital discharge.

In this rulemaking, we propose three new EPMs that, like the CJR model, would require provider participation in selected geographic areas. Episodes in the new EPMs would begin with admissions for hospitalizations in IPPS hospitals, and would extend 90 days post-hospital discharge. The episodes included in these three EPMs are AMI, CABG, and SHFFT excluding lower extremity joint replacement. The proposed AMI model includes beneficiaries discharged under AMI MS–DRGs (280–282), representing IPPS admissions for AMI that are treated with medical management. The proposed AMI model also includes beneficiaries discharged under PCI MS–DRGs (246–251) with AMI International Classification of Disease, Tenth Edition, Clinical Modification (ICD–10–CM) diagnosis codes for initial AMI diagnoses in the principal or secondary diagnosis code positions, representing IPPS admissions for AMI that are treated with PCIs. The proposed CABG model includes beneficiaries discharged under CABG MS–DRGs (231–236), representing IPPS admissions for this coronary revascularization procedure irrespective of AMI diagnosis. The proposed SHFFT model includes beneficiaries discharged under hip and femur procedures except major joint replacement MS–DRGs (480–482), representing IPPS admissions for hip-fixation procedures in the setting of hip fractures.

Similar to the selection of LEJR episodes for the CJR model (80 FR 73277), we selected the AMI, CABG, and SHFFT episodes because they represent high-expenditure, high-volume episodes-of-care experienced by Medicare beneficiaries. Based on analysis of historical episodes beginning in CY 2012–2014, the average annual number of historical episodes that began with IPPS hospitalizations and extended 90 days post-hospital discharge, and therefore would have been included in the proposed models, is approximately 168,000 for AMI; 48,000 for CABG; and 109,000 for SHFFT.[12] The total annual Medicare spending for these historical episodes was approximately $4.1 billion, $2.3 billion, and $4.7 billion, respectively.[13] Each of the episodes provides different opportunities in an EPM to improve the coordination and quality of care, as well as efficiency of care during the episode, based on varying current patterns of utilization and Medicare spending.

However, in contrast to LEJR episodes in CJR, which are predominantly elective and during which hospital readmissions are rare and substantial post-acute care provider utilization is common, the proposed AMI, CABG, and SHFFT model episodes have very different current patterns of care. Beneficiaries in these episodes commonly have chronic conditions that contribute to the initiation of the episodes and need both planned and unplanned care throughout the EPM episode following discharge from the initial hospitalization that begins the episode. Both AMI and CABG model episodes primarily include beneficiaries with cardiovascular disease, a chronic condition which likely contributed to the acute events or procedures that initiate the episodes. About half the average AMI model historical episode spending was for the initial hospitalization, with the majority of spending following discharge from the initial hospitalization due to hospital readmissions, while there was relatively less spending on SNF services, Part B professional services, and hospital outpatient services. In CABG model historical episodes, about three-quarters of episode spending was for the initial hospitalization, with the remaining episode spending relatively evenly divided between Part B professional services and hospital readmissions, and a lesser percentage on SNF services. Similar to AMI episodes, post-acute care provider use was relatively uncommon in CABG model historical episodes, while hospital readmissions during CABG model historical episodes were relatively common. SHFFT model historical episodes also were accompanied by substantial spending for hospital readmissions, and post-acute care provider use in these episodes also was high.[14] The number of affected beneficiaries and potential impact of the models on quality and Medicare spending present an important opportunity to further the Administration's goal of shifting health care payments to support the quality of care over the quantity of services by promoting better coordination among health care providers and suppliers and greater efficiency in the care of beneficiaries in these models, while reducing Medicare expenditures.[15] Pay-for-performance episode payment models such as the three EPMs proposed in this rulemaking financially incentivize improved quality of care and reduced cost by aligning the financial incentives of all providers and suppliers caring for model beneficiaries with these goals. This alignment leads to a heightened focus on care coordination and management throughout the episode that prioritizes the provision of those items and services which improve beneficiary outcomes and experience at the lowest cost.

We selected all of the proposed EPM episodes based on their clinical homogeneity, site-of-service, and MS–DRG assignment considerations. We anticipate these proposed new EPMs, like the CJR model, would benefit Medicare beneficiaries by improving the coordination and transition of care among various care settings to facilitate beneficiaries' return to their communities as their recoveries progress, improving the coordination of items and services paid 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 post-acute care spectrum spanning the episode-of-care (80 FR 73276). However, improving value in the EPMs through these means requires a cohort of beneficiaries with similar clinical features such that coordination and care redesign efforts can be targeted. Therefore, we propose EPM episodes built on common pathologic and treatment processes; that is, beneficiaries included in both the AMI and CABG models have cardiovascular pathologies that drive their clinical courses during the

[12] Episodes for AMI, CABG, and SHFFT beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CY 2012–2014.

[13] Episodes for AMI, CABG, and SHFFT beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CY 2012–2014.

[14] Episodes for AMI, CABG, and SHFFT beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that end in CY 2014.

[15] 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-msarter-spending-healthier-people.html* (January 26, 2015).

episodes, and SHFFT model beneficiaries all share similar diagnoses of hip fracture and treatment with hip fixation that drive their clinical courses during their respective episodes.

b. SHFFT Model

The SHFFT model was selected to complement the CJR model. The SHFFT model is being tested in the same hospitals participating in the CJR model as discussed in section III.B.4 of this proposed rule, so that all surgical treatment options for Medicare beneficiaries with hip fracture (hip arthroplasty and fixation) would be included in episode payment models. Hip fracture is a serious and sometimes catastrophic event for Medicare beneficiaries. In 2010, 258,000 people aged 65 and older were admitted to the hospital for hip fracture, with an estimated $20 billion in lifetime cost for all hip fractures in the United States in a single year.[16] In 2013, fracture of the neck of the femur (the most common location for hip fracture) was the eighth most common principal discharge diagnosis for hospitalized Medicare FFS beneficiaries, constituting 2.7 percent of discharges.[17] Mortality associated with hip fracture is 5–10 percent after 1 month and approximately 33 percent at 1 year.[18] Hip arthroplasty and hip fixation, or ''hip pinning,'' represent the two broad surgical options for treating hip fractures.[19] The CJR model episodes begin with admission to acute care hospitals for LEJR procedures assigned to MS–DRG 469 (Major joint replacement or reattachment of lower extremity with major complications or comorbidities) or MS–DRG 470 (Major joint replacement or reattachment of lower extremity without major complications or comorbidities) upon beneficiary discharge and paid under the IPPS, including total and partial hip replacement in the setting of hip fracture (80 FR 73280). Therefore, the SHFFT model, which would additionally test an episode payment for hip fixation, provides an opportunity to complete the transition to episode payment for the surgical treatment and recovery of the significant clinical condition of hip fracture.

c. AMI and CABG Models

The AMI and CABG models, which we propose to be tested at a single set of hospitals as discussed in section III.B.5 of this proposed rule, were selected to include all beneficiaries who have an AMI treated medically or with revascularization with PCI, as well as all beneficiaries who undergo CABG (whether performed during the care of an AMI or performed electively for stable ischemic heart disease or other indication). Both cardiac models represent clinical conditions that result in a significant burden of morbidity and expenditures in the Medicare population. CABG typically is the preferred revascularization modality for patients with ST elevation AMI where the coronary anatomy is not amenable to PCI or there is a mechanical complication (for example, ventricular septal defect, rupture of the free wall of the ventricle, or papillary-muscle rupture with severe mitral regurgitation); for patients with CAD other than ST elevation AMI where there is left main coronary artery disease or multi-vessel disease with complex lesions; and for patients with clinically significant CAD in at least one vessel and refractory symptoms despite medical therapy and PCI.[20] Despite the greater acute morbidity related to major cardiothoracic surgery, CABG is associated with lower longer-term rates of major adverse cardiac and cerebrovascular events in comparison to PCI for certain groups of patients.[21] Moreover, a recent study found that in a group of patients with ischemic cardiomyopathy, the rates of death from any cause, death from cardiovascular causes, and death from any cause or hospitalization for cardiovascular causes were significantly lower over 10 years among patients who underwent CABG in addition to receiving medical therapy than among those who received medical therapy alone.[22] While about 30 percent of CABGs are performed during the care of AMIs, we propose to include these particular AMI beneficiaries generally in the same episode as CABG for other indications, rather than in the AMI episode, since we anticipate hospitals will seek to improve the quality and efficiency of care for that surgical intervention, regardless of indication.[23]

We propose AMI as the episode for an EPM because we recognize it as a significant clinical condition for which evidence-based clinical guidelines are available for the most common AMI scenarios that begin with a beneficiary's presentation for urgent care, most commonly to a hospital emergency department. The hospital phase involves medical management for all patients, as well as potential revascularization, most commonly with PCI. Secondary prevention and plans for long-term management begin early during the hospitalization and extend following hospital discharge and are addressed in clinical guidelines.[24] [25] The AMI model is the first Innovation Center episode payment model that includes substantially different clinical care pathways (medical management and PCI) for a single clinical condition in one episode in a model and, as such, represents an important next step in testing episode payment models for clinical conditions which involve a variety of different approaches to treatment and management.

The American Heart Association estimates that every 42 seconds, someone in the United States has a myocardial infarction.[26] AMI remains

[16] Smith et al. Increase in Disability Prevalence Before Hip Fracture. J Am Geriatr Soc. 2015 Oct;63(10):2029–35.

[17] Krumholz HM, Nuti SV, Downing NS, Normand ST, Wang Y. Mortality, Hospitalizations, and Expenditures for the Medicare Population Aged 65 Years or Older, 1999–2013. JAMA. 2015; 314(4):355–365.

[18] Parker et al. Hip Fracture. BMJ. 2006 Jul 1;333(7557):27–30.

[19] American Academy of Orthopaedic Surgeons, OrthoInfo: Hip Fractures, *http://orthoinfo.aaos.org* (April 12, 2016).

[20] Alexander JH, Smith PK. Coronary-Artery Bypass Grafting. N Engl J Med. 2016 May 19;374(2):1954–1964.

[21] Sepehripour et al. Developments in surgical revascularization to achieve improved morbidity and mortality. Expert Rev Cardiovasc Ther. 2016 Mar;14(3):367–79. doi: 10.1586/14779072.2016.1123619. Epub 2015 Dec 17.

[22] Velazquez et al. Coronary Artery Bypass Surgery in Patients with Ischemic Cardiomyopathy. N Engl J Med. 2016 Apr 3.

[23] Episodes for CABG beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, that end in CY 2014.

[24] Amsterdam EA, Wenger NK, Brindis RG, Casey DE Jr, Ganiats TG, Holmes DR Jr, Jaffe AS, Jneid H, Kelly RF, Kontos MC, Levine GN, Liebson PR, Mukherjee D, Peterson ED, Sabatine MS, Smalling RW, Zieman SJ. 2014 ACC/AHA guideline for the management of patients with non–ST-elevation acute coronary syndromes: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2014;130:e344–e426.

[25] O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, Ettinger SM, Fang JC, Fesmire FM, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA, Morrow DA, Newby LK, Ornato JP,Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;127:

[26] Mozaffarian D, Benjamin EJ, Go AS, Arnett DK, Blaha MJ, Cushman M, Das SR, de Ferranti S, Després J-P, Fullerton HJ, Howard VJ, Huffman MD, Isasi CR, Jiménez MC, Judd SE, Kissela BM, Lichtman JH, Lisabeth LD, Liu S, Mackey RH, Magid DJ, McGuire DK, Mohler ER III, Moy CS, Muntner P, Mussolino ME, Nasir K, Neumar RW, Nichol G, Palaniappan L, Pandey DK, Reeves MJ, Rodriguez CJ, Rosamond W, Sorlie PD, Stein J, Towfighi A, Turan TN, Virani SS, Woo D, Yeh RW, Turner MB; on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke

one of the most common hospital diagnoses among Medicare FFS beneficiaries, and almost 20 percent of beneficiaries discharged for AMI are readmitted within 30 days of hospital discharge.[27] [28] In 2013, AMI was the sixth most common principal discharge diagnosis for hospitalized Medicare FFS beneficiaries, constituting 2.9 percent of discharges.[29] Of the approximately 395,000 Medicare FFS beneficiaries with short-term acute care hospital discharges (excluding Maryland) for AMI in FY 2014, 60 percent were discharged under MS–DRGs proposed to be included in the AMI model, specifically 33 percent under AMI MS–DRGs and 25 percent under PCI MS–DRGs.[30] An additional 3 percent of beneficiaries were in MS–DRGs assigned for death from AMI in the hospital. Although 5 percent of beneficiaries with hospital discharges for AMI were discharged under CABG MS–DRGs, we note that because both PCI and fibrinolysis can restore blood flow in an acutely occluded coronary artery more quickly than CABG, these interventions are currently preferred to CABG in most cases of AMI. Furthermore, over recent years cardiovascular clinical practice patterns have generally shifted away from surgical treatment of coronary artery occlusion toward percutaneous, catheter-based interventions.[31] The remaining 34 percent of beneficiaries with AMI diagnoses were distributed across a heterogeneous group of over 300 other MS–DRGs, such as septicemia, respiratory system diagnosis with ventilator support, and major cardiovascular procedures. For this latter group of beneficiaries, the AMI diagnosis appeared in a secondary position on the hospital claim in more than 90 percent of the cases, therefore most likely representing circumstances where the beneficiary hospitalized for another clinical condition experienced an AMI during the hospital stay. By focusing the AMI model on AMIs treated medically or with revascularization with PCI, we propose to test a condition-specific EPM that is discretely defined and includes a significant majority of beneficiaries with AMI in the AMI model. In CYs 2012–2014, the average Medicare spending for an AMI episode that extends 90 days post-hospital discharge was approximately $24,200.[32] From the AMI model, we expect to better understand the impact such an EPM can have on efficiency and quality of care for beneficiaries across the entire spectrum of AMI care, including diagnosis, treatment, and recovery, as well as short-term secondary prevention.

Beneficiaries in the proposed AMI and CABG models would all have CAD. In 2010 in the U.S, the prevalence of CAD in the population 65 years and older was about 20 percent.[33] Patients with CAD also often experience other conditions with significant health-related implications, including diabetes. To improve care for patients with CAD, most approaches in the private and public sectors focus on improving the efficiency and quality of care around procedures such as PCI and CABG. The BPCI models are an example of such an approach. As discussed previously in this section, our proposal for the AMI model extends beyond a procedure-based EPM to include beneficiaries hospitalized for medical management or PCI for AMI in a single EPM, and we propose to test the CABG model, which also would include beneficiaries with AMI, at the same participant hospitals. We believe that hospitalization for AMI, whether accompanied solely by medical management or including revascularization during the initial hospitalization or in a planned CABG readmission, is a sentinel event indicating the need for an increased focus on condition-specific management, as well as on care coordination and active management to prevent future acute events, both during the AMI and CABG model episodes and beyond. We also believe that improving the quality and efficiency of CAD care over a long period of time is important given the chronic nature of this condition that has serious implications for beneficiary health.

The AMI and CABG models provide an opportunity for us to incentivize CAD-specific care management and care coordination for AMI and CABG model beneficiaries that lay the groundwork for longer-term improvements in quality and efficiency of care for beneficiaries with CAD. We note that the quality measures proposed for use in the pay-for-performance methodologies of the AMI and CABG models do not currently include longer-term outcomes or patient experience outside of the AMI or CABG model episode itself, as discussed in sections III.E.2.b. and c. of this proposed rule, although we are interested in comments about potential future measures that could incorporate longer-term outcomes. Moreover, as discussed in section VI. of this proposed rule, we also propose to test a cardiac rehabilitation (CR)/intensive cardiac rehabilitation (ICR) incentive payment, hereinafter CR incentive payment, in AMI and CABG model participants located in some of the MSAs selected for AMI and CABG model participation, as well as in hospitals located in some of the MSAs that are not selected for AMI or CABG model participation. We would evaluate the effects of the CR incentive payment in the context of an episode payment model and Medicare FFS on utilization of CR/ICR, as well as short-term (within the period of time extending 90 days following hospital discharge from an AMI or CABG hospitalization) and longer-term outcomes. We believe this test may result in valuable findings about effective strategies to increase utilization of CR/ICR services that have a strong evidence-base for their effectiveness but a long history of underutilization.

2. Advanced Alternative Payment Model Considerations

a. Overview for the EPMs

The MACRA created two paths for eligible clinicians to link quality to payments: The MIPS and Advanced APMs. These two paths create a flexible payment system called the Quality Payment Program as proposed by CMS in the Quality Payment Program proposed rule (81 FR 28161 through 28586).

As proposed in the Quality Payment Program proposed rule, an APM must meet three criteria to be considered an Advanced APM (81 FR 28298). First, the APM must provide for payment for covered professional services based on quality measures comparable to measures described under the

statistics—2016 update: A report from the American Heart Association. Circulation. 2016 Jan 26; 133(4):447–54.

[27] Krumholz HM, Nuti SV, Downing NS, Normand ST, Wang Y. Mortality, Hospitalizations, and Expenditures for the Medicare Population Aged 65 Years or Older, 1999–2013. JAMA. 2015; 314(4):355–365.

[28] Dharmarajan K, Hsieh AF, Lin Z et al. Diagnoses and Timing of 30-Day Readmissions After Hospitalization for Heart Failure, Acute Myocardial Infarction, or Pneumonia. JAMA. 2013; 309(4):355–363.

[29] Krumholz HM, Nuti SV, Downing NS, Normand ST, Wang Y. Mortality, Hospitalizations, and Expenditures for the Medicare Population Aged 65 Years or Older, 1999–2013. JAMA. 2015; 314(4):355–365.

[30] Inpatient claims from all U.S. IPPS hospitals not in Maryland were derived from the October 2013–September 2014 Inpatient Claims File located in the Chronic Conditions Warehouse.

[31] Epstein et al. JAMA. 2011 May 4; 305(17): 1769–1776.

[32] Episodes for beneficiaries with AMI diagnosis initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CYs 2012–2014.

[33] National Center for Chronic Disease Prevention and Health Promotion, Division for Heart Disease and Stroke Prevention, August 10, 2015.

performance category described in section 1848(q)(2)(B)(i) of the Act, which is the MIPS quality performance category. Under the Quality Payment Program proposed rule, we proposed that the quality measures on which the Advanced APM bases payment for covered professional services (as that term is defined in section 1848(k)(3)(A) of the Act) must include at least one of the following types of measures, provided that they have an evidence-based focus and are reliable and valid (81 FR 28302):

- Any of the quality measures included on the proposed annual list of MIPS quality measures.
- Quality measures that are endorsed by a consensus-based entity.
- Quality measures developed under section 1848(s) of the Act.
- Quality measures submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act.
- Any other quality measures that CMS determines to have an evidence-based focus and be reliable and valid.

As we discussed in the Quality Payment Program proposed rule, because the statute identifies outcome measures as a priority measure type and we wanted to encourage the use of outcome measures for quality performance assessment in APMs, we further proposed in that rule that, in addition to the general quality measure requirements, an Advanced APM must include at least one outcome measure if an appropriate measure is available on the MIPS list of measures for that specific QP Performance Period, determined at the time when the APM is first established (81 FR 28302 through 28303).

Second, the APM must either require that participating APM Entities bear risk for monetary losses of a more than nominal amount under the APM or be a Medical Home Model expanded under section 1115A(c) of the Act. Except for Medical Home Models, we proposed in the Quality Payment Program proposed rule that, for an APM to meet the nominal amount standard, the specific level of marginal risk must be at least 30 percent of losses in excess of expected expenditures; a minimum loss rate, to the extent applicable, must be no greater than 4 percent of expected expenditures; and total potential risk must be at least 4 percent of expected expenditures (81 FR 28306).

Third, the APM must require participants to use CEHRT (as defined in section 1848(o)(4) of the Act), as specified in section 1833(z)(3)(D)(i)(I) of the Act, to document and communicate clinical care with patients and other health care professionals. Specifically, where the APM participants are hospitals, the APM must require each hospital to use CEHRT (81 FR 28298 through 28299).

In this proposed rule, we propose to adopt two different tracks for the EPMs—Track 1 in which EPMs and EPM participants would meet the criteria for Advanced APMs as proposed in the Quality Payment Program proposed rule, and Track 2 in which the EPMs and EPM participants would not meet those proposed criteria. For the proposed AMI, CABG, and SHFFT models, we propose pay-for-performance methodologies that use quality measures that we believe would meet the proposed Advanced APM quality measure requirements in the Quality Payment Program proposed rule. As discussed in sections III.E.2. and 3. of this proposed rule, all but one of the AMI, CABG, and SHFFT model measures used in the EPM pay-for-performance methodologies are NQF-endorsed and have an evidence-based focus and are reliable and valid. Therefore, we believe they would meet the proposed Advanced APM general quality measure requirements. The Excess Days in Acute Care after Hospitalization for AMI (AMI Excess Days) measure, which is proposed for the AMI model, is not currently NQF-endorsed, but we believe it meets the measure requirements by having an evidence-based focus and being reliable and valid because this measure has been proposed and adopted through rulemaking for use in the Hospital Inpatient Quality Reporting (HIQR) Program.

Each of the proposed EPM pay-for-performance methodologies includes one outcome measure that is NQF-endorsed, has an evidence-based focus, and is reliable and valid. The EPM quality measures are discussed in detail in section III.E. of this proposed rule, where we assign the quality measures to quality domains. For the AMI model, we propose to use the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (NQF #0230) (MORT–30–AMI) outcome measure. For the CABG model, we propose to use the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF# 2558) (MORT–30–CABG) outcome measure. Finally, for the SHFFT model, we propose to use the Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550) (Hip/Knee Complications) outcome measure. Thus, based on the proposed use of these three outcomes measures in the EPMs, we believe the proposed AMI, CABG, and SHFFT models would meet the requirement proposed for Advanced APMs in the Quality Payment Program proposed rule for use of an outcome measure that also meets the general quality measure requirements.

In terms of the proposed nominal risk criteria for Advanced APMs, beginning in performance year 2 for episodes ending between April 1, 2018 and December 31, 2018, EPM participants would begin to bear downside risk for excess actual EPM-episode spending above the quality-adjusted target price as discussed in section III.D.2.c. of this proposed rule. The marginal risk for excess actual EPM-episode spending above the quality-adjusted target price would be 100 percent over the range of spending up to the stop-loss limit, which would exceed 30 percent marginal risk, and there would be no minimum loss rate. As a result, we believe the EPMs would meet the marginal risk and minimum loss rate elements of the nominal risk criteria for Advanced APMs proposed in the Quality Payment Program proposed rule. Total potential risk for most EPM participants would be 5 percent of expected expenditures beginning in the second quarter of performance year 2, and increasing in subsequent performance years as discussed in section III.D.7.b. of this proposed rule. Therefore, we believe the total potential risk applicable to most EPM participants, with the lowest total potential risk being 5 percent for EPM episodes ending on or after April 1, 2018 in performance year 2, would meet the total potential risk element of the nominal risk amount standard for Advanced APMs proposed in the Quality Payment Program proposed rule because it is greater than the value of at least 4 percent of expected expenditures.

We note that we propose that EPM participants that are rural hospitals, sole community hospitals (SCHs), Medicare Dependent Hospitals (MDHs) and Rural Referral Centers (RRCs) would have a stop-loss limit of 3 percent beginning in the second quarter of performance year 2 as discussed in section III.D.7.c. of this proposed rule. Because 3 percent is less than the proposed threshold of at least 4 percent of expected expenditures for total potential risk proposed for Advanced APMs in the Quality Payment Program proposed rule, those rural hospitals, SCHs, MDHs, and RRCs that are EPM participants subject to special protections would be in Track 2 EPMs that would not meet the proposed nominal risk standard for Advanced

APMs for performance year 2. We recognize that this proposal might initially limit the ability of rural hospitals, SCHs, MDHs, and RRCs to be in Track 1 EPMs that are Advanced APMs. We believe this potential limitation on rural hospitals, SCHs, MDHs, and RRCs is appropriate for the following reasons: (1) Greater risk protections for these hospitals proposed for the EPMs beginning in the second quarter of performance year 2 and subsequent performance years compared to other EPM participants are necessary, regardless of their implications regarding Advanced APMs based on the nominal risk standard proposed in the Quality Payment Program proposed rule, because these hospitals have unique challenges that do not exist for most other hospitals, such as being the only source of health care services for beneficiaries or certain beneficiaries living in rural areas or being located in areas with fewer providers, including fewer physicians and post-acute care facilities; and (2) under the risk arrangements proposed for the EPMs, these hospitals would not bear an amount of risk in performance year 2 that we determined to be more than nominal in the Quality Payment Program proposed rule. However, we seek comment on whether we should allow EPM participants that are rural hospitals, SCHs, MDHs, or RRCs to elect a higher stop-loss limit for the part of performance year 2 where downside risk applies in order to permit these hospitals to be in Track 1 EPMs for that part of performance year 2. We note that by performance year 3, the stop-loss limit for these hospitals with special protections under the EPMs would increase to 5 percent under our proposal, so these hospitals could be in Track 1 EPMs based on the nominal risk standard proposed in the Quality Payment Program proposed rule.

As addressed in the Quality Payment Program proposed rule, it is necessary for an APM to require the use of CEHRT in order to meet the criteria to be considered to be an Advanced APM. Therefore, according to the requirements proposed in the Quality Payment Program proposed rule, so that the EPMs may meet the proposed criteria to be Advanced APMs, we propose to require EPM participants to use CEHRT (as defined in section 1848(o)(4) of the Act) to participate in Track 1 of the EPMs. We propose that Track 1 EPM participants must use certified health IT functions, in accordance with the definition of CEHRT under our regulation at 42 CFR 414.1305, to document and communicate clinical care with patients and other health care professionals as proposed in the Quality Payment Program proposed rule (81 FR 28299). We believe this proposal would allow Track 1 EPMs to be able to meet the proposed criteria to be Advanced APMs.

Without the collection of identifying information on eligible clinicians (physicians, nonphysician practitioners, physical and occupational therapists, and qualified speech-language pathologists) who would be considered Affiliated Practitioners as proposed in the Quality Payment program proposed rule under the EPMs, CMS would not be able to consider participation in the EPMs in making determinations as to whom could be considered a QP (81 FR 28320). As detailed in the Quality Payment Proposed rule, these determinations are based on whether the eligible clinician meets the QP threshold under either the Medicare Option starting in payment year 2019 or the All-Payer Combination Option, which is available starting in payment year 2021 (81 FR 28165). Thus, we make proposals in the following sections to specifically address these issues that might otherwise preclude the EPMs from being considered Advanced APMs, or prevent us from operationalizing them as Advanced APMs. Based on the proposals for Advanced APM criteria in the Quality Payment Program proposed rule, we seek to align the design of the proposed EPMs with the proposed Advanced APM criteria and enable CMS to have the necessary information on eligible clinicians to make the requisite QP determinations.

b. EPM Participant Tracks

To be considered an Advanced APM, the APM must require participants to use CEHRT (as defined in section 1848(o)(4) of the Act), as specified in section 1833(z)(3)(D)(i)(I) of the Act. We propose that all EPM participants must choose whether to meet the CEHRT use requirement. EPM participants that do not choose to meet and attest to the CEHRT use requirement would be in Track 2 of the EPMs. EPM participants selecting to meet the CEHRT use requirement would be in Track 1 of the EPMs and would be required to attest in a form and manner specified by CMS to their use of CEHRT that meets the definition in our regulation at § 414.1305 to document and communicate clinical care with patients and other health professionals, consistent with the proposal in the Quality Payment Program proposed rule for the CEHRT requirement for Advanced APMs (81 FR 28299). EPM participants choosing not to meet and attest to the CEHRT use requirement would not be required to submit an attestation.

We believe that the selection by EPM participants to meet and attest to the CEHRT use requirement would create no significant additional administrative burden on EPM participants. Moreover, the choice of whether to meet and attest to the CEHRT use requirement would not otherwise change any EPM participant's requirements or opportunity under the EPM. However, to the extent that eligible clinicians who enter into financial arrangements related to Track 1 EPM participants are considered to furnish services through an Advanced APM, those services could be considered for purposes of determining whether the eligible clinicians are QPs.

The proposals for CEHRT use and attestation for EPM participants are included in § 512.120(a). We seek comment on our proposals for EPM participant CEHRT use requirements.

c. Clinician Financial Arrangements Lists Under the EPMs

In order for CMS to make determinations as to eligible clinicians who could be considered QPs based on services furnished under the EPMs (to the extent the models are determined to be Advanced APMs), we require accurate information about eligible clinicians who enter into financial arrangements under the Track 1 EPMs under which the Affiliated Practitioners support the participants' cost or quality goals as discussed in section III.I. of this proposed rule. We note that eligible clinicians could be EPM collaborators engaged in sharing arrangements with an EPM participant; PGP members who are collaboration agents engaged in distribution arrangements with a PGP that is an EPM collaborator; or PGP members who are downstream collaboration agents engaged in downstream distribution arrangements with a PGP that is also an ACO participant in an ACO that is an EPM collaborator. These terms as they apply to individuals and entities with financial arrangements under the EPMs are discussed in section III.I. of this proposed rule. A list of physicians and nonphysician practitioners in one of these three types of arrangements could be considered an Affiliated Practitioner List of eligible clinicians who are affiliated with and support the Advanced APM Entity in its participation in the Advanced APM as proposed in the Quality Payment Program proposed rule. Therefore, this list could be used to make determinations of who would be

considered for a QP determination based on services furnished under the EPMs (81 FR 28320).

Thus, we propose that each EPM participant that chooses to meet and attest to the CEHRT use requirement must submit to CMS a clinician financial arrangements list in a form and manner specified by CMS on a no more than quarterly basis. The list must include the following information for the period of the EPM performance year specified by CMS:

- For each EPM collaborator who is a physician, nonphysician practitioner, or provider of outpatient therapy services during the period of the EPM performance year specified by CMS:

++ The name, tax identification number (TIN), and national provider identifier (NPI) of the EPM collaborator.

++ The start date and, if applicable, end date, for the sharing arrangement between the EPM participant and the EPM collaborator.

- For each collaboration agent who is a physician or nonphysician practitioner of a PGP that is an EPM collaborator during the period of the EPM performance year specified by CMS:

++ The TIN of the PGP that is the EPM collaborator, and the name and NPI of the physician or nonphysician practitioner.

++ The start date and, if applicable, end date, for the distribution arrangement between the EPM collaborator that is a PGP and the physician or nonphysician practitioner who is a PGP member.

- For each downstream collaboration agent who is a physician or nonphysician practitioner member of a PGP that is also an ACO participant in an ACO that is an EPM collaborator during the period of the EPM performance year specified by CMS:

++ The TIN of the PGP that is the ACO participant, and the name and NPI of the physician or nonphysician practitioner.

++ The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent that is both PGP and an ACO participant and the physician or nonphysician practitioner who is a PGP member.

- If there are no individuals that meet the requirements to be reported as EPM collaborators, collaboration agents, or downstream collaboration agents, the EPM participant must attest in a form and manner required by CMS that there are no individuals to report on the clinician financial arrangements list.

As discussed in the Quality Payment program proposed rule, those physicians or nonphysician practitioners who are included on the Affiliated Practitioner List as of December 31 of a performance period would be assessed to determine whether they qualify for APM Incentive Payments (81 FR 28320).

While the required submission of this information may create some additional administrative requirements for certain EPM participants, we expect that Track 1 EPM participants could modify their contractual relationships with their EPM collaborators and, correspondingly, require those EPM collaborators to include similar requirements in their contracts with collaboration agents and in the contracts of collaboration agents with downstream collaboration agents.

The proposal for the submission of a clinician financial arrangements list by EPM participants that meet and attest to the CEHRT use requirement for the EPMs is included in § 512.120(b). We seek comments on the proposal for submission of this information. We are especially interested in comments about approaches to information submission, including the periodicity and method of submission to CMS that would minimize the reporting burden on EPM participants while providing CMS with sufficient information about eligible clinicians in order to facilitate QP determinations to the extent EPMs are considered Advanced APMs.

d. Documentation Requirements

For each EPM participant that chooses to meet and attest to CEHRT use, we propose that the EPM participant must maintain documentation of their attestation to CEHRT use and clinician financial arrangements lists submitted to CMS. These documents would be necessary to assess the completeness and accuracy of materials submitted by an EPM participant in the Track 1 EPM and to facilitate monitoring and audits. For the same reason, we further propose that the EPM participant must retain and provide access to the required documentation in accordance with § 512.110.

The proposal for documentation of attestation to CEHRT use and clinician financial arrangements lists submitted to CMS is included in § 512.120(c). We seek comment on this proposal for required documentation.

3. Future Directions for Episode Payment Models

a. Refinements to the BPCI Initiative Models

The BPCI initiative Models 2, 3, and 4 would not currently qualify as Advanced APMs based on the two of the Advanced APM criteria in the Quality Payment Program proposed rule, payment based on quality measures and CEHRT use (81 FR 28298). Specifically, BPCI participants are not currently required to use CEHRT, and although CMS examines the quality of episode care in the BPCI evaluation, BPCI episode payments are not specifically tied to quality performance. Instead, BPCI episode payments are based solely on episode spending performance, although we expect that reductions in spending would generally be linked to improved quality through reductions in hospital readmissions and complications. However, building on the BPCI initiative, the Innovation Center intends to implement a new voluntary bundled payment model for CY 2018 where the model(s) would be designed to meet the criteria to be an Advanced APM.

b. Potential Future Condition-Specific Episode Payment Models

In the context of our proposal for the AMI and CABG models that include beneficiaries with CAD who experience an acute event or a major surgical procedure, we seek comment on model design features for potential future condition-specific episode payment models that could focus on an acute event or procedure or longer-term care management, including other models for beneficiaries with CAD that may differ from the design of the EPMs proposed in this rulemaking. We believe such future models may have the potential to be Advanced APMs that emphasize outpatient care and, like the proposed AMI and CABG models, could incentivize the alignment of physicians and other eligible professionals participating in the Advanced APM through accountability for the costs and quality of care. Such condition-specific episode payment models may provide for a transition from hospital-led EPMs to physician-led accountability for episode quality and costs, especially given the importance of care management over long periods of time for beneficiaries with many chronic conditions.

We request that commenters provide specific information regarding all relevant issues for potential future condition-specific episode payment models, including identifying beneficiaries for the model; including services in the episode definition; beginning and ending episodes; pricing episodes, including risk-adjustment; designating the accountable entity for the quality and cost of the episode, including the role of physician-led

opportunities; sharing of responsibility for quality and spending between primary care providers, specialty physicians, and other health care professionals; incentivizing the engagement of physicians and other providers and suppliers in episode care; measuring quality and including quality performance and improvement in the payment methodology; interfacing with other CMS models and programs responsible for population health and costs, such as ACOs and Primary Care Medical Homes (PCMHs); and other considerations specific to identifying future models as Advanced APMs; and any other issues of importance for the design of such an EPM.

c. Potential Future Event-Based Episode Payment Models for Procedures and Medical Conditions

Given the proposed EPM methodology discussed in section III.C.4.a. of this proposed rule for the three models that would begin the episodes with initial hospitalizations, the proposed AMI, CABG, and SHFFT episodes are similar to the LEJR episodes in the CJR model because they reflect clinical conditions for which care is almost always begun during an inpatient hospitalization, either on an emergency or elective basis. In addition, the clinical conditions represented by these EPM episodes generally result in straightforward assignment to MS–DRGs at discharge that are specific to clinical conditions included in the episodes. This contrasts with procedure-related clinical conditions for which the site-of-service can be inpatient or outpatient (for example, elective PCI for non-AMI beneficiaries) or hospitalization for medical conditions for which the ultimate MS–DRG assigned is less clear at the beginning of an episode (for example, hospitalization for respiratory symptoms which may lead to discharge from heart failure, pneumonia, or other MS–DRGs based on reporting of ICD–CM diagnosis codes on hospital claims).

To address the issues related to the development of future episode payment models for a broader range of clinical conditions, we seek comment on model design features that would be important for episode payment models targeting procedures that may be performed in both the inpatient and outpatient setting, as well as models focused on hospitalization for acute medical conditions which may overlap or interact (for example, sepsis related to pneumonia or acute kidney injury related to congestive heart failure exacerbation). In particular, episode payment models must clearly define the beginning of the episode as well as set an episode price that is appropriate for beneficiaries included in the episode, which has commonly been based on historical spending for such beneficiaries in both existing CMS models and the three proposed EPMs. These parameters pose specific challenges as the variety of clinical conditions targeted for episode payments expands beyond lower extremity orthopedic procedures and acute cardiac conditions, and we expect that such potential future models would need to be designed differently than the CJR model or the EPMs proposed in this rulemaking.

For example, because procedures such as PCI for non-AMI beneficiaries or cardioverter defibrillator implantations can occur in the inpatient or outpatient setting, an episode payment model would need to include beneficiaries receiving such procedures at all sites-of-service so as to not influence decisions on where procedures are performed based on payment-related rather than clinical considerations. Episode payment models that begin with the same procedure performed in the inpatient or outpatient setting would require methodological development beyond the approaches that have been used thus far in CMS's other EPMs that rely upon the MS–DRG for a hospitalization to begin an episode and identify historical episodes for setting episode prices. Such models that involve episode payment for procedures furnished in the inpatient or outpatient setting may allow for significant physician-led opportunities that would allow the models to be identified as Advanced APMs. We seek comment on how these types of procedures could be included in future episode payment models, including identifying the accountable entity, and the role of physician-led opportunities; defining the episode beginning and end; setting episode prices; applying risk-adjustment to account for differences in expected episode spending for a heterogeneous population of beneficiaries; and any other issues of importance for the design of such an episode payment model.

We also seek comment on potential future episode payment models that would include care for medical conditions that result in the serious health event of an inpatient hospitalization, which often represents, regardless of the specific reason for the hospitalization, a common pathway that includes failure of outpatient care management and care coordination for beneficiaries with chronic conditions. While we do include in the proposed AMI model beneficiaries who solely receive medical treatment, we note that beneficiaries with AMI are almost always hospitalized and their MS–DRGs at discharge are generally predictable and consistent based on their AMI diagnoses. This is not the case for a number of medical conditions for which grouping by MS–DRGs is more complicated or less consistent. Many non-procedural hospitalizations of Medicare beneficiaries are ultimately categorized based on the principal ICD–CM diagnosis code reported on a claim, which in turn is mapped to a Major Diagnostic Category (MDC) based on the involved organ system, which then leads to the assignment of any of various specific MS–DRGs based on the medical groups in the MDC. For example, the medical groups for the Respiratory System MDC are pulmonary embolism, infections, neoplasms, chest trauma, pleural effusion, pulmonary edema and respiratory failure, chronic obstructive pulmonary disease, simple pneumonia, RSV pneumonia and whooping cough, interstitial lung disease, pneumothorax, bronchitis and asthma, respiratory symptoms and other respiratory diagnoses.[34] Unlike a beneficiary who undergoes a surgical procedure or who is hospitalized for a specific medical condition such as AMI, the ultimate MS–DRG at discharge assigned to a beneficiary hospitalized for diagnosis and management of respiratory symptoms may not be clear during the hospitalization itself, or even afterward, until the inpatient claim is submitted and paid by Medicare. This makes it challenging for providers to engage in care delivery redesign targeted to a specific patient population identified by MS–DRG. Additionally, it is possible that beneficiaries hospitalized for certain medical conditions also may follow common clinical pathways before and after discharge for which similar care redesign strategies could be developed and used despite those beneficiaries' assignments to different MS–DRGs for their anchor hospitalizations. Thus, we believe that hospitalization for most medical conditions would require special consideration in the development of potential future episode payment models that goes beyond CMS's current approach of relying upon the MS–DRG for the anchor hospitalization to begin an episode and identify historical episodes for setting episode prices. We seek comment on design features needed to address these considerations, including defining the beginning and end of episodes; setting episode prices,

[34] Medical Severity Diagnosis Related Groups (MS–DRGs): Definitions Manual. Version 33.0A. 3M Health Information Systems. (October 1, 2015).

including risk-adjustment, that would support the provision of appropriate and coordinated care for beneficiaries following hospital discharge for a period of time during the episode; and any other issues of importance for the design of such an episode payment model.

d. Health Information Technology Readiness for Potential Future Episode Payment Models

We are particularly interested in issues related to readiness of providers and suppliers that are not hospitals to take on financial responsibility for episode cost and quality in potential future episode payment models. We have some experience in BPCI Models 2 and 3 with non-hospital providers and suppliers, specifically post-acute care providers and physician group practices (PGPs), who assume financial responsibility for the cost of episode care. In BPCI Model 2, PGPs may directly bear financial responsibility for episode cost for up to 48 clinical conditions for the anchor inpatient admission and up to 90 days post-hospital discharge. In BPCI Model 3, PGPs and post-acute care providers, including skilled nursing facilities, home health agencies, inpatient rehabilitation facilities, and long-term care hospitals, may directly bear financial responsibility for episode cost for up to 48 clinical conditions for a duration that extends up to 90 days following initiation of post-acute care following discharge from an inpatient hospitalization.

Under these circumstances, PGPs and post-acute care providers typically need to use health IT to assist them in effectively coordinating the care of BPCI beneficiaries across settings throughout the episodes. The risk-bearing entities participating in BPCI have expressed readiness to take on financial responsibility for episode cost, and they commonly rely upon health IT for assistance in managing the care for BPCI beneficiaries across settings for episodes that extend for a substantial period of time. However, a recent national survey of IT in nursing homes showed common use of IT for administrative activities but less use for clinical care.[35] Anecdotally, stakeholders have told us that accountable non-hospital providers and suppliers, especially those that are not integrated with health systems, may have less well-developed tools for following patients throughout episodes, potentially resulting in greater challenges in reducing the cost and improving the quality of episode care under the BPCI models. Therefore, we understand that limitations in the availability of health IT that can be used in beneficiary management across care settings may pose a significant barrier to the readiness of non-hospital providers and suppliers to assume financial responsibility for episodes in potential future episode payment models.

In the CJR model, acute care hospitals are financially responsible for cost and quality during LEJR episodes-of-care. CJR model participant hospitals may form partnerships with post-acute care providers such as skilled nursing facilities and home health agencies, as well as physicians and PGPs, to share financial risk and collaborate on care redesign strategies, as in BPCI. Although hospitals are the financially responsible entities under the CJR model, we recognize that partnerships with post-acute care providers could be a crucial driver of episode spending and quality, given that many beneficiaries in the CJR model receive post-acute care services after discharge from the hospital. We also recognize that tools such as health IT may be critical for certain care management and quality strategies targeted toward the goal of lower cost and higher quality episode care. Limitations in the availability of health IT may pose a barrier to effective post-acute care provider collaboration and sharing of financial risk in episode payment models even when hospitals are the financially responsible entities under such models, such as the CJR model and the three new EPMs proposed in this rulemaking.

We recognize that there is wide variation in the readiness of other providers and suppliers to bear financial responsibility for episodes, either directly or indirectly through sharing arrangements with the directly responsible entities where those arrangements may include upside and downside risk. For instance, adoption of health IT among providers in the post-acute care market, such as skilled nursing facilities, continues to lag behind hospitals and providers of ambulatory care services. In addition to facing significant resource constraints, post-acute care providers were not included as an eligible provider type under the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs. The recent extension of Medicaid 90/10 funding offers new opportunities for states to include post-acute care providers in projects focused on infrastructure development, but will not address the cost of health IT adoption among post-acute care providers.[36]

To ensure that post-acute care providers and other types of providers and suppliers can succeed under future episode payment models, either as the directly financially responsible entity or as collaborators with other directly financially responsible entities, we are interested in opportunities to increase provider readiness as part of the design of potential future episode payment models and the potential refinement of current episode payment models. Specifically, we would like to explore: Incentives to encourage post-acute care providers, as well as other providers and suppliers that furnish services to episode payment model beneficiaries, to make necessary investments in health IT infrastructure; payment mechanisms that could leverage savings achieved under episode payment models to contribute to these investments; and any other strategies to enhance the adoption, implementation, and upgrading of certified health IT. We seek comment on these ideas, as well as the following questions:

- What are key challenges associated with the inclusion of post-acute care providers as the financially responsible entity or as collaborators with other financially responsible entities in episode payment models today?
- What would be a sufficient financial incentive or bonus to enhance the adoption, implementation, and upgrading of certified health IT in post-acute care settings?
- How else can episode payment models encourage the use of certified health IT and information sharing among providers and suppliers caring for episode payment model beneficiaries to improve care coordination and patient outcomes?
- Within the existing CJR model, are there additional opportunities to encourage investment in adoption, implementation, and upgrading of certified health IT among post-acute care providers to support improvements in care coordination and patient outcomes? What CJR model refinements could enable direct investments to support these improvements, particularly among post-acute care providers who are unaffiliated with CJR model participant hospitals but who provide services to CJR model beneficiaries, including post-acute care providers who may enter into financial arrangements with CJR model participant hospitals as CJR collaborators?

[35] Alexander Gregory L. ''An Analysis of Nursing Home Quality Measures and Staffing.'' Quality management in health care 17.3 (2008): 242–251. PMC. Web. 16 July 2016.

[36] *https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16003.pdf.*

B. Proposed Definition of the Episode Initiator and Selected Geographic Areas

1. Background

The proposed new EPMs will complement the current CJR model and continue efforts to move Medicare towards paying providers based on quality and value. As discussed during rulemaking for the CJR model, CMS is interested in testing and evaluating the impact of an episode payment approach for a broad range of episodes in a variety of other circumstances. In addition to including hospitals that have not chosen to voluntarily participate in earlier models, we also are interested in expanding the range of episodes included beyond elective surgical procedures such that the impact on a broader range of beneficiaries, hospitals, and circumstances may be tested. We also are interested in evaluating the impact on hospitals when an increasing percentage of care to Medicare beneficiaries is paid for through alternative payment models.

As with CJR, we propose in § 512.105(c) that the hospital be the accountable financial entity and that these episode payment models be implemented in all IPPS hospitals in the geographic areas selected, subject to exclusions as specified in §§ 512.230 and 512.240 of the proposed rule. While these are considered new episode payment models and do not reflect an expansion or extension of any previous models, they do intentionally build significantly upon the work of BPCI and, most significantly, the framework established for CJR under 42 CFR part 510 published on November 24, 2015. Given the extensive consideration given to many of these issues during the CJR model planning and rulemaking periods, we believe this is important as we seek to build a model that is scalable across all providers and episode types. We also seek to limit the burden for hospitals and other providers that may be participating across multiple episode types. Therefore, to the extent applicable and appropriate, we have sought consistency with rules established for the CJR model. We seek comment on those areas where alternative options are proposed or should be considered that would not add additional operational burden or complexity.

2. Proposed Definition of Episode Initiator

Under the proposed EPMs, we propose, consistent with our definition under the CJR model that episodes would begin with the admission to an IPPS acute-care hospital that triggers an AMI, CABG or SHFFT episode as specified in section III.C.4.a. of this proposed rule. As with the CJR model, we propose that hospitals would be the only episode initiators in these episode payment models. For purposes of these episodes payment models 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. Under this proposal, all acute care hospitals in Maryland would be excluded and payments to Maryland hospitals would be excluded in the regional pricing calculations as described in section III.D.4. of this proposed rule. This is the same policy that is being followed with the CJR model. In addition, we also propose to exclude other all-payer state models which may be implemented in the future. We welcome comments on this proposal and whether there are potential approaches for including Maryland acute-care hospitals or, potentially, other hospitals in future all-payer state models in these episode payment models.

As implemented with the CJR model, we propose to designate IPPS hospitals as the episode initiators to ensure that all services covered under FFS Medicare and furnished by EPM participant hospitals in selected geographic areas to beneficiaries who do not meet the exclusion criteria specified in section III.C.4. of this proposed rule are included. In addition, the episodes must not be BPCI episodes that we are proposing to exclude as outlined in this section and in section III.C.4. of this proposed rule. We believe that utilizing the hospital as the episode initiator is a straightforward approach for these models because patients covered under these DRGs and diagnoses require hospital admission for these services, whether provided on an emergent or planned basis. Under these new models covering medical admissions and services that are not necessarily elective, we will be able to expand our testing of a more generalized bundled payment model. Finally, as described in section III.B.4., our proposed geographic area selection approach relies upon our definition of hospitals as the entities that initiate episodes.

3. Financial Responsibility for the Episode of Care

As with the CJR model, we continue to believe it is most appropriate to identify a single type of provider to bear financial responsibility for making repayment, if any, to CMS under the model and propose to make hospitals, as the episode initiators, financially responsible for the episode of care for the following several reasons:

- Hospitals play a central role in coordinating episode-related care and ensuring smooth transitions for beneficiaries undergoing services related to SHFFT, AMI and CABG episodes. A large portion of a beneficiary's recovery trajectory from an AMI, CABG, or SHFFT begins during the hospital stay.
- Most hospitals already have some infrastructure related to health information technology, patient and family education, and care management and discharge planning. This includes post-acute care coordination infrastructure and resources such as case managers, which hospitals can build upon to achieve efficiencies under these EPMs.
- By definition, these episodes always begin with an acute care hospital stay. While often preceded by an emergency room visit and possible transfer from another hospital's emergency room, or followed by post-acute care, these parties are not necessarily always present and would not be appropriate to target as the financially responsible party for this purpose.

EPM episodes may be associated with multiple hospitalizations through transfers. When multiple hospitalizations occur, we propose that the financial responsibility be given to the hospital to which the episode is attributed as described in section III.C.4. We recognize that, particularly where the admission may be preceded by an emergency room visit and subsequent transfer to a tertiary or other regional hospital facility, patients often wish to return home to their local area for post-acute care. Many hospitals have recently heightened their focus on aligning their efforts with those of community providers, both those in the immediate area as well as more outlying areas from which they receive transfers and referrals, to provide an improved continuum of care. In many cases, this is due to the incentives under other CMS models and programs, including ACO initiatives such as the Shared Savings Program, the Hospital Readmissions Reduction Program (HRRP), and the CJR model. By focusing on the hospital as the accountable or financially responsible entity, we hope to continue to encourage this coordination across providers and seek comment on ways we can best encourage these relationships within the scope of these EPMs.

In support of our proposal that hospitals be the episode initiators under these EPMs, we believe that hospitals

are more likely than other providers to have an adequate number of episode cases to justify an investment in episode management for these EPMs. We also believe that hospitals are most likely to have access to resources that would allow them to appropriately manage and coordinate care throughout these episodes. Finally, the hospital staff is already involved in discharge planning and placement recommendations for Medicare beneficiaries, and more efficient post-acute care service delivery provides substantial opportunities for improving quality and reducing costs under EPMs. For those hospitals that are already participating in CJR, we believe the efforts that have been put in place to support patients receiving LEJR will be supportive of the new EPMs proposed under this rule, particularly for SHFFT episodes which we propose to implement in the same geographic areas as the CJR model.

Finally, as noted when planning for the CJR model, although the BPCI initiative includes the possibility of a physician group practice as a type of episode initiating participant, the physician groups electing to participate in BPCI have done so because their practice structure supports care redesign and other infrastructure necessary to bear financial responsibility for episodes. These physician groups are not necessarily representative of the typical group practice. As with the CJR model, the infrastructure necessary to accept financial responsibility for episodes is not present across all physician group practices, and thus we do not believe it would be appropriate to designate physician group practices to bear the financial responsibility for making repayments to CMS under the proposed EPMs. We seek comment on our proposal to establish financial responsibility and accountability under the AMI, CABG, and SHFFT EPMs consistent with our implementation of the CJR model.

Currently, there are SHFFT, AMI, and CABG episodes being tested in BPCI Models 2, 3 or 4. The last remaining BPCI Model 1 hospital will end December 31, 2016 and will, therefore, not overlap with EPM. In addition, under BPCI, there are episodes for PCI, which, if an AMI were also involved, would fall under the AMI model being proposed here. We are proposing that IPPS hospitals located in an area selected for any one of the episode payment models proposed in this rule that also are episode initiators for episodes in the risk-bearing phase of BPCI Models 2 or 4, be excluded from participating in the AMI, CABG, or SHFFT EPMs if the applicable episode otherwise would qualify to be covered under BPCI. This exclusion would be in effect only during the time that the relevant qualifying episodes are included in one of the BPCI models. Likewise, we are proposing that if the EPM participant is not an episode initiator for overlapping episodes under BPCI Models 2 or 4, but these same episodes are initiated during the anchor hospitalization by a physician group practice (PGP) under BPCI Model 2 (where the services are provided at the episode initiating hospital) then the episode also shall be covered under BPCI and be excluded from the EPMs being proposed under this rule. Otherwise qualifying EPM episodes (that is, those that are not part of an overlapping BPCI AMI, CABG, PCI or SHFFT episode) at the participant hospital would be included in these new EPMs. However, because BPCI participation is voluntary and participating providers may select which episodes to participate in, a BPCI participating provider will participate in any of the proposed AMI, CABG, or SHFFT EPMs for any episodes not otherwise preempted under their BPCI participation. For example, a BPCI Model 2 hospital in an AMI episode model geographic area participating in BPCI only for CABGs will be an EPM participant in the AMI model. Similarly, an acute care hospital participating in BPCI for LEJR but not SHFFT episodes would be exempt from participation in the CJR model in a CJR model geographic area but would participate in the SHFFT model for SHFFT episodes. In addition, providers participating in BPCI may also collaborate with an EPM participant for episodes not covered under BPCI. It should be noted that due to differences in how the AMI episode is defined under the AMI model versus BPCI and the inclusion of PCI MS–DRGs under the latter, a patient with the same discharge MS–DRG and diagnoses may qualify for a PCI episode under BPCI and an AMI episode under the AMI model. Our intent is to give precedence to BPCI regardless of which episode a patient qualifies for if the patient would be covered under BPCI.

In section III.D.6. we discuss in more detail how we propose to handle situations when a beneficiary receives services that would qualify for inclusion in more than one CMS payment model during the same or overlapping periods of time. We welcome input on how these overlaps should be handled to best encourage ongoing care coordination while minimizing the impact on other models and limiting confusion and operational burden for providers.

While we propose that the EPM participant be financially responsible for the episode of care under these EPMs, we also believe that effective care redesign requires meaningful collaboration among acute care hospitals, post-acute care 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 to be aligned and engaged, financially and otherwise, with the EPM participants, with the potential to share financial responsibility with those EPM participants. We note that all relationships between and among providers and suppliers must comply with all relevant laws and regulations, including the fraud and abuse laws and all Medicare payment and coverage requirements unless otherwise specified further in this section and in sections III.I. and III.J. of this proposed rule. Depending on a hospital's current degree of clinical integration, new and different contractual relationships among hospitals and other health care providers may be important, although not necessarily required, for EPM success in a community. We acknowledge that financial incentives for other providers may be important aspects of the model in order for EPM participants to partner with these providers and incentivize certain strategies to improve episode efficiency.

While we acknowledge the important role of conveners in the BPCI model, and AMI, CABG, and SHFFT model participants may wish to enter into relationships with EPM collaborators and other entities in order to manage the episode of care or distribute risk, we propose that the ultimate financial responsibility of the episode remains with the EPM participant. Exceptions to this general rule for beneficiaries covered under certain risk bearing ACO arrangements are outlined in section III.D.6. As with the CJR model, we do not intend to restrict the ability of EPM participants to enter into administrative or risk sharing arrangements related to these EPMs, except to the extent that such arrangements are already restricted or prohibited by existing law. We refer readers to section III.I. of this proposed rule for further discussion of model design elements that may outline financial arrangements between EPM participants and other providers and suppliers.

4. Proposed Geographic Unit of Selection and Exclusion of Selected Hospitals

In order to determine the geographic unit of selection for these episode payment models, we conducted an analysis similar to that used for the CJR model. For the CJR 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 concluded that selection based on MSAs provided the best balance between choosing smaller geographic units while still capturing the impact of market patterns reflecting the mobility of patients and providers and limiting the potential risk for patient shifting and steerage between MSAs. HRRs are based on where patients receive selected tertiary care services which do not include orthopedic services. Therefore, HRRs may not be representative of where patients receive specialty orthopedic care or more routine orthopedic services such as hip and knee arthroplasty. Selection of states rather than MSAs would have greatly reduced the number of independent geographic areas subject to selection and, therefore, the statistical power of the evaluation. For similar reasons and to maintain consistency with the CJR model, we are, similarly, recommending implementation at the MSA level.

We also similarly considered whether these new models should be limited to hospitals where a high volume of these episodes occur, 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. However, as with the CJR model, 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 payments for these episodes 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.D.6. of this proposed rule as model participants would help to minimize the risk of participant hospitals shifting higher cost cases out of the EPM.

In determining where to implement these EPMs, we also considered whether implementation of the CJR model in the same geographic area should be a factor. We realize that there is likely to be considerable overlap in the selection criteria between MSAs where the SHFFT EPM might be appropriate and those MSAs where the CJR model is now being implemented. While limiting burden on hospitals is an important consideration, we also believe that the infrastructure being put in place as a result of the CJR model presents significant advantages for implementation of the SHFFT model. For similar reasons, and in order to minimize patient steerage and/or transfer for reasons due solely to the implementation of these new payment models, we believe that it is appropriate to implement the AMI model and CABG model together in the same geographic areas, albeit not necessarily in the same areas as the CJR model.

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 propose that the SHFFT model be implemented in those MSAs where the CJR model is being implemented. We also are proposing that the AMI and CABG models be implemented in MSAs selected independently based on the criteria discussed in this proposed rule. This will result in four separate categories of MSAs: (1) MSAs where only the CJR and SHFFT model episodes are being implemented; (2) MSAs where only the CABG model and AMI model episodes are being implemented; (3) MSAs where the CJR as well as the AMI, CABG, and SHFFT models are being implemented; and (4) MSAs where neither CJR nor any of the new episode payment models are being implemented. We believe this will provide an opportunity to test the impact of implementing EPMs across not only a greater diversity of episodes but also as an increasing percentage of hospital discharges. We seek comment on our proposal to implement the SHFFT model in the same geographic region as the CJR model and to implement both the AMI model and the CABG model in the same MSAs, some of which may overlap with MSAs where the CJR and SHFFT models also are being implemented.

5. Overview and Options for Geographic Area Selection for AMI and CABG Episodes

We propose that the AMI and CABG EPMs be implemented together in the same MSAs. These AMI/CABG-participating MSAs may or may not also be LEJR/SHFFT-participating MSAs. The selection of MSAs for AMI/CABG EPMs would occur through a random selection of eligible MSAs.

We propose to require participation in the AMI and CABG models of all hospitals, with limited exceptions as previously discussed in section III.B.4. of this proposed rule, paid under the IPPS that are physically located in a county in an MSA selected through the methodology outlined in section III.B.5.b. in this proposed rule, to test and evaluate the effects of an episode-based payment approach for the proposed EPMs. We propose 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 as of the date the selection is made.

Although MSAs are revised periodically, with counties added or removed from certain MSAs, we propose to maintain the same cohort of selected hospitals throughout the 5-year performance periods of the EPMs with limited exceptions as described later in this section. Thus, we propose neither to add hospitals to an EPM if after the start of such EPM new counties are added to one of the selected MSAs nor to remove hospitals from an EPM if counties are removed from one of the selected MSAs. We believe that this approach will best maintain the consistency of the participants in the EPMs, which is crucial for our ability to evaluate their respective results. However, 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.D. of this proposed rule for discussion of how target prices will be determined for such hospitals.)

The manner in which CMS tracks and identifies hospitals is through the CMS Certification Number (CCN). In keeping with this approach, these EPMs 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 an EPM's 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 applicable EPM if the physical address associated with the CCN is in the MSA selected, 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 the applicable EPM if the physical address associated with the CCN is not in the MSA.

We considered including hospitals in a given MSA based on whether the hospitals were classified into the MSA for IPPS wage index purposes. However, such a process would be more complicated, and we could not find any compelling reasons favoring such approach. For example, we could assign hospitals to metro divisions of MSAs when those divisions exist. In addition, there is the IPPS process of geographic reclassification by which a hospital's payments can be based on a geographic area other than the one where the hospital is physically located. For the purpose of the EPMs, it is simpler and more straightforward to use a hospital's physical location as the basis of its assignment to a geographic unit. This decision would have no impact on a hospital's payment under the IPPS. We seek comment on our proposal to include a hospital as an EPM participant based on the physical location associated with the CCN of the hospital in one of the counties included in a selected MSA.

a. Exclusion of Certain MSAs

We considered whether certain MSAs should be exempt from the possibility of selection for the AMI/CABG EPMs' implementation. We considered exclusions based on the anticipated number of AMI episodes and CABG episodes in the MSA. We also considered exclusions based on the degree to which such EPMs' episodes would be impacted by overlaps with other payment initiatives, including BPCI and ACOs.

First, we considered the advisability of MSA exclusions based on the number of episodes in a year. We identified qualifying AMI and CABG episodes that initiated between January 1, 2014, and December 31, 2014. AMI and CABG episodes were attributed to an MSA based on the location of the CCN associated with the initiating hospital using the Provider of Service file. Due to the smaller number of relevant AMI and CABG episodes occurring in MSAs, an exclusion rule that required a large number of episodes in each MSA would result in fewer MSAs eligible for selection than was necessary given the desired number of MSAs and the requirement that to have 50 percent or more of MSAs remain in a pool of possible comparison MSAs. From the perspective of evaluating changes to utilization and spending under EPMs, there is no analytic need to eliminate MSAs with small numbers. In fact, including smaller MSAs has the analytic advantage of giving CMS more experience operating EPMs in the smaller-MSA contexts that will help us generalize our EPM-evaluation findings.

We have a strong interest in being able to observe how well EPMs operate in areas with a lower volume of episodes, and, in particular, the consequences of the model for AMI episodes where CABG is not commonly performed or where standard practice is to refer all CABGs outside of the MSA. Given our desire to assess the operation of the AMI EPM in areas with little or no CABG episodes and the desire to have the two cardiac EPMs be administered together in the same MSAs, we propose that the MSA exclusion rules be based on the number of AMI episodes only. This will allow for the inclusion of MSAs with no CABGs.

There is no analytic requirement for a minimum number of cases and there are advantages to including smaller cities. At the same time, we acknowledge that areas with few AMI cases may believe that they will face challenges under the EPMs. Therefore, we propose an exclusion rule that MSAs with fewer than 75 AMI episodes (determined as discussed in section III.C. of this proposed rule) will be removed from the possibility of selection. Cases in hospitals paid under either the CAH methodology or the Maryland All-Payer Model are not included in the count of eligible episodes. We examined a number of different minimum-episode-number cutoffs. The use of the 75 AMIs in a year was a designed to balance limiting the impact of outlier cases on the MSA average episode spending and the desire to retain a non-negligible representation of MSAs in the under 100,000 population and the 100,000 to 200,000 population ranges in our selection pool. The application of Exclusion Rule 1: ''less than 75 qualifying AMI episodes in the reference year'' resulted in the removal of 49 MSAs from possible selection.

Second, we assessed exclusion rules based on overlap with BPCI. We propose Exclusion Rule 2 such that MSAs are removed from possible selection if there were fewer than 75 non-BPCI AMI episodes in the MSA in the reference year. For the purposes of this exclusion, the number of non-BPCI episodes was estimated by subtracting BPCI cases from the total number of cases used in Exclusion Rule 1. BPCI cases for this purpose are ones during the reference year associated with a hospital or a PGP BPCI Model 2 or 4 episode initiator participating in an AMI, PCI, or CABG episode as of January 1, 2016. Such criterion removed an additional 26 MSAs from potential selection.

Third, we propose to exclude MSAs from possible selection based on whether the number of non-BPCI AMI episodes calculated under Exclusion Rule 2 is less than 50 percent of the total number of AMI episodes calculated under Exclusion Rule 1. We anticipate that some degree of overlap in the BPCI and other EPMs will be mutually helpful. However, we acknowledge that some providers may have concerns that a BPCI Model 2 AMI and PCI participation rate of more than 50 percent may impair the ability of participants in either the EPMs or the BPCI models to succeed in the objectives of the initiative. As a result of this third criterion, 13 additional MSAs were removed from possible selection.

We considered whether there should be an exclusion rule based on the anticipated degree of overlap between the AMI and CABG EPMs and patients who are aligned prospectively to ACOs that are taking two-sided risk, such as ACOs participating in the Next Generation ACO model or Track 3 of the Shared Savings Program. We examined numbers associated with ACOs meeting this status as of May 1, 2016, and this examination did not result in any additional MSAs falling below the 75 AMI episodes threshold. Consequently, we are not proposing any MSA exclusion rule based on the presence of ACOs.

Please refer to Table 1 for the status of each MSA based on these exclusion criteria, available at *http://innovation.cms.gov/initiatives/epm*. After applying these three exclusions, 294 MSAs out of 384 total MSAs are eligible for selection using our proposed selection methodology.

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TABLE 1: MSA EXCLUSION RULE STATUS AND ELIGIBILITY FOR SELECTION STATUS FOR INCLUSION IN AMI AND CABG EPMS

CBSA_ OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
10180	Abilene, TX	Pass	Pass	Pass	Include
10380	Aguadilla-Isabela, PR	Fail	Fail	Pass	Exclude
10420	Akron, OH	Pass	Pass	Pass	Include
10500	Albany, GA	Pass	Pass	Pass	Include
10540	Albany, OR	Fail	Fail	Pass	Exclude
10580	Albany-Schenectady-Troy, NY	Pass	Pass	Fail	Exclude
10740	Albuquerque, NM	Pass	Pass	Pass	Include
10780	Alexandria, LA	Pass	Pass	Pass	Include
10900	Allentown-Bethlehem-Easton, PA-NJ	Pass	Pass	Pass	Include
11020	Altoona, PA	Pass	Pass	Pass	Include
11100	Amarillo, TX	Pass	Pass	Pass	Include
11180	Ames, IA	Pass	Pass	Pass	Include
11260	Anchorage, AK	Pass	Pass	Pass	Include
11460	Ann Arbor, MI	Pass	Pass	Pass	Include
11500	Anniston-Oxford-Jacksonville, AL	Pass	Pass	Pass	Include
11540	Appleton, WI	Pass	Pass	Pass	Include
11640	Arecibo, PR	Fail	Fail	Pass	Exclude
11700	Asheville, NC	Pass	Pass	Pass	Include
12020	Athens-Clarke County, GA	Pass	Pass	Pass	Include
12060	Atlanta-Sandy Springs-Roswell, GA	Pass	Pass	Pass	Include
12100	Atlantic City-Hammonton, NJ	Pass	Pass	Pass	Include
12220	Auburn-Opelika, AL	Pass	Pass	Pass	Include
12260	Augusta-Richmond County, GA-SC	Pass	Pass	Pass	Include
12420	Austin-Round Rock, TX	Pass	Pass	Pass	Include
12540	Bakersfield, CA	Pass	Pass	Fail	Exclude
12620	Bangor, ME	Pass	Pass	Pass	Include
12700	Barnstable Town, MA	Pass	Pass	Pass	Include
12940	Baton Rouge, LA	Pass	Pass	Pass	Include
12980	Battle Creek, MI	Fail	Fail	Pass	Exclude
13020	Bay City, MI	Pass	Pass	Pass	Include
13140	Beaumont-Port Arthur, TX	Pass	Pass	Pass	Include
13220	Beckley, WV	Pass	Pass	Pass	Include
13380	Bellingham, WA	Pass	Pass	Pass	Include
13460	Bend-Redmond, OR	Pass	Pass	Pass	Include
13740	Billings, MT	Pass	Pass	Pass	Include

CBSA_ OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
13780	Binghamton, NY	Pass	Fail	Fail	Exclude
13820	Birmingham-Hoover, AL	Pass	Pass	Pass	Include
13900	Bismarck, ND	Pass	Pass	Pass	Include
13980	Blacksburg-Christiansburg-Radford, VA	Fail	Fail	Pass	Exclude
14010	Bloomington, IL	Pass	Pass	Pass	Include
14020	Bloomington, IN	Pass	Pass	Pass	Include
14100	Bloomsburg-Berwick, PA	Pass	Pass	Pass	Include
14260	Boise City, ID	Pass	Pass	Pass	Include
14460	Boston-Cambridge-Newton, MA-NH	Pass	Pass	Pass	Include
14500	Boulder, CO	Pass	Fail	Pass	Exclude
14540	Bowling Green, KY	Pass	Fail	Fail	Exclude
14740	Bremerton-Silverdale, WA	Pass	Fail	Fail	Exclude
14860	Bridgeport-Stamford-Norwalk, CT	Pass	Pass	Pass	Include
15180	Brownsville-Harlingen, TX	Pass	Pass	Pass	Include
15260	Brunswick, GA	Pass	Pass	Pass	Include
15380	Buffalo-Cheektowaga-Niagara Falls, NY	Pass	Pass	Fail	Exclude
15500	Burlington, NC	Fail	Fail	Pass	Exclude
15540	Burlington-South Burlington, VT	Pass	Pass	Pass	Include
15940	Canton-Massillon, OH	Pass	Pass	Pass	Include
15980	Cape Coral-Fort Myers, FL	Pass	Pass	Pass	Include
16020	Cape Girardeau, MO-IL	Pass	Pass	Pass	Include
16060	Carbondale-Marion, IL	Pass	Pass	Pass	Include
16180	Carson City, NV	Pass	Pass	Pass	Include
16220	Casper, WY	Pass	Fail	Pass	Exclude
16300	Cedar Rapids, IA	Pass	Pass	Pass	Include
16540	Chambersburg-Waynesboro, PA	Pass	Pass	Pass	Include
16580	Champaign-Urbana, IL	Pass	Pass	Pass	Include
16620	Charleston, WV	Pass	Pass	Pass	Include
16700	Charleston-North Charleston, SC	Pass	Pass	Pass	Include
16740	Charlotte-Concord-Gastonia, NC-SC	Pass	Pass	Pass	Include
16820	Charlottesville, VA	Pass	Pass	Pass	Include
16860	Chattanooga, TN-GA	Pass	Pass	Pass	Include
16940	Cheyenne, WY	Pass	Pass	Pass	Include
16980	Chicago-Naperville-Elgin, IL-IN-WI	Pass	Pass	Pass	Include
17020	Chico, CA	Pass	Pass	Pass	Include
17140	Cincinnati, OH-KY-IN	Pass	Pass	Pass	Include
17300	Clarksville, TN-KY	Pass	Pass	Pass	Include
17420	Cleveland, TN	Fail	Fail	Pass	Exclude

CBSA_OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
17460	Cleveland-Elyria, OH	Pass	Pass	Pass	Include
17660	Coeur d'Alene, ID	Pass	Pass	Pass	Include
17780	College Station-Bryan, TX	Pass	Pass	Pass	Include
17820	Colorado Springs, CO	Pass	Pass	Pass	Include
17860	Columbia, MO	Pass	Pass	Pass	Include
17900	Columbia, SC	Pass	Pass	Pass	Include
17980	Columbus, GA-AL	Pass	Pass	Pass	Include
18020	Columbus, IN	Pass	Pass	Pass	Include
18140	Columbus, OH	Pass	Pass	Fail	Exclude
18580	Corpus Christi, TX	Pass	Pass	Pass	Include
18700	Corvallis, OR	Pass	Pass	Pass	Include
18880	Crestview-Fort Walton Beach-Destin, FL	Pass	Pass	Pass	Include
19100	Dallas-Fort Worth-Arlington, TX	Pass	Pass	Pass	Include
19140	Dalton, GA	Pass	Fail	Fail	Exclude
19180	Danville, IL	Fail	Fail	Pass	Exclude
19300	Daphne-Fairhope-Foley, AL	Pass	Pass	Pass	Include
19340	Davenport-Moline-Rock Island, IA-IL	Pass	Pass	Pass	Include
19380	Dayton, OH	Pass	Pass	Pass	Include
19460	Decatur, AL	Fail	Fail	Pass	Exclude
19500	Decatur, IL	Pass	Pass	Pass	Include
19660	Deltona-Daytona Beach-Ormond Beach, FL	Pass	Pass	Pass	Include
19740	Denver-Aurora-Lakewood, CO	Pass	Pass	Pass	Include
19780	Des Moines-West Des Moines, IA	Pass	Pass	Pass	Include
19820	Detroit-Warren-Dearborn, MI	Pass	Pass	Pass	Include
20020	Dothan, AL	Pass	Pass	Pass	Include
20100	Dover, DE	Pass	Pass	Pass	Include
20220	Dubuque, IA	Pass	Fail	Fail	Exclude
20260	Duluth, MN-WI	Pass	Pass	Pass	Include
20500	Durham-Chapel Hill, NC	Pass	Pass	Pass	Include
20700	East Stroudsburg, PA	Pass	Fail	Pass	Exclude
20740	Eau Claire, WI	Pass	Pass	Pass	Include
20940	El Centro, CA	Fail	Fail	Fail	Exclude
21060	Elizabethtown-Fort Knox, KY	Pass	Pass	Pass	Include
21140	Elkhart-Goshen, IN	Pass	Pass	Pass	Include
21300	Elmira, NY	Pass	Pass	Pass	Include
21340	El Paso, TX	Pass	Pass	Pass	Include
21500	Erie, PA	Pass	Pass	Pass	Include
21660	Eugene, OR	Pass	Pass	Pass	Include

CBSA_ OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
21780	Evansville, IN-KY	Pass	Pass	Pass	Include
21820	Fairbanks, AK	Fail	Fail	Pass	Exclude
22020	Fargo, ND-MN	Pass	Pass	Pass	Include
22140	Farmington, NM	Pass	Pass	Pass	Include
22180	Fayetteville, NC	Pass	Pass	Pass	Include
22220	Fayetteville-Springdale-Rogers, AR-MO	Pass	Pass	Pass	Include
22380	Flagstaff, AZ	Fail	Fail	Pass	Exclude
22420	Flint, MI	Pass	Pass	Pass	Include
22500	Florence, SC	Pass	Pass	Pass	Include
22520	Florence-Muscle Shoals, AL	Pass	Pass	Pass	Include
22540	Fond du Lac, WI	Fail	Fail	Pass	Exclude
22660	Fort Collins, CO	Pass	Pass	Pass	Include
22900	Fort Smith, AR-OK	Pass	Pass	Fail	Exclude
23060	Fort Wayne, IN	Pass	Pass	Pass	Include
23420	Fresno, CA	Pass	Pass	Pass	Include
23460	Gadsden, AL	Pass	Pass	Pass	Include
23540	Gainesville, FL	Pass	Pass	Pass	Include
23580	Gainesville, GA	Pass	Pass	Pass	Include
23900	Gettysburg, PA	Fail	Fail	Pass	Exclude
24020	Glens Falls, NY	Fail	Fail	Pass	Exclude
24140	Goldsboro, NC	Fail	Fail	Pass	Exclude
24220	Grand Forks, ND-MN	Pass	Pass	Pass	Include
24260	Grand Island, NE	Fail	Fail	Pass	Exclude
24300	Grand Junction, CO	Pass	Pass	Pass	Include
24340	Grand Rapids-Wyoming, MI	Pass	Pass	Pass	Include
24420	Grants Pass, OR	Fail	Fail	Pass	Exclude
24500	Great Falls, MT	Fail	Fail	Pass	Exclude
24540	Greeley, CO	Pass	Pass	Pass	Include
24580	Green Bay, WI	Pass	Pass	Pass	Include
24660	Greensboro-High Point, NC	Pass	Pass	Pass	Include
24780	Greenville, NC	Pass	Pass	Pass	Include
24860	Greenville-Anderson-Mauldin, SC	Pass	Pass	Pass	Include
25020	Guayama, PR	Fail	Fail	Pass	Exclude
25060	Gulfport-Biloxi-Pascagoula, MS	Pass	Pass	Pass	Include
25180	Hagerstown-Martinsburg, MD-WV	Pass	Fail	Fail	Exclude
25220	Hammond, LA	Fail	Fail	Pass	Exclude
25260	Hanford-Corcoran, CA	Fail	Fail	Pass	Exclude
25420	Harrisburg-Carlisle, PA	Pass	Pass	Pass	Include

CBSA_OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
25500	Harrisonburg, VA	Pass	Fail	Fail	Exclude
25540	Hartford-West Hartford-East Hartford, CT	Pass	Pass	Pass	Include
25620	Hattiesburg, MS	Pass	Pass	Pass	Include
25860	Hickory-Lenoir-Morganton, NC	Pass	Pass	Pass	Include
25940	Hilton Head Island-Bluffton-Beaufort, SC	Pass	Pass	Pass	Include
26140	Homosassa Springs, FL	Pass	Pass	Pass	Include
26300	Hot Springs, AR	Pass	Pass	Pass	Include
26380	Houma-Thibodaux, LA	Pass	Pass	Pass	Include
26420	Houston-The Woodlands-Sugar Land, TX	Pass	Pass	Pass	Include
26580	Huntington-Ashland, WV-KY-OH	Pass	Pass	Pass	Include
26620	Huntsville, AL	Pass	Pass	Pass	Include
26820	Idaho Falls, ID	Pass	Pass	Pass	Include
26900	Indianapolis-Carmel-Anderson, IN	Pass	Pass	Pass	Include
26980	Iowa City, IA	Pass	Pass	Pass	Include
27060	Ithaca, NY	Fail	Fail	Pass	Exclude
27100	Jackson, MI	Pass	Pass	Pass	Include
27140	Jackson, MS	Pass	Pass	Pass	Include
27180	Jackson, TN	Pass	Fail	Fail	Exclude
27260	Jacksonville, FL	Pass	Pass	Pass	Include
27340	Jacksonville, NC	Fail	Fail	Pass	Exclude
27500	Janesville-Beloit, WI	Pass	Pass	Pass	Include
27620	Jefferson City, MO	Pass	Pass	Pass	Include
27740	Johnson City, TN	Pass	Fail	Fail	Exclude
27780	Johnstown, PA	Pass	Pass	Pass	Include
27860	Jonesboro, AR	Pass	Pass	Pass	Include
27900	Joplin, MO	Pass	Pass	Pass	Include
27980	Kahului-Wailuku-Lahaina, HI	Fail	Fail	Pass	Exclude
28020	Kalamazoo-Portage, MI	Pass	Pass	Pass	Include
28100	Kankakee, IL	Pass	Pass	Pass	Include
28140	Kansas City, MO-KS	Pass	Pass	Pass	Include
28420	Kennewick-Richland, WA	Pass	Pass	Pass	Include
28660	Killeen-Temple, TX	Pass	Pass	Pass	Include
28700	Kingsport-Bristol-Bristol, TN-VA	Pass	Pass	Pass	Include
28740	Kingston, NY	Fail	Fail	Pass	Exclude
28940	Knoxville, TN	Pass	Pass	Pass	Include
29020	Kokomo, IN	Fail	Fail	Pass	Exclude
29100	La Crosse-Onalaska, WI-MN	Pass	Pass	Pass	Include
29180	Lafayette, LA	Pass	Pass	Pass	Include

CBSA_OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
29200	Lafayette-West Lafayette, IN	Pass	Pass	Pass	Include
29340	Lake Charles, LA	Pass	Pass	Pass	Include
29420	Lake Havasu City-Kingman, AZ	Pass	Pass	Pass	Include
29460	Lakeland-Winter Haven, FL	Pass	Pass	Pass	Include
29540	Lancaster, PA	Pass	Fail	Fail	Exclude
29620	Lansing-East Lansing, MI	Pass	Pass	Pass	Include
29700	Laredo, TX	Pass	Fail	Pass	Exclude
29740	Las Cruces, NM	Pass	Pass	Pass	Include
29820	Las Vegas-Henderson-Paradise, NV	Pass	Pass	Pass	Include
29940	Lawrence, KS	Fail	Fail	Pass	Exclude
30020	Lawton, OK	Pass	Pass	Pass	Include
30140	Lebanon, PA	Pass	Fail	Pass	Exclude
30300	Lewiston, ID-WA	Fail	Fail	Pass	Exclude
30340	Lewiston-Auburn, ME	Pass	Pass	Pass	Include
30460	Lexington-Fayette, KY	Pass	Pass	Pass	Include
30620	Lima, OH	Pass	Pass	Pass	Include
30700	Lincoln, NE	Pass	Pass	Pass	Include
30780	Little Rock-North Little Rock-Conway, AR	Pass	Pass	Pass	Include
30860	Logan, UT-ID	Fail	Fail	Pass	Exclude
30980	Longview, TX	Pass	Pass	Pass	Include
31020	Longview, WA	Fail	Fail	Pass	Exclude
31080	Los Angeles-Long Beach-Anaheim, CA	Pass	Pass	Pass	Include
31140	Louisville/Jefferson County, KY-IN	Pass	Pass	Pass	Include
31180	Lubbock, TX	Pass	Pass	Pass	Include
31340	Lynchburg, VA	Pass	Pass	Pass	Include
31420	Macon, GA	Pass	Pass	Pass	Include
31460	Madera, CA	Fail	Fail	Pass	Exclude
31540	Madison, WI	Pass	Pass	Pass	Include
31700	Manchester-Nashua, NH	Pass	Pass	Pass	Include
31740	Manhattan, KS	Fail	Fail	Pass	Exclude
31860	Mankato-North Mankato, MN	Fail	Fail	Pass	Exclude
31900	Mansfield, OH	Pass	Pass	Pass	Include
32420	Mayagüez, PR	Fail	Fail	Pass	Exclude
32580	McAllen-Edinburg-Mission, TX	Pass	Pass	Fail	Exclude
32780	Medford, OR	Pass	Pass	Pass	Include
32820	Memphis, TN-MS-AR	Pass	Pass	Pass	Include
32900	Merced, CA	Fail	Fail	Pass	Exclude
33100	Miami-Fort Lauderdale-West Palm Beach, FL	Pass	Pass	Pass	Include

CBSA_OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
33140	Michigan City-La Porte, IN	Pass	Pass	Pass	Include
33220	Midland, MI	Pass	Pass	Pass	Include
33260	Midland, TX	Pass	Fail	Pass	Exclude
33340	Milwaukee-Waukesha-West Allis, WI	Pass	Pass	Pass	Include
33460	Minneapolis-St. Paul-Bloomington, MN-WI	Pass	Pass	Pass	Include
33540	Missoula, MT	Pass	Pass	Pass	Include
33660	Mobile, AL	Pass	Pass	Pass	Include
33700	Modesto, CA	Pass	Pass	Pass	Include
33740	Monroe, LA	Pass	Pass	Pass	Include
33780	Monroe, MI	Pass	Pass	Pass	Include
33860	Montgomery, AL	Pass	Pass	Pass	Include
34060	Morgantown, WV	Pass	Pass	Pass	Include
34100	Morristown, TN	Fail	Fail	Pass	Exclude
34580	Mount Vernon-Anacortes, WA	Pass	Fail	Pass	Exclude
34620	Muncie, IN	Pass	Pass	Pass	Include
34740	Muskegon, MI	Pass	Pass	Pass	Include
34820	Myrtle Beach-Conway-North Myrtle Beach, SC-NC	Pass	Pass	Pass	Include
34900	Napa, CA	Pass	Fail	Fail	Exclude
34940	Naples-Immokalee-Marco Island, FL	Pass	Pass	Pass	Include
34980	Nashville-Davidson--Murfreesboro--Franklin, TN	Pass	Pass	Pass	Include
35100	New Bern, NC	Pass	Pass	Pass	Include
35300	New Haven-Milford, CT	Pass	Pass	Pass	Include
35380	New Orleans-Metairie, LA	Pass	Pass	Pass	Include
35620	New York-Newark-Jersey City, NY-NJ-PA	Pass	Pass	Pass	Include
35660	Niles-Benton Harbor, MI	Pass	Pass	Pass	Include
35840	North Port-Sarasota-Bradenton, FL	Pass	Pass	Pass	Include
35980	Norwich-New London, CT	Pass	Pass	Pass	Include
36100	Ocala, FL	Pass	Pass	Fail	Exclude
36140	Ocean City, NJ	Fail	Fail	Pass	Exclude
36220	Odessa, TX	Pass	Pass	Pass	Include
36260	Ogden-Clearfield, UT	Pass	Pass	Pass	Include
36420	Oklahoma City, OK	Pass	Pass	Pass	Include
36500	Olympia-Tumwater, WA	Pass	Pass	Pass	Include
36540	Omaha-Council Bluffs, NE-IA	Pass	Pass	Pass	Include
36740	Orlando-Kissimmee-Sanford, FL	Pass	Pass	Fail	Exclude
36780	Oshkosh-Neenah, WI	Fail	Fail	Pass	Exclude
36980	Owensboro, KY	Pass	Pass	Pass	Include
37100	Oxnard-Thousand Oaks-Ventura, CA	Pass	Pass	Fail	Exclude

CBSA_OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
37340	Palm Bay-Melbourne-Titusville, FL	Pass	Pass	Pass	Include
37460	Panama City, FL	Pass	Pass	Pass	Include
37620	Parkersburg-Vienna, WV	Pass	Pass	Pass	Include
37860	Pensacola-Ferry Pass-Brent, FL	Pass	Pass	Pass	Include
37900	Peoria, IL	Pass	Pass	Pass	Include
37980	Philadelphia-Camden-Wilmington, PA-NJ-DE-MD	Pass	Pass	Pass	Include
38060	Phoenix-Mesa-Scottsdale, AZ	Pass	Pass	Pass	Include
38220	Pine Bluff, AR	Fail	Fail	Pass	Exclude
38300	Pittsburgh, PA	Pass	Pass	Pass	Include
38340	Pittsfield, MA	Pass	Fail	Pass	Exclude
38540	Pocatello, ID	Fail	Fail	Pass	Exclude
38660	Ponce, PR	Fail	Fail	Pass	Exclude
38860	Portland-South Portland, ME	Pass	Pass	Pass	Include
38900	Portland-Vancouver-Hillsboro, OR-WA	Pass	Pass	Pass	Include
38940	Port St. Lucie, FL	Pass	Pass	Pass	Include
39140	Prescott, AZ	Pass	Pass	Pass	Include
39300	Providence-Warwick, RI-MA	Pass	Pass	Pass	Include
39340	Provo-Orem, UT	Pass	Pass	Pass	Include
39380	Pueblo, CO	Pass	Pass	Pass	Include
39460	Punta Gorda, FL	Pass	Pass	Pass	Include
39540	Racine, WI	Fail	Fail	Pass	Exclude
39580	Raleigh, NC	Pass	Pass	Pass	Include
39660	Rapid City, SD	Pass	Pass	Pass	Include
39740	Reading, PA	Pass	Pass	Pass	Include
39820	Redding, CA	Pass	Pass	Pass	Include
39900	Reno, NV	Pass	Pass	Pass	Include
40060	Richmond, VA	Pass	Pass	Pass	Include
40140	Riverside-San Bernardino-Ontario, CA	Pass	Pass	Pass	Include
40220	Roanoke, VA	Pass	Pass	Pass	Include
40340	Rochester, MN	Pass	Pass	Pass	Include
40380	Rochester, NY	Pass	Pass	Pass	Include
40420	Rockford, IL	Pass	Pass	Pass	Include
40580	Rocky Mount, NC	Pass	Pass	Pass	Include
40660	Rome, GA	Pass	Pass	Pass	Include
40900	Sacramento--Roseville--Arden-Arcade, CA	Pass	Pass	Pass	Include
40980	Saginaw, MI	Pass	Pass	Pass	Include
41060	St. Cloud, MN	Pass	Pass	Pass	Include
41100	St. George, UT	Pass	Pass	Pass	Include

CBSA_OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
41140	St. Joseph, MO-KS	Pass	Pass	Pass	Include
41180	St. Louis, MO-IL	Pass	Pass	Pass	Include
41420	Salem, OR	Pass	Pass	Pass	Include
41500	Salinas, CA	Pass	Pass	Pass	Include
41540	Salisbury, MD-DE	Pass	Pass	Pass	Include
41620	Salt Lake City, UT	Pass	Pass	Pass	Include
41660	San Angelo, TX	Pass	Pass	Pass	Include
41700	San Antonio-New Braunfels, TX	Pass	Pass	Fail	Exclude
41740	San Diego-Carlsbad, CA	Pass	Pass	Pass	Include
41860	San Francisco-Oakland-Hayward, CA	Pass	Pass	Pass	Include
41900	San Germán, PR	Fail	Fail	Pass	Exclude
41940	San Jose-Sunnyvale-Santa Clara, CA	Pass	Pass	Pass	Include
41980	San Juan-Carolina-Caguas, PR	Fail	Fail	Pass	Exclude
42020	San Luis Obispo-Paso Robles-Arroyo Grande, CA	Pass	Pass	Pass	Include
42100	Santa Cruz-Watsonville, CA	Pass	Fail	Fail	Exclude
42140	Santa Fe, NM	Pass	Pass	Pass	Include
42200	Santa Maria-Santa Barbara, CA	Pass	Pass	Pass	Include
42220	Santa Rosa, CA	Pass	Pass	Pass	Include
42340	Savannah, GA	Pass	Pass	Pass	Include
42540	Scranton--Wilkes-Barre--Hazleton, PA	Pass	Pass	Pass	Include
42660	Seattle-Tacoma-Bellevue, WA	Pass	Pass	Pass	Include
42680	Sebastian-Vero Beach, FL	Pass	Pass	Pass	Include
42700	Sebring, FL	Pass	Pass	Pass	Include
43100	Sheboygan, WI	Fail	Fail	Pass	Exclude
43300	Sherman-Denison, TX	Pass	Pass	Pass	Include
43340	Shreveport-Bossier City, LA	Pass	Pass	Pass	Include
43420	Sierra Vista-Douglas, AZ	Pass	Fail	Fail	Exclude
43580	Sioux City, IA-NE-SD	Pass	Pass	Pass	Include
43620	Sioux Falls, SD	Pass	Pass	Pass	Include
43780	South Bend-Mishawaka, IN-MI	Pass	Fail	Fail	Exclude
43900	Spartanburg, SC	Pass	Pass	Pass	Include
44060	Spokane-Spokane Valley, WA	Pass	Pass	Pass	Include
44100	Springfield, IL	Pass	Pass	Pass	Include
44140	Springfield, MA	Pass	Pass	Fail	Exclude
44180	Springfield, MO	Pass	Pass	Pass	Include
44220	Springfield, OH	Fail	Fail	Pass	Exclude
44300	State College, PA	Fail	Fail	Pass	Exclude
44420	Staunton-Waynesboro, VA	Pass	Pass	Pass	Include

CBSA_ OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
44700	Stockton-Lodi, CA	Pass	Pass	Pass	Include
44940	Sumter, SC	Fail	Fail	Fail	Exclude
45060	Syracuse, NY	Pass	Pass	Pass	Include
45220	Tallahassee, FL	Pass	Pass	Pass	Include
45300	Tampa-St. Petersburg-Clearwater, FL	Pass	Pass	Pass	Include
45460	Terre Haute, IN	Pass	Pass	Pass	Include
45500	Texarkana, TX-AR	Pass	Pass	Fail	Exclude
45540	The Villages, FL	Pass	Pass	Pass	Include
45780	Toledo, OH	Pass	Pass	Pass	Include
45820	Topeka, KS	Pass	Pass	Pass	Include
45940	Trenton, NJ	Pass	Pass	Pass	Include
46060	Tucson, AZ	Pass	Pass	Pass	Include
46140	Tulsa, OK	Pass	Pass	Pass	Include
46220	Tuscaloosa, AL	Pass	Pass	Pass	Include
46340	Tyler, TX	Pass	Pass	Pass	Include
46520	Urban Honolulu, HI	Pass	Pass	Pass	Include
46540	Utica-Rome, NY	Pass	Pass	Pass	Include
46660	Valdosta, GA	Pass	Fail	Pass	Exclude
46700	Vallejo-Fairfield, CA	Pass	Fail	Fail	Exclude
47020	Victoria, TX	Pass	Pass	Pass	Include
47220	Vineland-Bridgeton, NJ	Pass	Fail	Pass	Exclude
47260	Virginia Beach-Norfolk-Newport News, VA-NC	Pass	Pass	Fail	Exclude
47300	Visalia-Porterville, CA	Pass	Pass	Pass	Include
47380	Waco, TX	Pass	Pass	Pass	Include
47460	Walla Walla, WA	Fail	Fail	Pass	Exclude
47580	Warner Robins, GA	Pass	Pass	Pass	Include
47900	Washington-Arlington-Alexandria, DC-VA-MD-WV	Pass	Pass	Pass	Include
47940	Waterloo-Cedar Falls, IA	Pass	Pass	Pass	Include
48060	Watertown-Fort Drum, NY	Fail	Fail	Pass	Exclude
48140	Wausau, WI	Pass	Pass	Pass	Include
48260	Weirton-Steubenville, WV-OH	Pass	Pass	Pass	Include
48300	Wenatchee, WA	Pass	Pass	Pass	Include
48540	Wheeling, WV-OH	Pass	Pass	Pass	Include
48620	Wichita, KS	Pass	Pass	Pass	Include
48660	Wichita Falls, TX	Pass	Fail	Fail	Exclude
48700	Williamsport, PA	Pass	Pass	Pass	Include
48900	Wilmington, NC	Pass	Pass	Pass	Include
49020	Winchester, VA-WV	Pass	Pass	Pass	Include

CBSA_OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
49180	Winston-Salem, NC	Pass	Pass	Pass	Include
49340	Worcester, MA-CT	Pass	Pass	Pass	Include
49420	Yakima, WA	Pass	Pass	Pass	Include
49620	York-Hanover, PA	Pass	Pass	Pass	Include
49660	Youngstown-Warren-Boardman, OH-PA	Pass	Pass	Pass	Include
49700	Yuba City, CA	Pass	Pass	Pass	Include
49740	Yuma, AZ	Pass	Pass	Pass	Include

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b. Proposed Selection Approach

We propose the selection of 98 MSAs through the use of simple random selection from the 294 eligible MSAs.

Simple random selection is often considered to be an appropriate default approach to experimental design unless there is a compelling reason to depart from it. One common alternative approach is to perform random selection separately within subgroups. Selection within subgroups can be a useful approach to limiting differences between intervention and control groups to improve statistical power or for facilitating over or under sampling to allow the evaluation to examine effects of the intervention on particular types of MSAs or because those types of MSAs are of particular interest for policy reasons.

In CJR, we used a stratified random assignment approach in which we organized MSAs into strata based on MSA population size and historic LEJR episode payments. Under the CJR model, we believed a stratified approach was appropriate due to wide regional variation in prices, primarily associated with the use of post-acute services. The stratified approach served as a means to oversample in higher-expense MSAs as these areas have both the most need for and the most opportunity under the CJR model.

In assessing whether stratification would be proposed for the EPMs, we assessed a variety of factors described later in this section. Absent stratification, the rate at which a particular type of MSA will appear in the sample will be proportional to how often in appears among eligible MSAs. If a particular type of MSA is relatively common, it is likely to occur often enough that we do not need to deliberately over-sample for it. In the end, our analyses did not provide sufficient evidence that it is necessary to create selection subgroups of MSAs to guide the selection approach. As a result, we are proposing to use simple random selection from the entire pool of eligible MSAs.

(1) Factors Considered but Not Used

We considered a variety of possible MSA characteristics for possible use in classifying sub-groups. Though we did consider many of these variables important, we believe that a simple random selection, where warranted, is preferable.

Some of the factors we considered that we are not proposing to use in the selection methodology include the following:

- Measures associated with AMI-episode and CABG episode wage-adjusted spending, respectively. In considering how to operationalize such measures, we considered a number of alternatives including average total episode spending payments in an MSA, average episode spending associated with the initial hospital stay(s) and average episode spending occurring in the period after discharge from the initial hospital.
- Measures associated with variation in practice patterns associated with AMI and CABG episodes. In considering how to operationalize this measure, we considered a number of alternatives including the extent to which both an AMI and a CABG episode are associated with having a transfer hospital stay at the beginning of the episode, and the extent to which CABG hospitalizations occur following a hospital transfer from either within or from outside the same MSA.
- Measures associated with relative market share of providers with respect to AMI and/or CABG episodes, including the presence or absence of regional referral centers and the number of providers with the capacity to perform CABGs or otherwise treat complex cardiac patients.
- Health care supply measures of providers in the MSA including acute or post-acute bed counts, and number of relevant physician specialties such as cardiologists and cardiothoracic surgeons.
- MSA-level demographic measures such as: (1) average income; (2) distributions of population by age, gender or race; (3) percent dually eligible; and (4) percent with specific health conditions or other demographic composition measures.
- 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.

Though these measures are not proposed to be part of the selection process, we acknowledge that these and other market-level factors may be important to the proper understanding of the evaluation of the impact of EPMs. We intend to consider these and other measures in determining which MSAs are appropriate comparison markets for the evaluation and for possible subgroup analysis or risk-adjustment purposes. The evaluations will include beneficiary-, provider-, and market-level characteristics in how they will examine the performance of these proposed EPMs.

(2) Sample-Size Calculations and the Number of Selected MSAs

Our analyses of the necessary sample size led us to propose the selection of 98 MSAs, out of the 294 MSAs eligible

for selection and 384 total MSAs, to participate in both the AMI and CABG EPMs. In this section, we discuss the assumptions and modeling that went into our proposal to test these EPMs in 98 MSAs. The discussion of the method of selection of these 98 MSAs is addressed in the following section. In coming to the decision to target 98 MSAs, we are proposing an approach that limits the size of the intervention to the greatest degree possible, while still ensuring that we have sufficient statistical power to reliably evaluate the effects of the EPMs. Going below this threshold would jeopardize our ability to be confident in our results and to be able to generalize from the EPMs to the larger national context.

In calculating the necessary size of the AMI and CABG EPMs, a key consideration was to 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 both the AMI and the CABG EPMs was wage-adjusted total episode spending. The data used for the wage-adjusted total episode spending is the 3-year data pull previously described that covers AMI and CABG episodes with admission dates from July 1, 2012, through December 31, 2014. For the purposes of the sample-size calculation, we aim to be able to reliably identify between a 2-percent and 3-percent reduction in wage-adjusted episode spending after 1 year of experience. We chose this range because those numbers represent the anticipated amount of the discount proposed to apply under various conditions of the AMI and CABG EPMs' implementation.

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 positives'' and ''false negatives.'' A false positive occurs if a statistical test concludes that a model was successful (that is, saved money) when it in fact was not. A false negative occurs if a statistical test fails to find statistically-significant evidence that the model was successful, when it in fact was successful. In considering the minimum sample size needs of the AMI and CABG EPMs, 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 10-percent chance of a false positive and no more than a 30-percent chance of a false negative in order to minimize reduce sample size requirements to the greatest degree possible.

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. We are proposing to base the sample size calculation at the MSA level. The proposed EPMs are an example of what is known as a ''nested comparative study.'' Under a nested comparative study, assignment to an intervention or comparison arms of the study is based on membership in pre-existing, identifiable group where the groups are not formed at random, but rather through some physical, social, geographic, or other connection among their members. Because these groups are not formed at random, individual members of each group are likely to share important commonalities. In the context of the proposed EPMs spending and outcomes for patients cared for within a given MSA are relatively similar to one another due to such factors as the existence of common practice or referral patterns, the underlying health in the population, and the availability of providers in an area.

In statistical terms, these commonalities create a positive correlation (called an intra-class correlation) among hospitals or beneficiaries in the same MSA. Due to that intra-class correlation, the variability of any aggregate statistic—such as the estimated difference in outcomes between the intervention and comparison arms of the study—has two components—(1) variability attributable to variation among hospitals or beneficiaries in a given MSA; and (2) variability attributable to differences between MSAs. An accurate power analysis must account for both components of variability.

In determining the necessary sample size, we take into consideration the degree to which commonalities within MSAs exist and the number of independent beneficiaries and hospitals expected to be included in the EPM within each MSA. As part of this process, we empirically examined the number of beneficiaries, the number of hospitals, and the number of MSAs, as well as the level of correlation in episode payments between each level. Based on this empirical examination, we determined that the correlation was high enough that the degree of variability would be primarily driven by the number of MSAs in the model, indicating that the MSA is the appropriate unit of analysis for the power calculations.

Using the aforementioned assumptions, a power calculation for AMI was run which indicated that at 98 MSAs we would be able to reliably detect a 3-percent reduction in wage-adjusted episode spending after 1 year with a false-positive rate of 10 percent and a false-negative rate of between 20 percent and 40 percent. We are targeting a false-negative rate of 30 percent. The extent to which this rate can be lowered will depend on the ability of evaluation models to substantially reduce variation through risk adjustment and modeling. We believe it is prudent to choose a sample size where the targeted amount is in the middle of this expected band.

We separately assessed the sample-size needs associated with CABG episodes. At 98 MSAs, we anticipate being able to detect a 2.25-percent reduction in wage-adjusted episode expenditures after 1 year with a false-positive rate of 10 percent and a false-negative rate of between 20–40 percent. The effective number of MSAs where the CABG EPM will be tested will be reduced because approximately 6 percent of eligible MSAs had no CABG episodes in the reference year. However, our power calculations do not lead us to believe we need to increase the sample size based on this fact. The number of CABG MSAs can experience this reduction and maintain equivalent levels of power to the AMI episodes.

(3) Method of Selecting MSAs

As previously discussed, we are seeking to choose 98 MSAs from our pool of eligible MSAs through simple random selection. We propose to make the selection in the final rule using SAS Enterprise Guide 7.1 software to run a computer algorithm 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 will be generated using the

birthdate of the person executing the program.[37]

We seek comment on our proposal to implement the AMI and CABG models in the selected MSAs, some of which may overlap with MSAs where the CJR and SHFFT models also are being implemented.

C. Episode Definition for the EPMs

1. Background

Episode payment models incentivize improvement in the coordination and quality of care experienced by a Medicare beneficiary, as well as episode efficiency, by bundling payment for services furnished to the beneficiary for specific clinical conditions over a defined period of time. A key model design feature is the definition of the episodes included in the model. The definition of episodes has two significant dimensions—(1) a clinical dimension that describes which clinical conditions and associated services are included in the model; and (2) a time dimension that describes the beginning, middle, and end of the model.

2. Overview of Three Proposed Episode Payment Models

We propose three new EPMs—AMI, CABG, and SHFFT—that each begin with a hospitalization and extend 90 days after hospital discharge. The proposed AMI model generally includes beneficiaries discharged under an AMI MS–DRG (280–282), representing admission to an IPPS hospital for AMI that is treated with medical management, or an IPPS admission for a PCI MS–DRG (246–251) with an International Classification of Diseases (ICD)-Clinical Modification (CM) AMI diagnosis code describing an initial AMI diagnosis in the principal or a secondary diagnosis code position.

The proposed CABG model generally includes beneficiaries discharged under a CABG MS–DRG (231–236), representing an IPPS admission for this coronary revascularization procedure irrespective of AMI diagnosis. The proposed SHFFT model generally includes beneficiaries discharged under hip and femur procedures except major joint MS–DRG (480–482), representing an IPPS admission for a hip fixation procedure in the setting of a hip fracture.

One reason these particular episodes were chosen for the proposed EPMs is that the initiation of treatment for each of the three clinical conditions included in an episode occurs almost exclusively during a hospitalization, which we believe would minimize the possibility of shifting beneficiaries in or out of the EPM based on the site-of-service where treatment is initiated. The majority of evaluation and treatment for AMI is performed in the inpatient hospital setting, commonly beginning when beneficiaries present with symptoms to the emergency department of a hospital. Patients experiencing an AMI are almost uniformly admitted to the hospital for further evaluation and management.[38] Although PCIs can be performed and may be paid by Medicare in the hospital outpatient setting in addition to being performed during a hospitalization, the majority of patients experiencing an AMI who are candidates for procedural revascularization receive PCI procedures during the initial hospitalization for AMI where evaluation also occurs.[39] CABG procedures are furnished exclusively in the inpatient hospital setting. We note that all of the Current Procedural Terminology (CPT) codes that physicians report for CABG are listed on the hospital Outpatient Prospective Payment System (OPPS) inpatient-only list in Addendum E of the 2016 OPPS final rule with comment period that is posted on the CMS Web site.[40] The hip fixation procedures performed in the SHFFT model also are predominantly furnished in the inpatient hospital setting, and we further note that almost all of the CPT codes that describe these procedures also are on the OPPS inpatient-only list.

Hospitals' ability to identify EPM beneficiaries during the hospitalization that begins the episode (hereinafter the anchor hospitalization) also is an important consideration in developing episode payment models that, like the CJR model, rely upon MS–DRG assignment for IPPS claims following their submission in order to identify beneficiaries for model inclusion. This is especially important for medical management of conditions for which the predictability of the ultimate MS–DRG for the hospitalization is less certain than for surgical or procedural MS–DRGs. AMI represents a relative exception among medical conditions as it is associated with specific clinical and laboratory features that enable hospitals to identify beneficiaries with AMI during the anchor hospitalization whom would likely be included in an AMI model episode through their ultimate discharge under an AMI MS–DRG. We note that ICD–CM coding rules allow AMI diagnosis codes in both the primary and secondary position to map to AMI MS–DRGs.[41] In the case of procedural episodes such as CABG, SHFFT, and AMI model episodes for beneficiaries treated with PCI, the MS–DRG for the procedure performed would determine the ultimate MS–DRG assignment for the hospitalization unless additional surgeries higher in the MS–DRG hierarchy also are reported.[42] Therefore, we propose these three EPMs for clinical conditions where MS–DRG assignment is likely to be certain and known during the anchor hospitalization, even though treatment for AMI may involve only medical management. We believe hospitals participating in the proposed EPMs would be able to identify beneficiaries in EPM episodes through their AMI, CABG, and SHFFT episode MS–DRGs during the anchor hospitalization, allowing active coordination of EPM beneficiary care during and after hospitalization.

3. Clinical Dimensions of AMI, CABG, and SHFFT Model Episodes

As we stated in the CJR model Final Rule, we believe that a straightforward approach for hospitals and other providers to identify Medicare beneficiaries in these episode payment models would be important for the care redesign that is required for EPM success, as well as for operationalization of the proposed payment and other EPM policies (80 FR 73299). Therefore, as in the CJR model, we propose that an EPM episode would be initiated by an admission to an acute care hospital for an anchor hospitalization paid under EPM-specific MS–DRGs under the IPPS (80 FR 73300).

[37] 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/*.

[38] Amsterdam et al. 2014 AHA/ACC Guideline for the Management of Patients with Non-ST—Elevation Acute Coronary Syndromes. Circulation. 2014; 130:e344—e426.

[39] Episodes for beneficiaries with AMI initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, that end in CY 2014.

[40] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1633-FC.html.*

[41] Medical Severity Diagnosis Related Groups (MS–DRGs): Definitions Manual. Version 33.0A. 3M Health Information Systems. (October 1, 2015). *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html.*

[42] Medical Severity Diagnosis Related Groups (MS–DRGs): Definitions Manual. Version 33.0A. 3M Health Information Systems. (October 1, 2015). *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html.*

a. Definition of the Clinical Conditions Included in AMI, CABG, and SHFFT Model Episodes

(1) AMI (Medical Management and PCI) Model

We propose the AMI model to incentivize improvements in the coordination and quality of care, as well as episode efficiency, for beneficiaries treated for AMI with either medical management or coronary artery revascularization with PCI. We propose to define beneficiary inclusion in the AMI model by discharge under an AMI MS–DRG (280–282), representing those individuals admitted with AMI who receive medical therapy but no revascularization, and discharge under a PCI MS–DRG (246–251) with an ICD–10–CM diagnosis code of AMI on the IPPS claim for the anchor hospitalization in the principal or secondary diagnosis code position. We note that we would use AMI International Classification of Diseases, 9th revision clinical modification (ICD–9–CM) diagnosis codes to identify historical episodes for setting AMI model-episode benchmark prices in the early performance years of the AMI model. The Uniform Hospital Discharge Data Set (UHDDS) defines the principal diagnosis for hospitalization as ''that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care'' and other (secondary) diagnoses as ''all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received and/or the length of stay. Diagnoses that relate to an earlier episode which have no bearing on the current hospital stay are to be excluded.'' [43] We propose to include those beneficiaries discharged under PCI MS–DRGs with an AMI ICD–10–CM diagnosis code in the principal or secondary diagnosis code position to ensure that beneficiaries with an AMI that is not chiefly responsible for occasioning the hospitalization are included in the AMI model because the AMI itself is likely to substantially influence the hospitalization and post-discharge recovery (and be responsible for leading to the PCI) even if an AMI ICD–10–CM diagnosis code is reported in a secondary diagnosis code position. For example, a beneficiary receiving a PCI with an ICD–10–CM diagnosis code of pneumonia in the principal position and an AMI ICD–10–CM diagnosis code in a secondary position would be included in the AMI model, which would be appropriate because the course of the beneficiary's recovery and management during the AMI model episode would be primarily associated with the AMI and PCI. While pneumonia is typically an acute illness that may sometimes result in hospitalization, underlying chronic conditions may increase the likelihood that a beneficiary would be hospitalized for pneumonia, a condition that is more commonly treated on an outpatient basis. AMI in association with a hospitalization for pneumonia would represent a sentinel event for the beneficiary resulting from underlying CAD that signals a need for a heightened focus on medical management of CAD and other beneficiary risk factors for future cardiac events and that may themselves have increased the beneficiary's risk for pneumonia. Thus, care coordination and management in the 90 days post-hospital discharge for these beneficiaries would be focused on managing CAD and the beneficiary's cardiac function after the AMI.

We acknowledge that this proposal to identify beneficiaries included in the AMI model through a combination of MS–DRGs and AMI ICD–CM diagnosis codes represents a modification of the CJR model episode definition methodology. The CJR model defined episodes based on MS–DRGs alone, specifically MS–DRG 469 (Major joint replacement or reattachment of lower extremity with Major Complications or Comorbidities (MCC)) and MS–DRG 470 (Major joint replacement or reattachment of lower extremity without MCC), because the anchor hospitalization for the CJR model was defined by admission for a surgical procedure alone (80 FR 73280). However, the proposed AMI model is defined by admission for a medical condition that includes a range of treatment options, including medical treatment and PCI. Therefore, to identify beneficiaries admitted for AMI and treated with PCI requires ICD–CM diagnosis codes paired with MS–DRGs to identify the subset of PCI MS–DRG cases associated with AMI that would otherwise be excluded from an AMI model based solely on AMI MS–DRGs.

For the purposes of defining historical AMI model episodes, we propose to exclude beneficiaries discharged under PCI MS–DRGs with an AMI ICD–9–CM diagnosis code in the principal or secondary position if there is an intracardiac ICD–9–CM procedure code in any procedure code field. Intracardiac procedure codes do not represent PCI procedures indicated for the treatment of the coronary artery obstruction that results in AMI, but instead represent a group of procedures indicated for treating congenital cardiac malformations, cardiac valve disease, and cardiac arrhythmias. These intracardiac procedures are performed within the heart chambers rather than PCI procedures for AMI that are performed within the coronary blood vessels. To reflect this clinical distinction, the FY 2016 IPPS update removed intracardiac procedures from MS–DRGs 246–251 and assigned them to new MS–DRGs 273 and 274 (80 FR 49367). Therefore, to be consistent with our proposed definition of AMI model episodes that initiate with PCI MS–DRGs 246–251 (not with MS–DRGs 273 and 274) and an AMI ICD–9–CM diagnosis code in the principal or secondary position, we are proposing to define historical AMI model episodes for beneficiaries discharged under PCI MS–DRGS 246–251 as those that do not include the ICD–9–CM procedure codes in Table 2. These codes are also posted on the CMS Web site at *https://innovation.cms.gov/inititatives/epm*.

TABLE 2—PROPOSED ICD–9–CM PROCEDURE CODES IN ANY POSITION ON THE IPPS CLAIM FOR PCI MS–DRGS (246–251) THAT DO NOT DEFINE HISTORICAL AMI MODEL EPISODES

ICD–9–CM Procedure code	ICD–9–CM Procedure code description
35.52	Repair of atrial septal defect with prosthesis, closed technique.
35.96	Percutaneous balloon valvuloplasty.
35.97	Percutaneous mitral valve repair with implant.
37.26	Catheter based invasive electrophysiologic testing.
37.27	Cardiac mapping.
37.34	Excision or destruction of other lesion or tissue of heart, endovascular approach.

[43] *http://www.cdc.gov/nchs/data/icd/icd10cm_guidelines_2014.pdf.*

TABLE 2—PROPOSED ICD–9–CM PROCEDURE CODES IN ANY POSITION ON THE IPPS CLAIM FOR PCI MS–DRGS (246–251) THAT DO NOT DEFINE HISTORICAL AMI MODEL EPISODES—Continued

ICD–9–CM Procedure code	ICD–9–CM Procedure code description
37.36	Excision, destruction, or exclusion of left atrial appendage.
37.90	Insertion of left atrial appendage device.

In FY 2014, there were approximately 395,000 beneficiaries discharged from a short-term acute care hospitalization (excluding Maryland) with an AMI ICD–9–CM diagnosis code in the principal or secondary position on the IPPS claim. Of these beneficiaries, 58 percent were discharged under MS–DRGs that would initiate an AMI model episode, specifically an AMI MS–DRG (33 percent) and PCI MS–DRG (25 percent). Five percent of beneficiaries were discharged from CABG MS–DRGs and 3 percent were discharged from AMI MS–DRGs representing death during the hospitalization. The remaining 34 percent of beneficiaries with an AMI ICD–CM diagnosis code in the principal or secondary position were distributed across over approximately 300 other MS–DRGs, with the septicemia MS–DRGs accounting for 8 percent and the remainder accounting for 3 percent or less of beneficiaries with an AMI ICD–CM diagnosis code on the IPPS claim.[44] We note that the AMI ICD–9–CM diagnosis code was most commonly in a secondary position for discharges from these other MS–DRGs, likely representing beneficiaries hospitalized for another condition who experienced an AMI during that hospitalization. We note that CMS's AMI quality measures used in the Hospital Inpatient Quality Reporting (HIQR) Program are based on all beneficiaries discharged under any MS–DRG who have an AMI ICD–CM diagnosis code only in the principal position, reflecting the measures' focus on the most homogeneous beneficiary population with AMI as the condition responsible for occasioning the hospital admission. This is in contrast with our proposed use of an AMI ICD–10–CM diagnosis code in the principal or a secondary position for the AMI model in order to identify those beneficiaries receiving a PCI whose hospitalization and post-discharge recovery and management would primarily be associated with the PCI and AMI.

The proposed specifications for AMI episodes, including ICD–9–CM AMI diagnosis codes for historical episodes used to set the initial AMI model-episode benchmark prices and ICD–10–CM AMI diagnosis codes for the proposed performance years of the model, are displayed in Table 3. The ICD–9–CM intracardiac procedure codes used to exclude inpatient claims with PCI MS–DRGS 246–251 from anchoring AMI model historical episodes used to set initial AMI model-episode benchmark prices are displayed in Table 3.

Based on Medicare claims data for historical AMI episodes ending in CYs 2012–2014, the annual number of potentially eligible beneficiary discharges for the AMI model nationally was approximately 168,000.[45] This number is less than the approximately 229,000 discharges for beneficiaries with AMI discharged from AMI MS–DRGs 280–282 and PCI MS–DRGs 246–251 that could be expected to be included in the AMI model for several reasons. Discharges do not result in historical episodes when a beneficiary does not meet the beneficiary care inclusion criteria discussed in section III.C.4.a.(1) of this proposed rule; is not discharged alive from PCI MS–DRGS 246–251; is discharged from a transfer hospital during a chained anchor hospitalization; or is discharged from a readmission during an AMI model episode that does not initiate new model episodes.

The proposed list of ICD–9–CM and ICD–10–CM AMI diagnosis codes used to identify beneficiaries discharged under a PCI MS–DRG (MS–DRGs 246–251) in historical episodes and during the performance years of the model that will be included in the AMI model episodes are discussed in section III.C.4.a.(2) of this proposed rule. To make changes to this list as necessary based on annual ICD–10–CM coding changes or to address issues raised by the public throughout the EPM performance years, we propose implementing the following sub-regulatory process, which mirrors the sub-regulatory process as described in the CJR model final rule for updating hip fracture ICD–9–CM and ICD–10–CM diagnosis codes (80 FR 73340) and for updating the exclusions list (80 FR 73305 and 73315). We propose to use this process on an annual, or more frequent, basis to update the AMI ICD–10–CM diagnosis code list and to address issues raised by the public. As part of this process we propose the following standard when revising the list of ICD–10–CM diagnosis codes representing AMI: The ICD–10–CM diagnosis code is sufficiently specific that it represents an AMI. We propose to then post a list of potential AMI ICD–10–CM diagnosis codes to the CMS Web site at *https://innovation.cms.gov/inititatives/epm* to allow for public input on our planned application of these standards, and then adopt the AMI ICD–10–CM diagnosis code list with posting to the CMS Web site of the final AMI ICD–CM diagnosis code list after our consideration of the public input. We would provide sufficient time for public input based on the complexity of potential revisions under consideration, typically at least 30 days, and, while we would not respond to individual comments as would be required in a regulatory process, we could discuss the reasons for our decisions about changes in response to public input with interested stakeholders.

The proposals for identifying the beneficiaries included in the AMI model and the sub-regulatory process for updating the AMI ICD–10–CM diagnosis code list are included in § 512.100(c)(1) and (d), respectively. We seek comment on our proposals to identify beneficiaries included in the AMI model and the sub-regulatory process for updating the AMI ICD–10–CM diagnosis code list. The proposal to exclude inpatient claims with PCI MS–DRGS 246–251 from anchoring AMI model historical episodes used to set initial AMI model-episode benchmark prices when there is an ICD–9–CM intracardiac procedure code on the claim is included in § 512.100(d)(4). We seek comment on our proposal to exclude inpatient claims with PCI MS–DRGS 246–251 from anchoring AMI model historical episodes used to set initial AMI model-episode benchmark prices when there is an ICD–9–CM intracardiac procedure code on the claim.

[44] Inpatient claims from all U.S. IPPS hospitals not in Maryland were derived from the October 2013–September 2014 Inpatient Claims File located in the Chronic Conditions Warehouse.

[45] Episodes for AMI beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, that began in CYs 2012–2014.

(2) CABG Model

We propose the CABG model to incentivize improvements in the coordination and quality of care, as well as episode efficiency, for beneficiaries treated with CABG irrespective of AMI during the CABG hospitalization, thereby including beneficiaries undergoing elective CABG in the CABG model as well as beneficiaries with AMI who have a CABG during their initial AMI treatment. The CABG model is similar to the CJR model in that the anchor hospitalization is defined by admission for a surgical procedure, which is defined by the MS–DRGs for that procedure alone (80 FR 73280). All CABG procedures are performed in the inpatient hospital setting. Thus, we propose to include beneficiaries admitted and discharged from an anchor hospitalization paid under CABG MS–DRGs (231–236) under the IPPS in the CABG model. Based on Medicare claims data for historical CABG episodes beginning in CYs 2012–2014, the annual number of potentially eligible beneficiary discharges for the CABG model nationally was approximately 48,000.[46]

The proposal for identifying beneficiaries included in the CABG model is included in § 512.100(c)(2). We seek comment on our proposal to identify beneficiaries included in the CABG model.

(3) SHFFT (Excludes Lower Extremity Joint Replacement) Model

We propose the SHFFT model to incentivize improvements in the coordination and quality of care, as well as episode efficiency, for beneficiaries treated surgically for hip and femur fractures, other than hip arthroplasty. Together, the CJR and SHFFT models cover all surgical treatment options (that is, hip arthroplasty and fixation) for Medicare beneficiaries with hip fracture.

The SHFFT model is similar to the CJR model in that the anchor hospitalization is defined by admission for a surgical procedure, which is defined by the MS–DRGs for that procedure alone (80 FR 73280). Additionally, most SHFFT procedures are furnished in the inpatient hospital setting, consisting primarily of hip fixation procedures, with or without reduction of the fracture, as well as open and closed surgical approaches. Thus, we propose to include beneficiaries admitted and discharged from an anchor hospitalization paid under SHFFT MS–DRGs (480–482) under the IPPS in the SHFFT model. Based on Medicare claims data for historical SHFFT episodes beginning in CYs 20122014, the annual number of potentially eligible beneficiary discharges for the SHFFT model nationally was approximately 109,000.[47]

The proposal for identifying beneficiaries included in the SHFFT model is included in § 512.100(c)(3). We seek comment on our proposal to identify beneficiaries included in the SHFFT model.

b. Definition of the Related Services Included in EPM Episodes

The general principles for the proposed definition of related services are the same for the AMI, CABG, and SHFFT models, so we address them in a single discussion in this section. Like the CJR model, we are interested in testing inclusive AMI, CABG, and SHFFT model episodes to incentivize comprehensive, coordinated, patient-centered care for the beneficiary throughout the episode (80 FR 73303). Therefore, we propose to exclude Medicare items and services furnished during the EPM episodes only when unrelated to the EPM episode diagnosis and procedures based on clinical rationale that would result in standard exclusions from all of the episodes in a single EPM. Thus, we propose to include all items and services paid under Medicare Part A and Part B unless they fall under an exclusion because they are unrelated to the EPM episodes.

Also like the CJR model, we propose that the items and services ultimately included in the EPM episodes after the exclusions are applied are called related items and services, and that Medicare spending for related items and services be included in the historical data used to set EPM-episode benchmark prices and in the calculation of actual EPM episode payments that would be compared against the quality-adjusted target price to assess the performance of EPM participants (80 FR 73303 and 73315). Additionally, we propose that Medicare spending for unrelated items and services (excluded from the EPMs' episode definitions) would not be included in the historical data used to set EPM-episode benchmark prices or in the calculation of actual EPM episode payments. We propose that related items and services for EPM episodes would include the following items and services paid under Medicare Part A and Part B, after the EPM-specific exclusions are applied:

- Physicians' services.
- Inpatient hospital services.
- Inpatient psychiatric facility (IPF) services.
- Long-Term Care Hospital (LTCH) services.
- Inpatient Rehabilitation Facility (IRF) services.
- Skilled Nursing Facility (SNF) services.
- Home Health Agency (HHA) services.
- Hospital outpatient services.
- Independent outpatient therapy services.
- Clinical laboratory services.
- Durable medical equipment.
- Part B drugs.
- Hospice.

We note that inpatient hospital services would include services paid through IPPS operating and capital payments. The AMI, CABG, and SHFFT model episodes also could include certain per-member-per-month model payments as discussed in section III.D.6.d. of this proposed rule. These proposed items and services for the EPMs are the same items and services included in CJR model episodes (80 FR 73303 and 73315).

Similar to the CJR model and for the reasons explained in the CJR Final Rule, we propose to exclude drugs that are paid outside of the MS–DRGs included in the EPM episode definitions, specifically hemophilia clotting factors, identified by CPT code, diagnosis code, and revenue center on IPPS claims, from the EPM episodes (80 FR 73303 and 73315). Hemophilia clotting factors, in contrast to other drugs that are administered during a hospitalization and paid through the MS–DRG, are paid separately by Medicare in recognition that clotting factors are costly and essential to appropriate care of certain beneficiaries. Therefore, we believe there are no EPM episode efficiencies to be gained in the variable use of these high cost drugs.

We also propose to exclude IPPS new technology add-on payments for drugs, technologies, and services from these EPM episodes, excluding them from both the actual historical episode data used to set EPM-episode benchmark prices and from actual EPM episode payments that are reconciled to the quality-adjusted target prices like the CJR model (80 FR 73303–73304 and 73315). This would apply to both the anchor hospitalization and any related

[46] Episodes for CABG beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, that began in CYs 2012–2014.

[47] Episodes for SHFFT beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CYs 2012–2014.

readmissions during the EPM episodes. 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 under the MS–DRG system. We believe it would not be appropriate for the EPM to potentially diminish beneficiaries' access to new technologies or to burden hospitals who choose to use these new drugs, technologies, or services with concern about these payments counting toward EPM participants' actual EPM episode payment. Additionally, new drugs, technologies, or services approved for the add-on payments vary unpredictably over time in their application to specific clinical conditions.

Finally, we propose to exclude OPPS transitional pass-through payments for medical devices as defined in § 419.66 from the EPM episodes because, through the established OPPS review process, we have determined that these technologies have a substantial cost but also lead to substantial clinical improvement for Medicare beneficiaries. This proposal also is consistent with the CJR model final exclusions policy (80 FR 73308 and 73315).

We propose to follow the same general principles in determining other proposed excluded Part A and Part B services from the EPM episodes that we use in the CJR model in order to promote coordinated, high-quality, patient-centered care (80 FR 73304). These include identifying excluded (unrelated) services rather than included (related) services based on clinical review. We would operationalize these principles for the new EPMs, as we do for the CJR model, by excluding unrelated inpatient hospital admissions during the EPM episode by identifying MS–DRGs for exclusion on an EPM-specific basis (80 FR 73304 through 73312 and 73315). We would further exclude unrelated Part B services during the EPM episode based on the diagnosis code on the claim by identifying categories of ICD–CM codes for exclusion (identified by code ranges) on an EPM-specific basis. ICD–9–CM diagnosis code exclusions would apply to historical episodes used to construct EPM-episode benchmark prices, while ICD–10–CM diagnosis code exclusions would apply to EPM episodes during the EPMs' performance years. We propose to identify unrelated Part B services and readmissions based on the BPCI Model 2 Part B exclusions lists that apply to the anchor MS–DRG that initiates the EPM episode, or to the price MS–DRG if it is different than the anchor MS–DRG as described further in section III.D.4.b.(2)(a) of this proposed rule. This proposal is consistent with our use of the BPCI Model 2 LEJR ICD–9–CM, ICD–10–CM, and MS–DRG exclusions lists in the CJR model (80 FR 73304 and 73315).

The BPCI episode-specific exclusions lists were initially developed more than 3 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 lists have been shared with thousands of entities and individuals participating in episodes in one or more phases of BPCI, and have undergone refinement in response to stakeholder input about specific diagnoses for exclusion, resulting in only minimal changes over the last 3 years. Thus, the BPCI exclusions lists have 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 propose their use in the AMI, CABG, and SHFFT models based on our confidence related to our several years of experience that these definitions are reasonable and workable for AMI, CABG, and SHFFT model episodes, for both providers and CMS, and based on our rulemaking for the CJR model. We note that the BPCI Model 2 exclusions lists for the 48 clinical conditions being tested in the BPCI models include lists that apply to every MS–DRG that could be an anchor MS–DRG (or price MS–DRG, if applicable) for the proposed AMI, CABG, and SHFFT model episodes.

Similar to the CJR model, we propose to include in EPM episodes all Part A services furnished post-hospital discharge during the EPM episode, as these services are typically intended to be comprehensive in nature (80 FR 73304 and 73315). We specifically propose to exclude unrelated hospital readmissions for MS–DRGs that group to the following categories of diagnoses: Oncology, trauma medical admissions, surgery for chronic conditions unrelated to a condition likely to have been affected by care furnished during the EPM episode, and surgery for acute conditions unrelated to a condition resulting from or likely to have been affected by care during the EPM episode. The rationale for these exclusions is the same as the rationale for their exclusion in the CJR model (80 FR 73304).

Specifically with respect to Part B services, similar to the CJR model, we propose to exclude acute disease diagnoses unrelated to a condition resulting from or likely to have been affected by care during the EPM episode, and 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 care during the EPM episode or whether substantial services were likely to be provided for the chronic condition during the EPM episode (80 FR 73305 and 73315). Thus, we would include all Part B services with principal diagnosis codes on the associated Part B claims that are directly related (clinically and per coding conventions) to EPM episodes, claims for diagnoses that are related to the quality and safety of care furnished during EPM episodes, and claims for services for diagnoses that are related to preexisting chronic conditions such as diabetes, which may be affected by care furnished during EPM episodes.

In general, the anchor MS–DRG that initiates the AMI, CABG, or SHFFT episode would determine the exclusions list that applies to the EPM episode. For example, AMI model episodes may have different exclusions lists applied based on whether the AMI model episode is initiated by admission to the participant hospital that results in discharge from an AMI anchor MS–DRG or a PCI anchor MS–DRG with AMI ICD–10–CM diagnosis code. If a price MS–DRG applies to the AMI model episode that includes a chained anchor hospitalization as described in section III.D.4.b.(2)(a) of this proposed rule, the exclusions list that applies to the price MS–DRG would apply to the AMI model episode. Complete lists of proposed excluded MS–DRGs for readmissions and proposed excluded ICD–CM codes for Part B services furnished during EPM episodes after EPM beneficiary discharge from an anchor or chained anchor hospitalization in the AMI, CABG, and SHFFT models are posted on the CMS Web site at *https://innovation.cms.gov/initiatives/epm*.

Like the CJR model policy, we propose that these exclusion lists would be updated by sub-regulatory guidance on an annual basis, at a minimum, to reflect annual changes to ICD–10–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 throughout the course of the EPMs' performance period (80 FR 73304 through 73305 and 73315). The standards for this updating process reflect the aforementioned general principles for determining excluded services. That is, we propose to not

exclude any items or services that are directly related to the EPM episode diagnosis or procedure (for example, a subsequent admission for heart failure or repeat revascularization) or the quality or safety of care (for example, sternal wound infection following CABG); or to chronic conditions that may be affected by the EPM diagnosis or procedure and the post-discharge care (for example, diabetes). We propose to exclude items and services for chronic conditions that are generally not affected by the EPM diagnosis or procedure and the post-discharge care (for example, prostate removal for cancer), and for acute clinical conditions not arising from existing EPM episode-related chronic clinical conditions or complications from the EPM episode (for example, appendectomy).

Similar to the CJR model, we propose that the potential revised exclusions, which could include additions to or deletions from the exclusions lists, would be posted to the CMS Web site to allow for public input (80 FR 73305 and 73315). Through the process for public input on potential revised exclusions and then posting of the final revised exclusions, we propose to provide information to the public about when the revisions would take effect and to which episodes they would apply.

The proposal for included services for an EPM is included in § 512.210(a). The proposal for excluded services from the EPM episode is included in § 512.210(b). The proposal for updating the lists of excluded services for EPMs is included in § 512.210(c). We seek comment on our proposals for included and excluded services for the AMI, CABG, and SHFFT models and updating the lists of excluded services.

4. EPM Episodes

a. Beneficiary Care Inclusion Criteria and Beginning of EPM Episodes

(1) General Beneficiary Care Inclusion Criteria

Because of the clinical variability leading up to these EPM episodes and the challenge of identifying unrelated services given the multiple chronic conditions experienced by many EPM beneficiaries, we propose to follow the CJR model precedent and not begin an EPM episode prior to the anchor hospitalization (80 FR 73315 and 73318). We propose that all services that are already included in the IPPS payment based on established Medicare policies (for example, 3-day payment window payment policies) would be included in these EPM episodes, and that the defined population of Medicare beneficiaries whose care would be included in the EPMs would meet all of the following criteria on admission to the anchor or chained anchor hospitalization:

- Enrolled in Medicare Part A and Part B.
- Eligible for Medicare not on the basis of end-stage renal disease.
- Not enrolled in any managed care plan (for example, Medicare Advantage, Health Care Prepayment Plans, cost-based health maintenance organizations).
- Not covered under a United Mine Workers of America health plan, which provides health care benefits for retired mine workers.
- Have Medicare as their primary payer.
- Not aligned to an ACO in the Next Generation ACO model or an ACO in a track of the Comprehensive ESRD Care Initiative incorporating downside risk for financial losses.
- Not under the care of an attending or operating physician, as designated on the inpatient hospital claim, who is a member of a physician group practice that initiates BPCI Model 2 episodes at the EPM participant for the MS–DRG that would be the anchor MS–DRG under the EPM.
- Not already in any BPCI model episode.
- Not already in an AMI, SHFFT, CABG or CJR model episode with an episode definition that does not exclude the MS–DRG that would be the anchor MS–DRG under the applicable EPM.

For a discussion of our proposal to exclude certain ACO-aligned beneficiaries from EPM episodes, we refer to section III.D.6.c.(3) of this proposed rule. For a discussion of our proposals for addressing potential overlap of beneficiaries in episode payment models that are relevant to these last two criteria, we refer to sections III.D.6.c.(1) and (2) of this proposed rule.

The proposal for beneficiary care inclusion policies is included in § 512.230. We seek comment on our proposal of beneficiary care inclusion policies.

(2) Beginning AMI Model Episodes

We propose that, as long as the beneficiary meets the general beneficiary care inclusion criteria, then an AMI model episode would begin with admission of a Medicare beneficiary to an IPPS hospital for the following MS–DRGs, where the specific MS–DRG is called the anchor MS–DRG for the episode:

- AMI MS–DRGs—

++ 280 (Acute myocardial infarction, discharged alive with MCC);

++ 281 (Acute myocardial infarction, discharged alive with CC); and

++ 282 (Acute myocardial infarction, discharged alive without CC/MCC).

- PCI MS–DRGs, when the claim includes an AMI ICD–10–CM diagnosis code in the principal or secondary position on the IPPS claim as specified in Table 3—

++ 246 (Percutaneous cardiovascular procedures with drug-eluting stent with MCC or 4+ vessels/stents);

++ 247 (Percutaneous cardiovascular procedures with drug-eluting stent without MCC);

++ 248 (Percutaneous cardiovascular procedures with non-drug-eluting stent with MCC or 4+ vessels/stents);

++ 249 (Percutaneous cardiovascular procedures with non-drug-eluting stent without MCC);

++ 250 (Percutaneous cardiovascular procedures without coronary artery stent with MCC); and

++ 251 (Percutaneous cardiovascular procedures without coronary artery stent without MCC).

Table 3 displays the ICD–9–CM codes that we propose to use to identify historical AMI episodes for beneficiaries discharged from PCI MS–DRGs, as well as the ICD–10–CM diagnosis codes that would be used to identify AMI model episodes for beneficiaries discharged from PCI MS–DRGs throughout the duration of the AMI model. The proposed sub-regulatory process for updating this AMI ICD–10–CM diagnosis code list is described previously in section III.C.3.a.(1) of this proposed rule.

We first identified the ICD–9–CM diagnosis codes for the initial AMI episode-of-care that were historically used to report care for a newly diagnosed AMI patient admitted to the hospital. These codes all have a fifth digit of ''1'' and were applicable until the patient was discharged from acute medical care, including for any transfers to and from other acute care facilities that occurred. These AMI ICD–9–CM diagnosis codes would be used to identify historical AMI episodes for developing AMI model-episode benchmark prices for anchor PCI MS–DRGs. We propose to cross-walk the ICD–9–CM diagnosis codes for the initial AMI episode-of-care to the ICD–10–CM diagnosis codes that would be reported for similar beneficiaries during the AMI model performance years. The proposed crosswalk in Table 3 is consistent with the crosswalk CMS posted for public comment regarding ICD–9–CM to ICD–10–CM diagnosis

codes used for HIQR Program measures, including AMI quality measures.[48]

TABLE 3—PROPOSED ICD–9–CM AND ICD–10–CM AMI DIAGNOSIS CODES IN THE PRINCIPAL OR SECONDARY POSITION ON THE IPPS CLAIM FOR PCI MS–DRGS (246–251) THAT INITIATE AMI MODEL EPISODES

ICD–9–CM Diagnosis code	ICD–9–CM Description	ICD–10–CM Diagnosis code	ICD–10–CM Description
410.01	Acute myocardial infarction of anterolateral wall, initial episode of care.	121.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall.
		122.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall.
410.11	Acute myocardial infarction of other anterior wall, initial episode of care.	121.01	ST elevation (STEMI) myocardial infarction involving left main coronary artery.
		121.02	ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery.
		121.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall.
		122.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall.
410.21	Acute myocardial infarction of inferolateral wall, initial episode of care.	121.10	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall.
		122.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall.
410.31	Acute myocardial infarction of inferoposterior wall, initial episode of care.	121.11	ST elevation (STEMI) myocardial infarction involving right coronary artery.
		122.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall.
410.41	Acute myocardial infarction of other inferior wall, initial episode of care.	121.19	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall.
		122.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall.
410.51	Acute myocardial infarction of other lateral wall, initial episode of care.	121.29	ST elevation (STEMI) myocardial infarction involving other sites.
		122.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites.
410.61	True posterior wall infarction, initial episode of care.	121.29	ST elevation (STEMI) myocardial infarction involving other sites.
		122.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites.
410.71	Subendocardial infarction, initial episode of care	121.4	Non-ST elevation (NSTEMI) myocardial infarction.
		122.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction.
410.81	Acute myocardial infarction of other specified sites, initial episode of care.	121.21	ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery.
		121.29	ST elevation (STEMI) myocardial infarction involving other sites.
		122.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites.
410.91	Acute myocardial infarction of unspecified site, initial episode of care.	121.3	ST elevation (STEMI) myocardial infarction of unspecified site.
		122.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site.

The proposal for beginning AMI model episodes is included in § 512.240(a)(1). We seek comment on our proposal to begin AMI model episodes.

(3) Beginning CABG Model Episodes

We propose that, as long as a beneficiary meets the general beneficiary care inclusion criteria, a CABG model episode would begin with the admission of a Medicare beneficiary to an IPPS hospital for a CABG that is paid under the following CABG MS–DRGs and the specific MS–DRG is called the anchor MS–DRG for the episode:

- 231 (Coronary bypass with percutaneous transluminal coronary angioplasty (PTCA) with MCC).
- 232 (Coronary bypass with PTCA without MCC).
- 233 (Coronary bypass with cardiac catheterization with MCC).
- 234 (Coronary bypass with cardiac catheterization without MCC).
- 235 (Coronary bypass without cardiac catheterization with MCC).
- 236 (Coronary bypass without cardiac catheterization without MCC).

The proposal for beginning CABG episodes is included in § 512.240(b)(1). We seek comment on our proposal to begin CABG model episodes.

[48] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/HIQR-ICD9-to-ICD10-Tables.pdf.*

(4) Beginning SHFFT Episodes

We propose that as long as a beneficiary meets the general inclusion criteria, a SHFFT model episode would begin with the admission of a Medicare beneficiary to an IPPS hospital for surgical treatment of hip or femur fracture (other than joint replacement) that is paid under the following SHFFT MS–DRGs and where the specific MS–DRG is called the anchor MS–DRG for the episode:

- 480 (Hip and femur procedures except major joint with MCC).
- 481 (Hip and femur procedures except major joint with complication or comorbidity (CC).
- 482 (Hip and femur procedures except major joint without CC or MCC).

The proposal for beginning SHFFT model episodes is included in § 512.240(c)(1). We seek comment on our proposal to begin SHFFT model episodes.

(5) Special Policies for Hospital Transfers of Beneficiaries With AMI

The asymmetric distribution of cardiac care across hospitals makes transfer, either from an inpatient admission or from the emergency department (without inpatient admission) of one hospital to another, a common consideration in the treatment course for beneficiaries with an initial diagnosis of AMI. Therefore, transfer for cardiac care is an important consideration for the AMI and CABG models.

The availability of revascularization and intensive cardiac care are particularly important considerations in the transfer of beneficiaries with an AMI. A substantial portion of hospitals do not have revascularization capability (that is, a cardiac catheterization lab for PCI or cardiothoracic surgeons who can perform CABG) or cardiovascular intensive care units (CVICU) and, therefore, must transfer beneficiaries to provide access to these services. In the PCI and CABG examples, the discharge from the transfer hospital that accepted the beneficiary would result in discharge under the MS–DRGs for PCI (246–251) or CABG (231–236). For the CVICU example, the transfer hospital's discharge MS–DRG would be AMI (280–282). There is evidence of the asymmetric distribution of cardiac care in the 2014 IPPS and critical access hospital claims data: while 4,332 hospitals submitted at least one claim for an AMI MS–DRG, only 1,755 (41 percent) and 1,156 (27 percent) of these hospitals filed at least one claim for PCI or CABG MS–DRGs, respectively.[49]

The potential transfer scenarios are best illustrated by the care pathways experienced by beneficiaries with AMI. These beneficiaries typically present to a hospital's emergency department where the evaluation identifies the AMI diagnosis and determines the initial indicated treatments. Depending on the beneficiary's clinical needs and the hospital's treatment capacity, the beneficiary could be—

- Admitted to the initial treating hospital, with no transfer to another hospital during the initial hospitalization for AMI. We refer to this scenario as no transfer;
- Admitted to the initial treating hospital and later transferred to a transfer hospital. We refer to this scenario as inpatient-to-inpatient transfer and the transfer hospital as an i–i transfer hospital; or
- Transferred from the initial treating hospital to a transfer hospital without admission to the initial treating hospital. We refer to this scenario as outpatient-to-inpatient transfer and the transfer hospital as an o–i transfer hospital.

Our proposals and alternatives considered for these scenarios are described in detail in this section. In our proposals for AMI or CABG model episodes for initial AMI care, our overarching policy is that every AMI or CABG model episode would begin at the first AMI or CABG model participant to which the beneficiary is admitted for an AMI MS–DRG, PCI MS–DRG with an AMI ICD–CM diagnosis code, or CABG MS–DRG. The AMI or CABG model participant where the episode begins would then be financially responsible for the AMI or CABG model episode unless the episode is canceled.

Based on our analysis of Medicare claims data, about 75 percent of historical AMI episodes and CABG episodes for beneficiaries with AMI begin through the emergency department of the hospital where the anchor hospitalization for the AMI or CABG model episode would occur. In another 18 percent of historical AMI episodes and CABG episodes for beneficiaries with AMI, the anchor hospitalization occurs at a transfer hospital following an emergency department visit at another hospital without admission to that hospital for an MS–DRG that would initiate an AMI or CABG model episode.[50]

In each of these scenarios, policies to determine which episode type applies, the beginning of the episode, and the specific hospital with financial responsibility for the episode must be determined (for example, AMI or CABG, if CABG is provided as an initial treatment in an outpatient-to-inpatient or inpatient-to-inpatient scenario). In this section, we discuss each of the scenarios in detail and provide a summary of the scenarios in Table 4.

In the no transfer scenario, the episode would begin upon admission to an AMI or CABG model participant under circumstances that meet the criteria discussed in sections III.C.4.a.(1) and (2) or (3) of this proposed rule, and the AMI or CABG model episode that applies would be determined by the specific MS–DRG for the anchor hospitalization. Financial responsibility for the episode would be attributed to the sole treating hospital involved in the initial AMI care. Under this proposal, the treating hospital's quality measure performance would determine the effective discount factor to be applied to the AMI or CABG model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule.

The inpatient-to-inpatient transfer scenario has several potential outcomes. If the beneficiary initially presents for AMI care to a hospital that is not an AMI model participant and is admitted and then transferred to an i–i transfer hospital that is an AMI or CABG model participant, the episode would first initiate at the i–i transfer hospital and, therefore, the i–i transfer hospital would be financially responsible for the AMI or CABG model episode. The i–i transfer hospital's quality measure performance would determine the effective discount factor to be applied to the AMI or CABG model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule.

Conversely, if a beneficiary initially presents for AMI care to an AMI model participant and is admitted and then transferred to an i–i transfer hospital (hereinafter a chained anchor hospitalization) and the i–i transfer hospital is not an AMI or CABG model participant, the episode would initiate at the initial treating hospital and would only be canceled for beneficiaries discharged from the i–i transfer hospital

[49] AMI, CABG and PCI MS–DRG inpatient claims from all U.S. IPPS hospitals and CAHs derived from the 2014 Geographic Variations Inpatient Claims File located in the Chronic Conditions Warehouse.

[50] Episode for beneficiaries with AMI initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that end in CY 2014.

under MS–DRGs that are not anchor MS–DRGs for AMI or CABG model episodes is discussed in section III.C.4.b. of this proposed rule. The initial treating hospital's quality measure performance would determine the effective discount factor to be applied to the AMI or CABG model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule. We also refer to section III.D.4.b.(2)(a) of this proposed rule for further discussion of price MS–DRGs that may differ from the anchor MS–DRG in AMI model episodes that include a chained anchor hospitalization, in order to provide pricing adjustments for episodes where the initial treating hospital is responsible for the AMI model episode.

Inpatient-to-inpatient transfers between AMI and CABG model participant hospitals are further considered in this section and specifically include beneficiaries experiencing an AMI who are transferred for revascularization (that is, PCI or CABG) or a higher level of medical AMI care. We note that of all beneficiaries experiencing an AMI in historical episodes, about half received no revascularization (PCI or CABG) during the anchor hospitalization or the 90-day post-hospital discharge period, about 40 percent received a PCI, and less than 10 percent had CABG surgery.[51] Moreover, three-quarters of CABG procedures and over 90 percent of PCIs for beneficiaries experiencing an AMI occurred at the hospital that first admitted the beneficiary for an inpatient hospitalization.[52]

However, given the asymmetric distribution of cardiac care capacity there will be beneficiaries who initiate an AMI model episode by admission to an initial treating hospital but then require transfer to an i–i transfer hospital for additional treatment during the AMI model episode, resulting in a chained anchor hospitalization. For historical AMI episodes ending in CY 2014, only about 12 percent of beneficiaries who would have initiated an AMI model episode through admission and assignment to an AMI MS–DRG at the initial treating hospital were transferred to an i–i transfer hospital, with 30 percent and 20 percent receiving PCI or CABG, respectively, at the i–i transfer hospital. Another 20 percent were discharged from the i–i transfer hospital in the chained anchor hospitalization under an AMI MS–DRG. The remaining 30 percent of beneficiaries were discharged from the i–i transfer hospital in the chained anchor hospitalization under other MS–DRGs that would not have initiated AMI or CABG model episodes, including cardiac valve surgery, septicemia, and renal failure. From the perspective of hospital capacity and transfer patterns, most hospitals transferred less than 10 percent of beneficiaries initiating a historical AMI episode under an AMI MS–DRG at the first admitting hospital, and only a handful of hospitals transferred the majority of their patients in this scenario.[53] This small number of hospitals that transferred the majority of their patients includes a range of urban and rural hospitals with 50 to 250 beds.

The need to transfer a beneficiary in an AMI model episode during the anchor hospitalization for appropriate care that results in a chained anchor hospitalization where the hospitals are both AMI or CABG model participants raises considerations about whether attribution of the AMI model episode should be to the first treating hospital that admitted the beneficiary or the i–i transfer hospital, as well as considerations about the specific model (AMI or CABG) for attribution of the episode in some circumstances. For example, if the first treating hospital initiates an AMI model episode by admitting a beneficiary and then transfers the beneficiary to another hospital where the beneficiary is treated and ultimately discharged from acute care, ending the chained anchor hospitalization under a CABG MS–DRG, then we need to determine whether the beneficiary would be included in the AMI or CABG model, which hospital assumes financial responsibility for the beneficiary's episode, and under what circumstances, if any, would the AMI model episode be canceled if a transfer occurs.

In considering the model episode that includes the beneficiary's care and accountability for the beneficiary in inpatient-to-inpatient transfer scenarios between AMI and CABG model participant hospitals that result in a chained anchor hospitalization for AMI, several factors are relevant, including the timing of final discharge disposition of the beneficiary, including to post-acute care; the location of the post-acute care; the identity and location of the physician who is most responsible for managing the beneficiary's care after discharge; and consistency across other CMS transfer policies. We note that while 64 percent of CABG beneficiaries in historical episodes received post-acute care services following discharge from the anchor hospitalization (most commonly home health services—43 percent received home health services only and 13 percent a combination of home health and SNF services), only 36 percent of historical AMI beneficiaries received post-acute services.[54] Of further relevance for beneficiaries with an AMI diagnosis is that significant follow up care is usually performed by cardiologists who manage the patient's underlying cardiovascular disease, rather than the interventional cardiologist or cardiothoracic surgeon that perform the revascularization procedure. PCI procedures, billed by interventional cardiologists, have a 0-day global period, reflecting that follow up care is not typically furnished by interventional cardiologists. We further note that patients in commercial programs that require travel to regional centers of excellence for CABG generally only stay in the remote location away from the patient's home for a week or so post-hospital discharge. We expect that beneficiaries hospitalized for treatment of AMI, even if they are transferred to a revascularization hospital resulting in a chained anchor hospitalization, would receive most follow up care in their local communities, a view that was supported by many commenters on the CJR model proposed rule who asserted that many patients requiring post-acute care prefer to return to their home communities for that care following hospital discharge (80 FR 23457). Finally, consistency across other CMS program policies when a beneficiary with an AMI experiences an inpatient-to-inpatient transfer is relevant to developing policies for the proposed AMI and CABG models. Specifically, we note that the Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for AMI (NQF #2431) measure used in the hospital value-based purchasing (HVBP) Program attributes payments for transferred beneficiaries to the hospital that

[51] Episodes for beneficiaries with AMI initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, and that end in CY 2014.

[52] Episodes for beneficiaries with AMI initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, and that end in CY 2014.

[53] Episodes for AMI beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that end in CY 2014.

[54] Episodes for AMI and CABG beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that end in CY 2014.

admitted the patient for the initial AMI hospitalization.[55]

Based on these considerations, we propose that once an AMI model episode is initiated at an AMI model participant hospital through an inpatient hospitalization, the AMI model episode would continue under the financial responsibility of that participant hospital, regardless of whether the beneficiary is transferred to another AMI or CABG model participant hospital for further medical management of AMI, or for a PCI or CABG during a chained anchor hospitalization. Under this proposal, the initial treating hospital's quality measure performance would determine the effective discount factor to be applied to the AMI model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule. Our proposal to cancel AMI model episodes for beneficiaries discharged from the i–i transfer hospital under MS–DRGs that are not anchor MS–DRGs for AMI or CABG model episodes is discussed in section III.C.4.b. of this proposed rule. We also refer to section III.D.4.b.(2)(a) of this proposed rule for further discussion of price MS–DRGs that may differ from the anchor MS–DRG in AMI model episodes that include a chained anchor hospitalization, in order to provide pricing adjustments for episodes where the initial treating hospital is responsible for the AMI model episode.

We note that we do not propose to cancel the AMI model episode even if the transfer and admission to the i–i transfer hospital would otherwise initiate a CABG model episode at the i–i transfer hospital. We believe that once the AMI model episode has been initiated, all related care during the episode (including hospital care for transfers and related readmissions for CABG) should be fully attributed to the AMI model episode in the manner described in this section for the episode and that the first hospital that initiated the AMI model episode should be financially responsible for the AMI episode. Therefore, we do not propose to cancel the AMI model episode if a CABG is performed during a chained anchor hospitalization, nor do we propose that a beneficiary could simultaneously be in an AMI and CABG model episode for overlapping periods of time due to the different MS–DRGs that apply during the chained anchor hospitalization. Instead, we would make an AMI model episode pricing adjustment for these circumstances by paying the AMI model participant based on a price MS–DRG that is different from the anchor MS–DRG to reflect Medicare payment for the CABG as discussed in section III.D.4.b.(2)(a) of this proposed rule.

We considered several alternatives to our proposal for AMI model episode attribution for inpatient-to-inpatient transfer scenario where both hospitals are AMI or CABG model participants. First, we considered canceling the AMI model episode initiated at the initial treating hospital when a transfer occurs, and basing any AMI or CABG model episode initiation on the MS–DRG for the final i-i transfer hospital admission in the chained anchor hospitalization as long as that latter hospital is an AMI or CABG model participant. This would place financial responsibility for the episode on the i-i transfer hospital if the beneficiary goes on to be discharged from acute care at that hospital. Attributing episodes under this alternative policy would assign beneficiaries to the final i-i transfer hospital for the AMI or CABG model episode based on the model episode definitions in sections III.C.4.a.(2) and (3) of this proposed rule. That is, if the beneficiary is discharged from the final admission in the chained anchor hospitalization under an AMI MS–DRG or a PCI MS–DRG, then the AMI model episode initiated at the initial treating hospital would be canceled and the i-i transfer hospital accepting the beneficiary on referral would initiate an AMI model episode. Similarly, if the beneficiary is discharged from the final admission in the chained anchor hospitalization under a CABG MS–DRG, then the AMI model episode initiated at the first hospital would be canceled and the i-i transfer hospital accepting the beneficiary on referral would initiate a CABG model episode. Under this alternative, the i-i transfer hospital's quality measure performance would determine the effective discount factor to be applied to the AMI or CABG model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule. However, we do not propose this alternative because we believe that post-acute care and care management following hospital discharge are more likely to be effectively provided near the beneficiary's home community, rather than near the i-i transfer hospital accepting the beneficiary upon referral.

Second, we considered proposing an episode hierarchy such that, during a chained anchor hospitalization, the most resource-intensive MS–DRG during the whole chained anchor hospitalization would determine the model episode and the financially responsible hospital for the episode. For example, if we establish CABG, PCI, and AMI MS–DRGs in descending order of inpatient hospital resource-intensity, we would initiate a model episode based on the most resource-intensive MS–DRG during the chained anchor hospitalization and attribute the model episode to the hospital discharging the beneficiary under that MS–DRG. Under this scenario, either the initial treating or i-i transfer hospital's quality measure performance would determine the effective discount factor to be applied to the AMI or CABG model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule, depending on the specific hospital discharging the beneficiary under the most resource-intensive MS–DRG during the chained anchor hospitalization. However, we do not propose this alternative because we believe, like the first alternative we considered, this could frequently lead to episode responsibility being attributed to the i-i transfer hospital when the local hospital first caring for the beneficiary with AMI may be better positioned to coordinate care in the beneficiary's home community.

Thus, our proposal would place responsibility for care during the 90-day post-hospital discharge period in the AMI model episode on the AMI model participant hospital to which the beneficiary initially presented for AMI care and was admitted, rather than on the i-i transfer hospital to which the beneficiary was transferred after initiating the AMI model episode. Given the broad episode definition of AMI model episodes, we believe that the post-discharge care required following hospitalization that includes CABG, PCI, or medical management is best coordinated and managed by the hospital that originally admitted the beneficiary for the AMI. Such post-discharge care could include follow up for adherence to cardiac rehabilitation referral and management of the beneficiary's underlying CAD and comorbidities. Even in the case of the more common surgical complications of CABG, such as wound infection, the beneficiary commonly would be admitted to the local hospital for treatment.

We further propose that, as discussed in section III.I.3 of this proposed rule, hospitals may be collaborators in the AMI, CABG, and SHFFT models in order to increase the financial alignment of hospitals and other EPM collaborators with EPM participants that are

[55] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

financially responsible for EPM episodes. Therefore, we expect that community hospital participants in the AMI model would be able to enter into collaboration agreements with i-i transfer hospitals accepting AMI model beneficiaries on referral to allow sharing of episode reconciliation payments or repayment responsibility with the i-i transfer hospitals if those hospitals play a significant role in care redesign of AMI or CABG care pathways or management of beneficiaries throughout AMI or CABG model episodes, including during the 90 days post-hospital discharge. We expect that community hospitals would need to coordinate closely with i-i transfer hospitals accepting AMI model beneficiaries on referral as the beneficiaries in AMI model episodes are discharged from those hospitals, in order to improve the quality and efficiency of AMI model episodes. This coordination could potentially be enhanced if i-i transfer hospitals are AMI model collaborators with financial incentives that are aligned with those of the AMI model participants through sharing arrangements.

The proposal for AMI model episode attribution in circumstances that involve inpatient-to-inpatient transfers of beneficiaries with AMI is included in § 512.240(a)(2). We seek comment on our proposal for AMI model episode attribution in circumstances that involve inpatient-to-inpatient transfers of beneficiaries with AMI, including comment on the alternatives considered.

In the outpatient-to-inpatient transfer scenario where a beneficiary with AMI is transferred from the emergency department of the initial treating hospital without admission to that hospital as an inpatient to an o-i transfer hospital for admission, we propose that the AMI or CABG model episode would begin at the o-i transfer hospital based on the MS–DRG (and AMI ICD–CM diagnosis code if a PCI MS–DRG applies) that is assigned to that anchor hospitalization. That is, if a beneficiary receives initial AMI care in a hospital emergency department without admission and is transferred to an AMI or CABG model participant (the o-i transfer hospital) for admission, then the AMI or CABG model episode would begin in the first hospital involved in the beneficiary's AMI or CABG care that admits the beneficiary as an inpatient, specifically the o-i transfer hospital. Therefore, the o-i transfer hospital would be financially responsible for the AMI or CABG model episode. This proposed attribution is in accordance with the proposed AMI and CABG model rules, as discussed in sections III.C.4.a.(2) and (3) of this proposed rule, that initiate an AMI model episode with a hospitalization that results in discharge from an AMI MS–DRG or PCI MS–DRG with an AMI ICD–CM diagnosis code in the principal or secondary position from an AMI model participant or a CABG model episode with a hospitalization that results in discharge from a CABG MS–DRG. Under this proposal, the o-i transfer hospital's quality measure performance would determine the effective discount factor to be applied to the AMI or CABG model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule. Under this proposal, regardless of whether the initial treating hospital is an AMI or CABG model participant, an AMI or CABG model episode would only be initiated at the o-i transfer hospital if that hospital is an AMI or CABG model participant.

We considered an overarching alternative policy that would begin every AMI or CABG model episode at the first AMI or CABG model participant at which either:

- The beneficiary presented to the emergency department for initial AMI care before being transferred to an o-i transfer hospital; or
- The beneficiary was admitted for an AMI MS–DRG, PCI MS–DRG with an AMI ICD–CM diagnosis code, or a CABG MS–DRG.

The AMI or CABG model participant where the episode begins would then be financially responsible for the AMI or CABG model episode unless the episode is canceled. Under this alternative, there would no changes to our proposals for attributing episodes with no transfers or inpatient-to-inpatient transfers.

However, under this alternative, if the beneficiary presented for initial AMI care to the emergency department of an AMI or CABG model participant, the AMI or CABG model episode would begin at this initial treating hospital when a beneficiary is transferred from the emergency department for his or her first inpatient hospitalization which occurs at an o–i transfer hospital. This would place financial responsibility for the AMI or CABG model episode on the initial treating hospital despite the fact that the beneficiary was transferred from that hospital without being admitted, and the initial treating hospital's quality measure performance would determine the effective discount factor to be applied to the AMI or CABG model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule.

Identifying the emergency department visit at the initial treating hospital would require using Field (Form Locator) 15—Point of Origin for Admission or Visit code on the CMS 1450 IPPS claim from the o–i transfer hospital to identify transfer from another hospital and linking that claim to the hospital outpatient claims from the initial treating hospital for the emergency department visit and other hospital outpatient services that occurred within a certain period of time prior to the o–i transfer hospital admission and that are related to the AMI care. The episode would be assigned to the AMI model even if the beneficiary received a CABG at the o–i transfer hospital, and we would assign financial responsibility for the AMI model episode to the initial treating hospital. Under this alternative, the initial treating hospital's quality measure performance would determine the effective discount factor to be applied to the AMI model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule. We would also need to identify other types of related services to include in the episode that would begin prior to the o–i transfer hospital admission, such as physicians' services for care in the emergency department.

This alternative would have the benefit of consistently including all care in each AMI or CABG model episode that occurs following presentation of a beneficiary with AMI to the emergency department of an AMI or CABG model participant in the AMI or CABG model episode, regardless of whether an AMI or CABG model episode involves no transfer, o–i transfer, or i–i transfer. However, because this alternative would begin the AMI model episode prior to the initial hospital admission, we would need to establish additional policies for identifying the beneficiaries who initiate these episodes and define the timeframe and services that would be included in the AMI or CABG model episode prior to admission to the o–i transfer hospital.

We do not propose this alternative because we believe the policies necessary to begin the AMI or CABG model episode at the first treating hospital when an inpatient hospitalization does not occur would be complex, challenging to operationalize, and require assumptions about the relationship of care to the AMI based solely on administrative claims data that are insufficient to ensure we can accurately identify related care. We believe it remains problematic to define the services to be included in AMI or CABG model episodes if those services precede an inpatient hospitalization that

would otherwise initiate the AMI or CABG model episode. For example, we would need to define the timeframe for beginning an AMI or CABG model episode with an emergency department visit for AMI that results in a transfer to the o–i transfer hospital, as well as the Part A and Part B services to be included in the AMI or CABG model episode that would result. As we discuss in section III.C.4.a.(1) of this proposed rule, we do not propose to begin any EPM episode prior to the anchor hospitalization because of the clinical variability leading up to all EPM episodes and the challenge of identifying unrelated services prior to the inpatient hospitalization. Thus, we do not propose to make an exception for transfers from the emergency department of the initial treating AMI or CABG model participant hospital when the beneficiary with AMI is not admitted to that hospital.

We seek comment on the proposal for AMI and CABG model episode initiation and attribution for the outpatient-to-inpatient transfer scenario, as well as the alternative considered that would begin an episode upon presentation of a beneficiary for initial AMI care to the emergency department of an AMI or CABG model participant when the care results in an outpatient-to-inpatient transfer.

Table 4 provides a summary of our proposals for episode initiation and attribution at the beginning of AMI care for no transfer, inpatient-to-inpatient transfer, and outpatient-to-inpatient transfer scenarios, including a description of how these relate to the participation in the AMI or CABG models of hospitals providing initial AMI care.

TABLE 4—PROPOSED INITIATION AND ATTRIBUTION OF AMI AND CABG MODEL EPISODES THAT INVOLVE NO TRANSFER, OR OUTPATIENT-TO-INPATIENT OR INPATIENT-TO-INPATIENT TRANSFERS AT THE BEGINNING OF AMI CARE

Scenario	Episode initiation and attribution
No transfer (participant): Beneficiary admitted to an initial treating hospital that is a participant in the AMI or CABG model for an AMI MS–DRG, PCI MS–DRG with AMI ICD–CM diagnosis code, or CABG MS–DRG.	Initiate AMI or CABG model episode based on anchor hospitalization MS–DRG. Attribute episode to the initial treating hospital.
No transfer (nonparticipant): Beneficiary admitted to an initial treating hospital that is not a participant in the AMI or CABG model for an AMI MS–DRG, PCI MS–DRG with AMI ICD–CM diagnosis code, or CABG MS–DRG.	No AMI or CABG model episode is initiated.
Inpatient-to-inpatient transfer (nonparticipant to participant): Beneficiary admitted to an initial treating hospital that is not an AMI or CABG model participant and later transferred to an i–i transfer hospital that is an AMI or CABG model participant for an AMI MS–DRG, PCI MS–DRG with AMI ICD–CM diagnosis code, or CABG MS–DRG.	Initiate AMI or CABG model episode based on the MS–DRG at i–i transfer hospital. Attribute episode to the i–i transfer hospital.
Inpatient-to-inpatient transfer (participant to participant or participant to nonparticipant): Beneficiary admitted to an initial treating hospital that is an AMI or CABG model participant for an AMI MS–DRG, PCI MS–DRG with AMI ICD–CM diagnosis code, or CABG MS–DRG and later transferred to an i–i transfer hospital for an AMI, PCI, or CABG MS–DRG, regardless of whether the i–i transfer hospital is an AMI or CABG model participant.	Initiate AMI or CABG model episode based on anchor hospitalization MS–DRG at initial treating hospital. If the chained anchor hospitalization results in a final AMI, PCI, or CABG MS–DRG, calculate episode benchmark price based on the AMI, PCI or CABG MS–DRG with the highest IPPS weight. If the final MS–DRG is not an AMI, PCI, or CABG MS–DRG, cancel the episode. Attribute episode to the initial treating hospital.
Outpatient-to-inpatient transfer (nonparticipant to participant or participant to participant): Beneficiary transferred without admission from the initial treating hospital, regardless of whether the initial treating hospital is an AMI or CABG model participant, to a o–i transfer hospital that is an AMI or CABG model participant and is discharged from the o–i transfer hospital for an AMI MS–DRG, PCI MS–DRG with AMI ICD–CM diagnosis code, or CABG MS–DRG.	Initiate AMI or CABG model episode based on anchor hospitalization MS–DRG at o–i transfer hospital. Attribute episode to the o–i transfer hospital.
Outpatient-to-inpatient transfer (participant to nonparticipant): Beneficiary transferred without admission from the initial treating hospital that is an AMI or CABG participant to an o–i transfer hospital that is not an AMI or CABG model participant.	No AMI or CABG model episode is initiated.

b. Middle of EPM Episodes

Similar to the CJR model, we propose that once an EPM episode begins, it would continue until the end of the episode as described in the following section, unless certain circumstances arise during the episode (80 FR 73318). When an EPM episode is canceled, we propose that the services furnished to beneficiaries prior to and following the EPM episode cancellation would continue to be paid by Medicare as usual but there would be no actual EPM episode spending calculation that would be reconciled against the EPM quality-adjusted target price.

Specifically, we propose that the following circumstances occurring during an EPM episode would cancel the EPM episode:

- The beneficiary ceases to meet any of the general beneficiary inclusion criteria described in section III.C.4.a.(1) of this proposed rule, except the three criteria regarding inclusion in other episode payment model episodes.
- The beneficiary dies during the anchor hospitalization.
- The beneficiary initiates any BPCI model episode.

For purposes of cancellation of EPM episodes for beneficiary overlap with other episode payment models, we propose that if a beneficiary in an EPM episode would initiate any BPCI model episode, the EPM episode would be canceled. We refer to section III.D.6.c.(1) of this proposed rule for further discussion of our proposals addressing potential overlap of beneficiaries in the proposed EPMs with BPCI. We also refer to section III.D.6.c.(3) of this proposed rule for discussion of our proposal to cancel EPM episodes for beneficiaries who become aligned with specified ACOs during EPM episodes.

Our proposal to only cancel the EPM episode if a beneficiary dies during the anchor hospitalization differs from the final CJR model policy that cancels an

episode if a beneficiary dies any time during the episode (80 FR 73318). As discussed in the CJR model Final Rule for LEJR episode, we believe that it also would be appropriate to cancel an episode in the AMI, CABG, and SHFFT models when a beneficiary dies during the anchor hospitalization as there would be limited incentives for efficiency that could be expected during the anchor hospitalization itself (80 FR 73318). We agreed with commenters on the CJR model proposed rule that we should cancel CJR model episodes for death any time during those episodes, because beneficiary deaths following LEJR would be uncommon and expected to vary unpredictably, leading to extremely high or low episode spending that was not typical for a LEJR episode. A recent analysis that pooled results from 32 studies showed the incidence of mortality during the first 30 and 90 days following hip replacement to be 0.30 percent and 0.65 percent, respectively, confirming our expectation of low mortality rates during LEJR episodes.[56] In contrast, the 30-day national CABG and AMI mortality rates as displayed on Hospital Compare are significantly higher at approximately 3 percent and 14 percent respectively.[57] Several CMS programs use 30-day mortality measures for CABG and AMI as measures of hospital quality, and these measures are proposed for use in the pay-for-performance methodology for the CABG and AMI models as discussed in section III.E.3.f. of this proposed rule. Similarly, a 2009 study shows a 30-day hip fracture mortality rate for Medicare beneficiaries of approximately 5 percent, significantly higher than the mortality rate following LEJR procedures.[58] Thus, we would expect that deaths during SHFFT model episodes would be more common than in CJR model episodes. Because beneficiaries in AMI, CABG, and SHFFT model episodes are at significant risk of death during these episodes that extends 90 days post-hospital discharge, we consider mortality to be a harmful beneficiary outcome that should be targeted for improvement through care redesign incentivized by the EPMs for these clinical conditions. Therefore, we do not believe it would be appropriate to exclude beneficiaries from AMI, CABG, or SHFFT model episodes who die any time during the episode like we do in the CJR model. Instead, we propose to maintain beneficiary episodes in the EPMs even if death occurs during the episodes, meaning we would calculate actual EPM episode spending when beneficiaries die following discharge from the anchor hospitalization but within the 90-day post-hospital discharge episode duration and reconcile it against the quality-adjusted target price. We believe this proposal would encourage EPM participants to actively manage EPM beneficiaries to reduce their risk of death, especially as death is often preceded by expensive care for emergencies and complications. Because of the higher mortality rates for all of the proposed EPM episodes than for LEJR episodes in the CJR model, we do not consider mortality following hospital discharge to be atypical and, therefore, we propose to cancel EPM episodes only for death during the anchor hospitalization.

We further propose that the following circumstances also would cancel an AMI model episode in the circumstances of a chained anchor hospitalization when the beneficiary is discharged from acute care under an MS–DRG from the final transfer hospital in the chained anchor hospitalization that could not, itself, initiate an AMI or CABG model episode, regardless of whether the final transfer hospital is an AMI or CABG model participant (that is, the episode would be canceled if the final transfer hospital MS–DRG is any MS–DRG other than an AMI MS–DRG, PCI MS–DRG, or CABG MS–DRG);

While we would begin an AMI model episode with the first hospitalization in the chained anchor hospitalization that would initiate an episode as discussed in section III.C.4.a.(5) of this proposed rule, we understand that a variety of types of care at i–i transfer hospitals could occur following the discharge from the hospital that began the AMI model episode during the chained anchor hospitalization, most commonly further medical management of AMI and revascularization that could be appropriately included in the AMI model episode. We further note that less than 0.2 percent of beneficiaries in historical AMI episodes have more than one inpatient-to-inpatient transfer during the chained anchor hospitalization.[59] However, in some cases transfer to another hospital during an AMI episode could result in a final i–i transfer hospital MS–DRG for care that would not itself have initiated an AMI (or CABG) model episode if all inpatient hospital care were furnished at a single hospital. For example, a beneficiary in an AMI model episode could be transferred to another hospital where the beneficiary undergoes cardiac valve surgery or treatment for renal failure or stroke. In some of these cases, further treatment at the i–i transfer hospital could be due to potentially avoidable complications resulting from insufficient care management during the AMI model episode that is initiated at the first hospital. In other cases the care at the i–i transfer hospital could be unavoidable and clinically appropriate, resulting from the beneficiary's evolving AMI or other associated chronic conditions and the specific capabilities of the hospital that initiated the AMI model episode. Therefore, we believe it would be most appropriate to cancel AMI model episodes under the circumstances when a beneficiary in an AMI model episode is discharged from acute care under an MS–DRG from the final i–i transfer hospital in the chained anchor hospitalization that is not an AMI, PCI, or CABG MS–DRG that could initiate an AMI or CABG model episode (that is, the episode would be canceled if the final transfer hospitalization MS–DRG is any MS–DRG other than an AMI, PCI, or CABG MS–DRG). We note that we would not require an AMI ICD–10–CM diagnosis code on all claims in a chained anchor hospitalization for a beneficiary in an AMI model episode in order to provide to an adjusted payment at the price MS–DRG for the AMI model episode as discussed in section III.D.4.b.(2)(a) of this proposed rule. We also would not cancel the AMI model episode if an AMI ICD–10–CM diagnosis code is not on the claim for the final transfer hospitalization, as long as the discharge is under an AMI, PCI, or CABG MS–DRG. Because the beneficiary would be in an AMI model episode during a chained anchor hospitalization, we would treat the beneficiary who is transferred to an i–i transfer hospital according to all policies that apply to the diagnosis of AMI in the CABG and AMI models, regardless of whether an AMI ICD–10–CM diagnosis code was on the PCI or CABG MS–DRG claim from the final i–i transfer hospital. Overall, this proposal would treat the hospital that initiated the AMI model episode and then transferred the beneficiary most similarly to a hospital that furnished all of the beneficiary's inpatient care itself,

[56] Berstock JR, Beswick AD, Lenguerrand E, Whitehouse MR, Blom AW. Mortality after total hip replacement surgery: A systematic review. Bone & Joint Research. 2014; 3(6):175–182. doi:10.1302/2046–3758.36.2000239.

[57] *https://www.medicare.gov/hospitalcompare/search.html.*

[58] Brauer CA, Coca-Perraillon M, Cutler DM, Rosen AB. Incidence and Mortality of Hip Fractures in the United States. JAMA. 2009;302(14):1573–1579. doi:10.1001/jama.2009.1462.

[59] Episodes for AMI beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that end in CY 2014.

with respect to whether or not the beneficiary's care is ultimately included as an episode in the AMI model.

Finally, we do not propose to cancel an AMI episode altogether for a CABG readmission during the 90-day post-hospital discharge period or cancel the AMI model episode and initiate a CABG model episode because planned CABG readmission following an anchor hospitalization that initiates an AMI model episode may be an appropriate clinical pathway for certain beneficiaries. Instead, we propose to provide an adjusted AMI model-episode benchmark price that includes a CABG readmission in such circumstances so as not to financially penalize participant hospitals for relatively uncommon, costly, clinically appropriate care patterns for beneficiaries in AMI model episodes. We refer to section III.D.4.b.(2)(c) of this proposed rule for discussion of the adjusted AMI model-episode benchmark price that would apply in the case of CABG readmission during an AMI model episode.

The proposals for cancellation of EPM episodes are included in § 512.240(a)(3), (b)(2), and (c)(2). We seek comment on our proposals for cancellation of EPM episodes.

c. End of EPM Episodes

(1) AMI and CABG Models

We propose a 90-day post-hospital discharge episode duration for AMI model episodes. AMI in general, whether managed medically or with revascularization, has a lengthy recovery period, during which the beneficiary has a higher than average risk of additional cardiac events and other complications, as well as higher utilization of diagnostic testing and related cardiac procedures. AMI frequently serves as a sentinel event that marks the need for a heightened focus on medical management of coronary artery disease and other beneficiary risk factors for future cardiac events, cardiac rehabilitation over multiple months, and beneficiary education and engagement. Given the broad episode definition for AMI model episodes that includes beneficiaries receiving both medical and PCI management for an acute event, we do not believe that an episode longer than 90 days would be feasible due to the higher risk of including unrelated services in the episode beyond several months after hospital discharge. However, we believe that 90-day post-hospital discharge episodes would provide substantial incentives for aggressive medical management, cardiac rehabilitation, and beneficiary education and engagement, whereas a shorter episode duration would have less effect. We acknowledge that ongoing disease management for beneficiaries with cardiovascular disease must extend long after the conclusion of the proposed AMI model episodes. Nevertheless, we believe the proposed 90-day post-hospital discharge episode duration remains appropriate for an episode payment model focused around a hospitalization. We expect that the medical management and care coordination during AMI model episodes would continue to be provided as beneficiaries transition out of AMI model episodes, potentially into a primary care medical home or other model or program with accountability for population health, such as an ACO.

We further note based on analysis of historical episodes that about 10 percent of beneficiaries hospitalized with AMI who received a CABG received the CABG between 2 and 90 days post-discharge from the anchor hospitalization (these beneficiaries would be in AMI model episodes), while the remaining 90 percent of CABGs for beneficiaries hospitalized with AMI were provided during the initial hospitalization (these beneficiaries would in CABG model episodes). In contrast, fewer than 3 percent of those AMI model beneficiaries who received an inpatient or outpatient PCI during an AMI model episode received the PCI between 2 and 90 days post-discharge from the anchor hospitalization, while more than 97 percent received the PCI during the anchor hospitalization.[60] We refer to section III.D.4.b.(2)(c) of this proposed rule for further discussion of pricing adjustments and alternatives considered for setting EPM-episode benchmark prices for AMI model episodes where PCI or CABG occurs during the AMI episode but post-discharge from the anchor or chained anchor hospitalization.

Finally, for similar reasons, we believe CABG model episodes should extend 90 days post-hospital discharge. About one-third of CABG procedures are performed in the context of a hospital admission for AMI, leading to the same considerations discussed previously in this section around the appropriate episode duration for beneficiaries with AMI. The remaining CABG model beneficiaries are likely to have significant ischemic heart disease, making the occurrence of CABG itself a sentinel event, like AMI, that marks the need for a heightened focus on medical management of CAD and other beneficiary risk factors for future cardiac events, cardiac rehabilitation over multiple months, and beneficiary education and engagement. Moreover, CABG procedures have 90-day global periods under the Physician Fee Schedule, consistent with the lengthy period of recovery associated with major chest surgery. Thus, a 90-day post-hospital discharge episode duration is consistent with the recovery period from CABG surgery. We acknowledge that ongoing disease management for beneficiaries with cardiovascular disease must extend long after the conclusion of the proposed CABG model episodes. Nevertheless, we believe the proposed 90-day post-hospital discharge episode duration remains appropriate for an episode payment model focused around a hospitalization. We expect that the medical management and care coordination during CABG model episodes would continue to be provided as beneficiaries transition out of CABG model episodes, potentially into a primary care medical home or other model or program with accountability for population health, such as an ACO.

As in the CJR model, we propose that the day of discharge from the anchor hospitalization counts as day 1 of the post-hospital discharge period (80 FR 73324). However, in the case of an AMI model episode that includes a chained anchor hospitalization, we would count the day of discharge from the final hospitalization in the chained anchor hospitalization as day 1 of the post-hospital discharge period. Since the post-hospital discharge period is intended to extend 90 days for recovery following hospital discharge, we believe it is appropriate under these circumstances to begin the 90-day count when the beneficiary is ultimately discharged from acute care for the first time during the AMI model episode. However, the hospital that initiated the AMI model episode in the chained anchor hospitalization would continue to be responsible in the AMI model for the episode discussed previously in section III.C.4.a.(5) of this proposed rule.

The proposals for the end of AMI and CABG model episodes are included in §§ 512.240(a)(1) and (b)(1), respectively. We seek comment on our proposals to end AMI and CABG model episodes.

(2) SHFFT Model

We believe that SHFFT model beneficiaries are similar to CJR model beneficiaries who undergo hip replacement for fracture. We believe

[60] Episodes for AMI beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that end in CY 2014.

that the same episode duration as the CJR model of 90 days is appropriate for SHFFT model episodes in order to include the full time for recovery of function for these beneficiaries, which extends beyond 60 days based on patterns of post-acute care provider use (80 FR 73319 through 73324). Therefore, we propose a 90-day post-hospital discharge duration for SHFFT model episodes.

The proposal for the end of SHFFT model episodes are included in § 512.240(c)(1). We seek comment on our proposal to end SHFFT model episodes.

III. Provisions of the Proposed Regulations

D. Methodology for Setting EPM Episode Prices and Paying EPM Participants in the AMI, CABG, and SHFFT Models

1. Background

a. Overview

We propose that the AMI, CABG, and SHFFT models would provide incentives for EPM participants to work with other health care providers and suppliers to improve the quality and efficiency of care for Medicare beneficiaries by paying EPM participants or holding them responsible for repaying Medicare based on EPM participants' performance with respect to the quality and spending for AMI, CABG, and SHFFT episodes in a manner similar to the CJR model. Given the general similarity between the design of the CJR model and these EPMs, there is precedent for adopting the general payment and pricing parameters used under the CJR model, with modification to appropriately pay for EPM episodes that include the different clinical conditions treated in AMI, CABG, and SHFFT model episodes. The following sections describe our proposals for the:

- Performance year, retrospective episode payments, and two-sided risk EPMs.
- Adjustments to actual EPM-episode payments and to historical episode payments used to set episode prices.
- EPM episode price-setting methodologies.
- Process for reconciliation.
- Adjustments for overlaps with other Innovation Center models and CMS programs.
- Limits or adjustments to EPM participants' financial responsibility.

b. Key Terms for EPM Episode Pricing and Payment

For purposes of ease of understanding of the technical discussion that follows around EPM episode pricing and payment, we are providing the following definitions of terms that are used in sections that precede their technical definition and cross-references to other sections of this proposed rule for more detailed discussion of the policies associated with these terms.

- Anchor hospitalization—hospitalization that initiates an EPM episode and has no subsequent inpatient-to-inpatient transfer chained anchor hospitalization.
- Chained anchor hospitalization—an anchor hospitalization that initiates an AMI model episode and has at least one subsequent inpatient-to-inpatient transfer.
- Anchor MS–DRG—MS–DRG assigned to the first hospitalization discharge, which initiates an EPM episode.
- Price MS–DRG—for EPM episodes without a chained anchor hospitalization, the price MS–DRG is the anchor MS–DRG. For AMI model episodes with a chained anchor hospitalization, the price MS–DRG is the MS–DRG assigned to the AMI model episode according to the hierarchy described in III.D.4.b.(2)(i).
- Episode benchmark price—dollar amount assigned to EPM episodes based on historical EPM-episode data (3 years of historical Medicare payment data grouped into EPM episodes according to the EPM episode definitions as discussed in sections III.C.3. and III.C.4. of this proposed rule) prior to the application of the effective discount factor, as described throughout sections III.D.4.b through e. of this proposed rule.
- CABG readmission AMI model episode benchmark price—episode benchmark price assigned to certain AMI model episodes with price MS–DRG 280–282 or 246–251 and with a readmission for MS–DRG 231–236, as described in sections III.D.4.b.(2)(c) and III.D.4.e. of this proposed rule.
- Quality-adjusted target price—dollar amount assigned to EPM episodes as the result of reducing the episode benchmark price by the EPM participant's effective discount factor based on the EPM participant's quality performance, as described in sections III.D.4.b.(10) and III.E.3.f. of this proposed rule.
- Excess EPM-episode spending—dollar amount corresponding to the amount by which actual EPM-episode payments for all EPM episodes attributed to an EPM participant exceed the quality-adjusted target prices for the same EPM episodes, as discussed in section III.D.2.c. of this proposed rule.

2. Performance Years, Retrospective Episode Payments, and Two-Sided Risk EPMs

a. Performance Period

Consistent with the methodology for the CJR model, we propose 5 performance years (PYs) for the EPMs, which would include EPM episodes for the periods displayed in the following Table 5:

TABLE 5—PERFORMANCE YEARS FOR EPMS

Performance year (PY)	Calendar year	EPM episodes included in performance year
1	2017	EPM episodes that start on or after July 1, 2017 and end on or before December 31, 2017.
2	2018	EPM episodes that end between January 1, 2018 and December 31, 2018, inclusive.
3	2019	EPM episodes that end between January 1, 2019 and December 31, 2019, inclusive.
4	2020	EPM episodes that end between January 1, 2020 and December 31, 2020, inclusive.
5	2021	EPM episodes that end between January 1, 2021 and December 31, 2021, inclusive.

As displayed in Table 5, some EPM episodes that would begin in a given calendar year may be captured in the following performance year due to some EPM episodes ending after December 31st of a given calendar year. For example, EPM episodes beginning in December 2017 and ending in March 2018 would be part of performance year 2. We believe that the proposed period of time for the EPMs, which generally aligns with the performance period for other Innovation Center models, for example, the CJR and Pioneer ACO models, should be sufficient to test and gather the data needed to evaluate the EPMs (80 FR 73325). In contrast, we would be concerned whether an EPM with fewer than 5 performance years would be sufficient for these purposes.

We also recognize that our proposal would allow only 6 months of EPM episodes for PY1 as compared to 9 months for the CJR model. We considered extending the first PY, for example, to 18 months. As discussed further in section III.D.2.c. of this proposed rule, however, we are instead proposing to delay the requirement for participants to begin accepting downside risk until the second quarter of PY2. As such, EPM participants would have a comparable transition period to that of CJR participants with respect to when they must accept downside risk while still allowing us to make timely reconciliation payments to EPM participants as well as to most effectively align EPM reconciliation with the reconciliation processes for other models and programs with which the EPMs overlap (for example, the Shared Savings Program, Pioneer ACO model, Comprehensive Primary Care Initiative, and Oncology Care Model). We believe that it is important to synchronize the timing of reconciliation for EPMs with other efforts that need this information when making their financial calculations. We seek comment on this proposal.

b. Retrospective Payment Methodology

Consistent with the CJR model, we propose to apply a retrospective payment methodology to the proposed EPMs (80 FR 73329). Under this proposal, all providers and suppliers caring for Medicare beneficiaries in EPM episodes would continue to bill and be paid as usual under the applicable Medicare payment systems. After the completion of an EPM performance year, Medicare claims for services furnished to EPM beneficiaries would be grouped into EPM episodes and aggregated, and EPM participants' actual EPM episode-payments compared to quality-adjusted target prices (which account for the level of EPM episode quality), as described in section III.D.5.a. of this proposed rule. Based on an EPM participant's performance (taking into account quality and spending), we would determine if Medicare would make a payment to the participant (reconciliation payment), or if the participant owes money to Medicare (resulting in Medicare repayment).

We considered an alternative option of paying for EPM episodes prospectively by paying one lump sum amount to the EPM participant for the expected spending for the EPM episode which extends 90 days post-hospital-discharge. However, as was the case when we established regulations for the CJR model, we continue to believe that such an option would be challenging to implement at this time given the payment infrastructure changes for both EPM participants and Medicare that would need to be developed to pay and manage prospective episode payments under these EPMs (80 FR 73329). Moreover, we continue to believe that a retrospective payment approach can accomplish the objective of testing episode payments 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.

We seek comment on this proposal.

c. Two-Sided Risk EPMs

As we did for the CJR model, we propose to establish two-sided risk for hospitals participating in the EPMs. Under this proposal, for each of performance years 1 through 5, we would make EPM-episode reconciliation payments to EPM participants that achieve reduced actual EPM payments relative to their quality-adjusted target prices (80 FR 73229–7333). Likewise, beginning with episodes ending in the second quarter of performance year 2 and extending through each of performance years 3 through 5, we would hold EPM participants responsible for repaying Medicare when their actual EPM-episode payments exceed their quality-adjusted target prices. As such, our proposal differs from CJR in that we are proposing a modestly shorter period in which EPM participants would accept downside risk in order to allow them a comparable transition period to that of CJR participants in which to do so. Accordingly, we will refer to the two portions of performance year 2 as—

- Performance Year 2 (NDR) or PY2 (NDR) for the first quarter, that is January 1, 2018 to March 31, 2018, in which EPM participants assume no downside risk and therefore would have no Medicare repayment responsibility; and
- Performance Year 2 (DR) or PY2 (DR) for the second, third and fourth quarters, that is April 1, 2018 to December 31, 2018, in which EPM participants assume downside risk and would have Medicare repayment responsibility. We believe that our proposal to establish two-sided risk would provide appropriate incentives for EPM participants to improve their care quality and efficiency under the EPMs. We also continue to believe, as we indicated in the CJR Final Rule, that we would diminish these incentives if we instead proposed to establish one-sided risk, in which an EPM participant could qualify for a reconciliation payment but not be held responsible for Medicare repayments (80 FR 73329). In recognition that EPM participants may need to make infrastructure, care coordination and delivery, and financial preparations for the EPMs, which can take several months or longer to implement, we do believe that it is reasonable to delay EPM participant responsibility for repaying excess EPM-episode spending in performance year 1 to more strongly align EPM-participant incentives with care quality. Thus, similar to what we did for the CJR model, we are proposing to phase-in this repayment responsibility beginning in the second quarter of EPM performance year 2 as displayed in Table 6.

We refer to section III.E.3.f. of this proposed rule for additional information on the effective discount factors used to calculate quality-adjusted target prices, as well as the quality categories that determine an EPM participant's effective discount factor that would be applied to the EPM benchmark episode price at reconciliation to calculate the repayment amount during the phase-in period in EPM performance year 2 (quarters 2 through 4) and performance year 3. Table 6 also presents the phase-in of the proposed stop-loss limits and discount percentages, which are discussed in detail in section III.D.7.b. and III.D.4.b.(10) of this proposed rule.

We seek comment on this proposal.

TABLE 6—STOP-LOSS THRESHOLDS AND DISCOUNT PERCENTAGE RANGES FOR MEDICARE REPAYMENTS BY PY

	PY1	PY2 (NDR)	PY2 (DR) %	PY3 %	PY4 %	PY5 %
Stop-loss threshold	n/a as no downside risk in PY1 and PY2 (DR)		5	10	20	20

TABLE 6—STOP-LOSS THRESHOLDS AND DISCOUNT PERCENTAGE RANGES FOR MEDICARE REPAYMENTS BY PY—Continued

	PY1	PY2 (NDR)	PY2 (DR) %	PY3 %	PY4 %	PY5 %
Discount percentage (range) for Repayment, Depending on Quality Category			0.5–2.0	0.5–2.0	1.5–3.0	1.5–3.0

* Stop-loss thresholds for certain hospitals, including rural and sole-community hospitals are 3% for PY2 (DR) and 5% for PY3–PY5.

3. Adjustments to Actual EPM-Episode Payments and to Historical Episode Payments Used to Set Episode Prices

a. Overview

We propose to calculate actual EPM-episode payments and historical episode payments (3 years of historical Medicare payment data grouped into EPM episodes according to the EPM episode definitions as discussed in sections III.C.3. and III.C.4. of this proposed rule) to calculate EPM quality-adjusted target prices for each performance year of the EPMs as we did for the CJR model—that is, for each non-cancelled EPM episode, we would calculate these amounts based on Medicare payments for Parts A and B claims for services included in the EPM episode definition. As was the case for the CJR model, we also propose to include certain payment adjustments in the EPMs for: (1) Special payment provisions under existing Medicare payment systems; (2) payments for services that straddle episodes; and (3) high payment episodes (80 FR 73330 through 73336). We also propose to additionally include an adjustment for reconciliation payments and Medicare repayments when updating EPM participant episode benchmark and quality-adjusted target prices (80 FR 73330 through 73331). We refer to section III.D.6. of this proposed rule for discussion of adjustments for overlaps with other Innovation Center models and CMS programs.

b. Special Payment Provisions

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 HVBP Program, the Hospital-Acquired Condition (HAC) Reduction Program, and the HIQR Program and Outpatient Quality Reporting (OQR) Program. IPPS hospitals and CAHs are subject to the Medicare Electronic Health Record (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 certain requirements related to low volume Medicare discharges and distance from another hospital receive a low volume add-on payment. Also, some IPPS hospitals qualify to be sole community hospitals (SCHs) or Medicare Dependent Hospitals (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 post-acute care 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: Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP); Skilled Nursing Facility Quality Reporting Program (SNF QRP); Inpatient Psychiatric Facility Quality Reporting Program (IPF QRP); Home Health Quality Reporting Program (HH QRP); Long-Term Care Hospital Quality Reporting Program (LTCH QRP); and 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.

Ambulatory Surgical Centers (ASCs) have their own Quality Reporting Program (ASC QRP). Physicians also have a set of special payment provisions based on quality and reporting: Medicare EHR Incentive Program for Eligible Professionals; Physician Quality Reporting System (PQRS); and Physician Value-based Modifier Program.

Consistent with how we determine payments under the CJR model, we propose to adjust both the actual and historical EPM-episode payments used to set EPM-episode benchmark and quality-adjusted target prices by excluding these special payments from EPM-episode calculations using the CMS Price Standardization methodology (80 FR 73333). We believe that in applying this methodology to exclude these payments from our calculations, we would best maintain appropriate incentives for both the proposed EPMs and the existing incentive programs. Also, not excluding add-on payments based on the characteristics of providers caring for EPM beneficiaries, such as more indigent patients, having low Medicare hospital volume, being located in a rural area, supporting greater levels of physician training, and having a greater proportion of beneficiaries with HIV, from actual EPM-episode payments could inappropriately result in certain EPM participants that receive more add-on payments having worse episode payment performance compared to quality-adjusted target prices than what their performance would otherwise have been. Additionally, not excluding enhanced payments for MDHs and SCHs could result in higher or lower quality-adjusted target prices just because EPM participants received their enhanced payments in 1 historical year but not the other, regardless of actual utilization. We also believe that excluding special payments would ensure an EPM participant'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 under the proposed models. In addition to the various incentives, enhanced payments, 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.

For more information on the CMS Price (Payment) Standardization Detailed Methodology, we refer to the QualityNet Web site at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350* and to 80 FR 73331.

Accordingly, we propose to exclude these special payments from EPM-episode calculations using the CMS Price Standardization methodology at § 512.300(e)(2). We seek comment on our proposal to exclude special payments using the CMS Price Standardization methodology.

c. Services That Straddle Episodes

A service that straddles an EPM episode is one that begins before the start of or continues beyond the end of an EPM episode that extends 90 days post-hospital discharge. Under the CJR model, we prorate payments so that they include only the portion of the payment that is included in the CJR model episode, using separate approaches to prorate payments under each payment system, for example, IPPS, non-IPPS and other inpatient services, and home health services (80 FR 73333 through 73335). We propose to apply the CJR model methodologies for prorating payments when calculating actual EPM-episode payments and when calculating historical EPM-episode payments used to set EPM-episode benchmark and quality-adjusted target prices. We believe these methodologies would most accurately account for spending within EPM episodes under the proposed EPMs.

The proposed methodologies for prorating payments are included in § 512.300(f). We seek comment on our proposed methodologies for prorating payments.

d. High-Payment EPM Episodes

For the CJR model, we defined a high-payment episode as an episode with payments 2 standard deviations or more above the mean calculated at the regional level (80 FR 73336 through 73337). As with the CJR model, we propose applying a high-payment episode ceiling when calculating actual EPM-episode payments and when calculating historical EPM-episode payments used to set EPM-episode benchmark and quality-adjusted target prices. We propose to apply the ceiling according to the following groupings that align with our proposed EPM price-setting methodology.

First, for SHFFT model episodes, we propose to calculate and apply the ceiling separately for each SHFFT price MS–DRG at the regional level.

Second, for AMI model episodes with price MS–DRGs 280–282 or 246–251 without readmission for CABG MS–DRGs, we propose to calculate and apply the ceiling separately for each price MS–DRG at the regional level.

Third, for CABG model episodes, we propose to apply ceilings separately to the payments that occurred during the anchor hospitalization of the CABG model episode and to the payments that occurred after the anchor hospitalization. For the anchor hospitalization portion of CABG model episodes, we propose to calculate and apply the ceiling separately by each price MS–DRG in 231–236 at the regional level. For the post-anchor hospitalization portion we propose to calculate and apply the ceiling separately for the following groupings at the regional level:

- With AMI ICD–CM diagnosis code on the anchor inpatient claim and price MS–DRG with major complication or comorbidity (231, 233, or 235).
- With AMI ICD–CM diagnosis code on the anchor inpatient claim and price MS–DRG without major complication or comorbidity (232, 234, or 236).
- Without AMI ICD–CM diagnosis code on the anchor inpatient claim and price MS–DRG with major complication or comorbidity (231, 233, or 235).
- Without AMI ICD–CM diagnosis code on the anchor inpatient claim and price MS–DRG without major complication or comorbidity (232, 234, or 236).

Fourth, for AMI model episodes with price MS–DRG 231–236, we propose to apply ceilings separately to the payments that occurred during the chained anchor hospitalization and to the payments that occurred after the chained anchor hospitalization. For the anchor hospitalization portion of the episode, we propose to apply the regional level ceiling calculated for the anchor hospitalization portion of a CABG model episode for the corresponding price MS–DRG, as described previously. For the post-anchor hospitalization portion of the episode, we propose to apply the regional level ceiling calculated for the post-anchor hospitalization portion of a CABG model episode for the corresponding price MS–DRG with AMI diagnosis.

Fifth, for AMI model episodes with price MS–DRG 280–282 or 246–251 and with readmission for CABG MS–DRGs, we propose to apply the ceiling separately to the payments during the CABG readmission and all other payments during the episode. For payments during the CABG readmission portion of the AMI model episode we propose to apply the regional level ceiling calculated for the anchor hospitalization portion of a CABG model episode for the corresponding CABG readmission MS–DRG, as described previously. For all other payments during the AMI model episode, we propose to apply the regional level ceiling calculated for AMI model episodes with price MS–DRG 280–282 or 246–251 and without readmission for CABG MS–DRGs corresponding to the AMI price MS–DRG.

We believe that this ceiling would protect EPM participants from variable repayment risk for especially-high payment EPM episodes where the clinical scenarios for these cases each year may differ significantly and unpredictably.

The proposal for capping high payment EPM episodes is included in § 512.300(e)(1). We seek comment on our proposal to cap high payment EPM episodes.

e. Treatment of Reconciliation Payments and Medicare Repayments When Calculating Historical EPM-Episode Payments To Update EPM-Episode Benchmark and Quality-Adjusted Target Prices

For the CJR model, we exclude CJR model reconciliation payments and Medicare repayments from the expenditure data used to update historical claims when calculating CJR model target prices, although we received comments on the proposed rule encouraging us to include these payments. For example, commenters supported their inclusion because CJR-participating hospitals otherwise would be providing care coordination services that would not be paid directly or accounted for under applicable Medicare FFS payments systems and thus might be funded through reconciliation payments. Further, by excluding reconciliation payments from our calculations, commenters suggested that we may underestimate their actual resource costs when updating target prices for the care necessary during episodes. The CJR Final Rule discussed our view that including reconciliation payments would have the effect of Medicare paying CJR model participant hospitals their target prices, regardless of whether such participant was below, above, or met their episode target price. We also noted that we had not discussed any alternatives in the CJR model proposed rule, and that we might

consider including these payments in updating historical claims through future rulemaking (80 FR 73332).

After further consideration, we are proposing to include both reconciliation payments and Medicare repayments when calculating historical EPM-episode payments to update EPM-episode benchmark and quality-adjusted target prices. We concur with the views expressed by commenters on the CJR model proposed rule that including these payments would more fully recognize the total resource costs of care under an EPM than would their exclusion. As indicated in section V.5 of this proposed rule, we are also proposing to modify our policy for the CJR model to also include reconciliation payments and Medicare repayments when updating target prices under that model We also considered an option where we would include only reconciliation payments when updating but not Medicare repayments; however, we believe this option would not achieve our intention of more fully capturing the costs of care under the EPM. We would further note that the inclusion of both reconciliation payments and Medicare repayments could have differential effects on an EPM participant's benchmark and quality-adjusted target prices based on whether or not it received a reconciliation payment or made a Medicare repayment. For example, all else equal, including an EPM reconciliation payment when updating an EPM participant's EPM-episode benchmark and quality-adjusted target prices would modestly increase the quality-adjusted target prices in performance years 3 through 5 in comparison to not including the reconciliation payment. Conversely, all else equal, including a Medicare repayment when updating an EPM participant's EPM-episode benchmark and quality-adjusted target prices would reduce the next performance year's quality-adjusted target price in comparison to not including the Medicare repayment.

Following analogous logic, we also propose to include BPCI Net Payment Reconciliation Amounts in our calculations when updating EPM-episode benchmark and quality-adjusted target prices. We would note, however, that the effects of these proposals would largely be confined to PY3 of the EPMs and diminish as EPM-participant historical EPM-episode updates are eventually determined based on regional payments in subsequent years of the EPMs. This is because the net sum of EPM reconciliation payments, Medicare repayments, and BPCI Net Payment Reconciliation Amounts would represent a small portion of the total historical EPM-episode payments captured in regional pricing.

When updating EPM-episode benchmark and quality adjusted target prices for CABG model episodes, we propose to apportion EPM reconciliation payments and BPCI Net Reconciliation Payment Amounts proportionally to the anchor hospitalization and post-anchor hospitalization portions of CABG model historical episodes. We also propose to calculate the proportions based on regional average historical episode payments that occurred during the anchor hospitalization portion of CABG model episodes and regional average historical episode payments that occurred during the post-anchor anchor hospitalization portion of CABG model episodes that were initiated during the 3 historical years. This aligns with the general proposal to calculate the CABG model-episode benchmark price as the sum of the corresponding CABG anchor hospitalization benchmark price and the corresponding CABG post-anchor hospitalization benchmark price, as discussed in III.D.4.b.(2)(ii) and III.D.4.d. of this proposed rule.

The proposal to include both reconciliation payments and Medicare repayments when calculating historical EPM-episode payments to update EPM-episode benchmark and quality-adjusted target prices is included in § 512.300(c)(8). We seek comment on our proposal to include both reconciliation payments and Medicare repayments when calculating historical EPM-episode payments to update EPM-episode benchmark and quality-adjusted target prices.

4. EPM-Episode Price-Setting Methodologies

a. Overview

Whether an EPM participant receives a reconciliation payment or is made responsible to repay Medicare under the proposed EPM is based on the EPM participant's actual EPM-episode payments relative to quality-adjusted target prices, as well as the EPM participant's eligibility for reconciliation payment based on acceptable, good, or excellent quality performance. While our proposals for relating EPM participant quality performance to EPM payments are further discussed in section III.E.3.f of this proposed rule, the remainder of this section will discuss the proposed approach to establishing EPM-episode benchmark and quality-adjusted target prices.

For the purposes of price-setting, any references in this proposed rule to AMI ICD–CM diagnosis codes means those ICD–9–CM and ICD–10–CM diagnosis codes for historical EPM episodes or ICD–10–CM diagnosis codes for EPM episodes during the EPM performance years that can be found in the specific EPM episode definitions parameters spreadsheet. Also, for the purposes of price-setting, any references in this proposed rule to intracardiac ICD–CM procedure codes means those ICD–9–CM procedure codes for historical EPM episodes that can be found in the specific EPM episode definitions parameters spreadsheet. The EPM episode definitions parameters spreadsheets are posted on the CMS Web site at *https://innovation.cms.gov/inititatives/epm*.

We propose to establish EPM-episode benchmark and quality-adjusted target prices for each EPM participant based on the following MS–DRGs and diagnoses included in the AMI, CABG, and SHFFT models as discussed in sections III.C.3 and III.C.4. of this proposed rule:

(1) AMI Model

- AMI MS–DRGs—

++ 280 (Acute myocardial infarction, discharged alive with MCC);

++ 281 (Acute myocardial infarction, discharged alive with CC);

++ 282 (Acute myocardial infarction, discharged alive without CC/MCC); and

- PCI MS–DRGs, when the claim includes an AMI ICD–CM diagnosis code in the principal or secondary position on the inpatient claim and when the claim does not include an intracardiac ICD–CM procedure code in any position on the inpatient claim—

++ 246 (Perc cardiovasc proc with drug-eluting stent with MCC or 4+ vessels/stents);

++ 247 (Perc cardiovasc proc with drug-eluting stent without MCC);

++ 248 (Perc cardiovasc proc with non-drug-eluting stent with MCC or 4+ vessels/stents);

++ 249 (Perc cardiovasc proc with non-drug-eluting stent without MCC);

++ 250 (Perc cardiovasc proc without coronary artery stent with MCC); and

++ 251 (Perc cardiovasc proc without coronary artery stent without MCC).

(2) CABG Model DRGs—

- 231 (Coronary bypass with PTCA with MCC);
- 232 (Coronary bypass with PTCA without MCC);
- 233 (Coronary bypass with cardiac cath with MCC);
- 234 (Coronary bypass with cardiac cath without MCC);

• 235 (Coronary bypass without cardiac cath with MCC); and
• 236 (Coronary bypass without cardiac cath without MCC).

(3) SHFFT Model DRGs—

• 480 (Hip and femur procedures except major joint with MCC);
• 481 (Hip and femur procedures except major joint with CC); and
• 482 (Hip and femur procedures except major joint without CC or MCC).

We propose to generally apply the CJR model methodology to set EPM-episode benchmark and quality-adjusted target prices, with the addition of some adjustments based on the specific clinical conditions and care patterns for EPM episodes included in the AMI, CABG, and SHFFT models (80 FR 73337 through 73338). The proposed price-setting methodology incorporates the following features:

• Set different EPM benchmark and quality-adjusted target prices for EPM episodes based on the assigned price MS–DRG in one of the included MS–DRGs to account for patient and clinical variations that impact EPM participants' costs of providing care. Inpatient claims with PCI MS–DRGs 246–251 that contain an intracardiac ICD–CM procedure code in any position would not anchor an historical episode, nor be considered when assigning a price MS–DRG. This is because beginning in FY 2016, inpatient claims containing an intracardiac ICD–10–CM procedure code in any position no longer map to MS–DRGs 246–251.

• Adjust EPM benchmark and quality-adjusted target prices for certain EPM episodes involving chained anchor hospitalizations, specific readmissions, or the presence of an AMI ICD–CM diagnosis code for CABG MS–DRGs.

• Use 3 years of historical Medicare FFS payment data grouped into EPM episodes according to the EPM episode definitions in sections III.C.3 and III.C.4. of this proposed, termed historical EPM episodes and historical EPM-episode payments. The specific set of 3 historical years would be updated every other performance year.

• Apply Medicare payment system (for example, IPPS, OPPS, IRF PPS, SNF, MPFS.) updates to the historical EPM-episode data to ensure we incentivize EPM participants based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond such participants' control. Because different Medicare payment system updates become effective at two different times of the year, we would calculate one set of EPM-benchmark and quality-adjusted target prices for EPM episodes initiated between January 1 and September 30 and another set for EPM episodes initiated between October 1 and December 31.

• Blend together EPM-participant hospital-specific and regional historical EPM-episode payments, transitioning from primarily hospital-specific to completely regional pricing over the course of the 5 performance years, to incentivize both historically-efficient and less-efficient EPM participants to furnish high quality, efficient care in all years of the EPM Regions would be defined as each of the nine U.S. Census divisions.

• Normalize for hospital-specific wage-adjustment variations in Medicare payment systems when combining hospital-specific and regional historical EPM episodes.

• Pool together EPM episodes by groups of price MS–DRGs to allow a greater volume of historical cases and allow us to set more stable prices.

• Apply an effective discount factor on EPM-episode benchmark prices to serve as Medicare's portion of reduced expenditures from the EPM episode, with any remaining portion of reduced Medicare spending below the quality-adjusted target price potentially available as reconciliation payments to the EPM participant where the anchor hospitalization occurred.

• Further discussion on each of the proposed features and sequential steps to calculate EPM-episode benchmark and quality-adjusted target prices can be found in sections III.D.4.b through e. of this proposed rule, which immediately follow.

We also propose to calculate and communicate EPM-episode benchmark and quality-adjusted target prices to EPM participants prior to the performance period in which the prices apply (that is, prior to January 1, 2018, for prices covering EPM episodes that start between January 1, 2018, and September 30, 2018; prior to October 1, 2018, for prices covering EPM episodes that start between October 1, 2018, and December 31, 2018). We believe that prospectively communicating EPM-episode benchmark and quality-adjusted target prices to EPM participants would help them make infrastructure, care coordination and delivery, and financial refinements they may deem appropriate to prepare for the new episode target prices under the model.

The proposal to prospectively communicate quality-adjusted target prices are included in § 512.300(c)(9). We seek comment on our proposal to prospectively communicate these prices.

b. EPM-Episode Benchmark and Quality-Adjusted Target Price Features

(1) Risk-Stratifying EPM-Episode Benchmark Prices Based on MS–DRG and Diagnosis

To account for some of the clinical and resource variations that would be expected to occur under the EPMs, we propose generally to apply the episode pricing methodology that was applied to the CJR model to develop the EPM-episode benchmark prices, hereinafter called the standard EPM-episode benchmark price. In addition, for each EPM participant, we propose to risk-stratify and establish special EPM-episode benchmark prices for episodes in different pricing scenarios as described in this section, as well as sections III.D.4.c. through e. of this proposed rule. For purposes of this proposed rule, risk-stratification means the methodology for developing the EPM-episode benchmark price that accounts for clinical and resource variation in historical EPM episodes so that the quality-adjusted target price (calculated from the EPM-episode benchmark price) can be compared to actual EPM episode payments for EPM beneficiaries with similar care needs to those in historical EPM episodes.

For the SHFFT model, we propose to set the price MS–DRG equal to the anchor MS–DRG. We propose to calculate standard SHFFT model-episode benchmark prices based on price MS–DRGs following the general payment methodology that was applied to the CJR model with risk stratification according to the anchor MS–DRG (80 FR 73337 through 73358).

Similarly, for AMI model episodes without chained anchor hospitalizations and without readmissions for CABG MS–DRGs, we propose to set the price MS–DRG equal to the anchor MS–DRG. We propose to calculate standard AMI model-episode benchmark prices based on price MS–DRGs following the general payment methodology that was applied to the CJR model with risk stratification according to the anchor MS–DRG (80 FR 73337 through 73358). We propose to apply the CJR model payment methodology separately to AMI model episodes with anchor AMI MS–DRGs 280–282 and anchor PCI MS–DRGs 246–251 with a corresponding AMI ICD–CM diagnosis code on the inpatient claim for the anchor hospitalization and without an intracardiac ICD–CM procedure code in any position on the inpatient claim for the anchor hospitalization.

For episodes in the AMI model with chained anchor hospitalizations and no readmissions for CABG MS–DRGs, we

propose to set the price MS–DRG based on the hierarchy described in section III.D.4.b.(2)(a) and to calculate AMI model-episode benchmark prices based on price MS–DRGs as described in sections III.D.4.b.(2)(a) and III.D.4.c. of this proposed rule.

For AMI model episodes without chained anchor hospitalizations and with readmissions for CABG MS–DRGs, we propose to set the price MS–DRG as the anchor MS–DRG and to calculate CABG readmission AMI model-episode benchmark prices as described in sections III.D.4.b.(2)(b), III.D.4.b.(2)(c), and III.D.4.e of this proposed rule.

For AMI model episodes with chained anchor hospitalizations that do not include CABG MS–DRGs and with readmissions for CABG MS–DRGs, we propose to set the price MS–DRG based on the hierarchy described in section III.D.4.b.(2)(a) and to calculate CABG readmission AMI model-episode benchmark prices as described in sections III.D.4.b.(2)(b), III.D.4.b.(2)(c), and III.D.4.e. of this proposed rule.

For CABG model episodes, we propose to set the price MS–DRG as the anchor MS–DRG and to calculate CABG model-episode benchmark prices as the sum of the CABG anchor hospitalization portion price and the CABG post-anchor hospitalization portion price, which would be calculated by applying the general payment methodology that was applied to the CJR model separately to the expenditures that occurred during the anchor hospitalization of the CABG model episode and to the expenditures that occurred after the anchor hospitalization as discussed in sections III.D.4.b.(2)(b) and III.D.4.d. of this proposed rule (80 FR 73337 through 73358).

Finally, we propose that after assigning an EPM-episode benchmark price to each EPM episode, the EPM-episode quality-adjusted target price would be the EPM-episode benchmark price reduced by the effective discount factor for the corresponding EPM that corresponds to the EPM participant's quality category, as discussed in sections III.D.4.b.(10) and III.E.3.f. of this proposed rule.

(2) Adjustments To Account for EPM-Episode Price Variation

We also have considered further adjustments to account for clinical and resource variation that could affect EPM participants' costs for EPM episodes. As was the case for the CJR model, we continue to believe that no standard risk adjustment approach that is widely-accepted throughout the nation exists for the proposed EPM episodes (80 FR 73338 through 73339). Thus, we are not proposing to make risk adjustments based on beneficiary-specific demographic characteristics or clinical indicators. Likewise, we continue to believe that CMS Hierarchical Condition Categories (HCC) used to adjust for risk in the Medicare Advantage program would not be appropriate for risk-adjusting EPM episodes as such categories are used to predict total Medicare expenditures in an upcoming year for MA plans and may not be appropriate for use in predicting expenditures over a shorter period of time, such as the EPM episodes. Further, the validity of HCC scores for predicting Medicare expenditures for shorter episodes-of-care or specifically for the AMI, CABG, and SHFFT model episodes that we are proposing has not been determined. Thus, we do not propose to risk-adjust EPM-episode benchmark or quality-adjusted target prices using HCC scores for the currently proposed EPMs. We refer to the CJR Final Rule for additional discussion of our assessment of risk-adjustment options for the CJR model, which informs our views on their appropriateness for the proposed EPMs (80 FR 73338 through 73340).

However, we believe there are circumstances that could account for spending variation in EPM episodes where certain pricing adjustments could be appropriate. We have identified several scenarios where increased EPM-episode efficiencies would be limited for certain groups of EPM beneficiaries and a standard EPM-episode benchmark price based on the anchor MS–DRG would, therefore, not account for circumstances where clinically-appropriate care could consistently result in higher EPM-episode payments. For example, as discussed in section III.C.4.a.(5) of this proposed rule, variation could arise from the asymmetric distribution of cardiac care across hospitals, which makes transfers, either from a hospitalization or from the emergency department (without inpatient admission) of one hospital to another, a common consideration in the treatment course for beneficiaries with an initial diagnosis of AMI, resulting in a chained anchor hospitalization for inpatient-to-inpatient transfers. Alternately, we recognize that certain episodes involving hospital readmissions for clinically-appropriate planned follow-up care may have higher episode spending than episodes with a single hospitalization or with chained anchor hospitalizations involving transfers that do not have any readmissions. Further, a beneficiary who has a CABG in the context of hospitalization for an AMI may have different spending in the 90 days post-hospital-discharge due to different health needs than a beneficiary who has an elective CABG. Accordingly, we propose specific policies and payment adjustments in recognition of the systematic, consistent variation in EPM-episode spending that could result from such circumstances.

(a) Adjustments for Certain AMI Model Episodes With Chained Anchor Hospitalizations

In section III.C.4.a.(5) of this proposed rule, we proposed that once an AMI model episode is initiated at an AMI model participant, the AMI model episode continues under the responsibility of that specific participant, regardless of whether the beneficiary is transferred to another hospital for further medical management of AMI or revascularization through PCI or CABG during a chained anchor hospitalization. Given there could be significant differences between the discharge MS–DRG from the hospital that initiates the AMI episode and the hospital to which a beneficiary is transferred, as well as the Medicare payment associated with these different MS–DRGs and the post-discharge spending for these beneficiaries, we believe it would be appropriate to adjust the AMI model-episode benchmark prices for certain AMI model episodes involving a chained anchor hospitalization.

More specifically, we believe that it would be appropriate to make an adjustment when a final hospital discharge MS–DRG in the chained anchor hospitalization is an anchor MS–DRG under either the AMI or CABG model. Thus, for episodes involving a chained anchor hospitalization with a final discharge diagnosis of any of AMI MS–DRG 280–282, PCI MS–DRG 246–251 without an intracardiac ICD–CM procedure code in any position on the inpatient claim, or CABG MS–DRG 231–236, we propose to set a chain-adjusted AMI model-episode benchmark price or ''price MS–DRG'' based on the AMI, PCI, or CABG MS–DRG in the chained anchor admission with the highest IPPS weight. If a CABG MS–DRG occurs in a chained anchor hospitalization that was initiated with an AMI MS–DRG or PCI MS–DRG without an intracardiac ICD–CM procedure code in any position on the corresponding inpatient claim, we propose that the AMI model episode would begin with and be attributed to the first hospital, and we propose to set the price MS–DRG to the CABG MS–DRG in the chained anchor

hospitalization with the highest IPPS weight.

If the price MS–DRG is an AMI or PCI MS–DRG, we propose to set the episode benchmark price as the standard AMI model-episode benchmark price for the price MS–DRG, subject to a possible adjustment for readmission for CABG MS–DRGs, as described in section III.D.4.b.(2)(c) of this proposed rule. If the price MS–DRG is a CABG MS–DRG, we propose to set the AMI model-episode benchmark price as the CABG model-episode benchmark price for the corresponding CABG MS–DRG, with no further adjustment in the event of a readmission for CABG MS–DRGs.

Table 7 displays the weights for CABG, PCI, and AMI MS–DRGs established in the FY 2016 IPPS final rule, which are subject to change each FY through the annual IPPS rulemaking (80 FR 49325 through 49886).

TABLE 7—FY 2016 IPPS WEIGHTS FOR MS–DRGS 231–236, 246–251, AND 280–282

MS–DRG	MS–DRG title	Weights
231	CORONARY BYPASS W PTCA W MCC	7.8056
232	CORONARY BYPASS W PTCA W/O MCC	5.7779
233	CORONARY BYPASS W CARDIAC CATH W MCC	7.3581
234	CORONARY BYPASS W CARDIAC CATH W/O MCC	4.9076
235	CORONARY BYPASS W/O CARDIAC CATH W MCC	5.8103
236	CORONARY BYPASS W/O CARDIAC CATH W/O MCC	3.8013
246	PERC CARDIOVASC PROC W DRUG-ELUTING STENT W MCC OR 4+ VESSELS/STENTS	3.2494
247	PERC CARDIOVASC PROC W DRUG-ELUTING STENT W/O MCC	2.1307
248	PERC CARDIOVASC PROC W NON-DRUG-ELUTING STENT W MCC OR 4+ VES/STENTS	3.0696
249	PERC CARDIOVASC PROC W NON-DRUG-ELUTING STENT W/O MCC	1.9140
250	PERC CARDIOVASC PROC W/O CORONARY ARTERY STENT W MCC	2.6975
251	PERC CARDIOVASC PROC W/O CORONARY ARTERY STENT W/O MCC	1.6863
280	ACUTE MYOCARDIAL INFARCTION, DISCHARGED ALIVE W MCC	1.6971
281	ACUTE MYOCARDIAL INFARCTION, DISCHARGED ALIVE W CC	1.0232
282	ACUTE MYOCARDIAL INFARCTION, DISCHARGED ALIVE W/O CC/MCC	0.7557

We believe that this proposal could minimize potential disincentives to AMI model participants from transferring patients when different or higher levels of care are needed. This is because the AMI model-episode benchmark prices we set would be more representative of the AMI spending based on the totality of care furnished during the chained anchor hospitalization and post-discharge period within the AMI model episode and for which the AMI model participants would be held accountable. We also believe that our proposal could encourage AMI model participants that frequently transfer patients after admission to improve their efficiency and the quality of care by transferring beneficiaries needing higher levels of care prior to hospital admission and managing those beneficiaries admitted to reduce the need for later transfers.

As an alternative, we also considered an approach where we would set the target price taking into consideration IPPS payments for both the MS–DRG assigned to the first admission in the chained anchor hospitalization and the MS–DRG assigned to the final admission in the chained anchor hospitalization. We could apply this approach to all AMI model participant hospitals or to only a subset of hospitals based on special situations that could lead to more common transfer scenarios that are unavoidable, such as small bed-size, rural location, interventional or cardiac surgery capacity, or other characteristic of the hospitals. All AMI model episodes involving chained anchor hospitalizations would include at least two IPPS payments for the chained anchor hospitalization, compared to one IPPS payment for most AMI episodes with only an anchor hospitalization that does not result in an inpatient-to-inpatient transfer. The alternative approach would likely result in a higher AMI-model episode benchmark price than under our proposal for AMI model episodes including a chained anchor hospitalization. Therefore, we believe this alternative approach could have the effect of further reducing potential disincentives to hospitals from transferring patients when different or a higher level of care is needed; however, we are not convinced this approach would ultimately improve care quality and efficiency under the AMI model.

First, we are concerned that this alternative approach could serve as an incentive for hospitals to admit and then transfer patients when doing so might not be medically necessary, which would neither enhance care quality nor efficiency. A recent study showed that non-procedure hospitals, defined as hospitals that lack onsite cardiac catheterization and coronary revascularization facilities, vary substantially in their use of the transfer process for Medicare beneficiaries admitted with AMI.[61] Beneficiaries transferred from hospitals that had a high transfer rate experienced greater use of invasive cardiac procedures after admission to the transfer hospital than beneficiaries transferred from hospitals with a low transfer rate. However, higher transfer rates were not associated with a significantly lower risk-standardized mortality rate at 30 days, and at one year, there was only a 1.1 percent mortality rate difference between hospitals with higher and lower transfer rates. As such, we believe this alternative approach could be appropriate for only a subset of AMI model participant hospitals based on specific hospital characteristics that could lead to a higher frequency of unavoidable transfers for AMI model beneficiaries rather than appropriate for hospitals overall. In addition, if we were to adopt this alternative approach, we believe it would also be necessary to incorporate methods for monitoring changes in the frequency of AMI model participant hospital patient transfers over the model's performance years, as well as assessing the appropriateness of those transfers. For example, to address changes in transfer frequency, we might compare how often an AMI model participant hospital transferred a beneficiary following an inpatient admission within each performance year relative to the frequency of transfers during its initial 3-year historical period. To address

[61] Barreto-Filho J, Wang Y, Rathore SS et al. Transfer Rates From Nonprocedure Hospitals After Initial Admission and Outcomes Among Elderly Patients With Acute Myocardial Infarction. JAMA Intern Med. 2014;174(2):213–222. doi:10.1001/jamainternmed.2013.11944.

appropriateness of transfers, we might consider reviewing and comparing a sample of a hospital's transfers within a performance year as compared to the historical period. Furthermore, we might also propose future changes to this approach where changes in the frequency or appropriateness of transfers were identified.

Second, in contrast to our proposal, we believe that this alternative approach would not have the benefit of encouraging AMI model participant hospitals to make an early decision and transfer patients prior to rather than following inpatient admission when doing so prior to admission would be appropriate for the beneficiary's clinical circumstances and the hospital's capabilities. While we recognize that in some cases, an AMI model beneficiary admitted to the initial treating hospital may need to be transferred to a referral hospital that can provide a different or higher level of care, we believe it is important that the AMI model's payment methodology support the goal of rapid decision-making by the AMI model participant hospital about the AMI model beneficiary's care pathway based on clinical guidelines that often incorporate a time dimension in the guidelines for care.

Thus, on balance, we believe our proposed methodology would best establish appropriate incentives to improve care quality and efficiency under the AMI model by encouraging timely decisions about admission to the initial treating hospital and incentivizing only those transfers that are necessary to meet AMI model beneficiary's health care during the course of their hospitalization. Our proposal would adjust the AMI model-episode benchmark price that applies to the episode when a chained anchor hospitalization occurs and results in more costly care at the transfer hospital than would be expected based on the anchor MS–DRG at the initial treating hospital who would be accountable for the episode under the AMI model, thus accounting for the care at the referral hospital.

In contrast, some chained anchor hospitalizations could begin an episode based on an MS–DRG that anchors an episode in the model such as an AMI MS–DRGs that subsequently also includes an MS–DRG that does not anchor an episode under the model (for example, heart failure, renal failure, or cardiac valve replacement). Some of these non-anchor MS–DRGs could be related to the AMI episode but are unavoidable, for example, cardiac valve surgery, while others could potentially reflect complications resulting from inadequate care management during the episode (for example, heart or renal failure).

As discussed in section III.C.4.b. of this proposed rule, we propose to cancel an AMI model episode when the final MS–DRG in a chained anchor hospitalization is from an MS–DRG that would not an anchor MS–DRG under the AMI or CABG model. We believe that, in tandem, these proposals would allow for appropriate pricing of AMI model episodes that continue and include chained anchor hospitalizations.

The proposals to establish pricing for AMI model episodes involving chained anchor hospitalizations are included in § 512.300(c)(7)(i). We seek comment on our proposals for pricing AMI episodes involving chained anchor hospitalizations and the alternative proposals we considered. We also seek comment on the alternative considered that would account for both the MS–DRGs at the first and last hospitals caring for the AMI model beneficiary during the chained anchor hospitalization in setting the AMI-model episode benchmark price for episodes involving a chained anchor hospitalization. In particular, under such an alternative, we seek comment on the clinical circumstances in which inpatient-to-inpatient transfers are unavoidable and whether or not there are hospital characteristics that would lead us to expect higher frequencies of unavoidable inpatient-to-inpatient transfers for AMI model beneficiaries than hospitals overall. We also seek comment on how we could discourage unintended consequences under this alternative, such as less timely decisions about the most appropriate hospital to treat the beneficiary and increased beneficiary transfers that are unnecessary or inappropriate for improved quality of AMI model episode care.

(b) Adjustments for CABG Model Episodes

Among Medicare beneficiaries historically discharged under a CABG MS–DRG, average episode spending was substantially higher for those beneficiaries who also had AMI ICD–CM diagnosis codes on their inpatient claims ($57,000) than those who did not ($44,000).[62] About 30 percent of CABG beneficiaries had AMI ICD–CM diagnosis codes on their claims, while about 70 percent did not, and this percentage of CABG beneficiaries with AMI varied substantially across IPPS hospitals furnishing CABG procedures.[63] While average spending, in total, was substantially higher for CABG beneficiaries with AMI than without AMI, average spending during the anchor hospitalization was not substantially higher. Rather, much of this variation in CABG model episode spending occurred after discharge from the anchor hospitalization and correlated both with the presence of AMI and whether the CABG beneficiary was discharged from the anchor hospitalization in a CABG MS–DRG with major complication or comorbidity (MS–DRGs 231, 233, or 235) as opposed to a CABG MS–DRG without major complication or comorbidity (MS–DRGs 232, 234, or 236). Specifically, we found that average CABG episode spending after discharge from the anchor hospitalization was—

- $9,000 for non-AMI CABG beneficiaries discharged from MS–DRGs 232, 234, or 236;
- $11,000 for CABG beneficiaries with AMI discharged from MS–DRGs 232, 234, or 236;
- $16,000 for non-AMI CABG beneficiaries discharged from MS–DRGs 231, 233, or 235; and
- $20,000 for CABG beneficiaries with AMI discharged from MS–DRGs 231, 233, or 235.[64]

Thus, for CABG model episodes, we propose to set CABG model-episode benchmark prices by first splitting historical CABG model-episode expenditures into expenditures that occurred during anchor hospitalizations and expenditures that occurred after discharge from the anchor hospitalizations.

We propose to calculate the CABG anchor hospitalization benchmark price by following the general payment methodology that was applied to the CJR model, with expenditures limited to those that occurred during the anchor hospitalization and risk stratification according to the price CABG MS–DRG (80 FR 73337 through 73358).

We also propose to calculate the CABG post-anchor hospitalization benchmark price by following the general payment methodology that was applied to the CJR model, with

[62] Episodes for CABG model beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, that began in CYs 2012–2014.

[63] Episodes for CABG model beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, that began in CYs 2012–2014.

[64] Episodes for CABG model beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, that began in CYs 2012–2014.

expenditures limited to those that occurred after the anchor hospitalization and risk-stratification according to the presence of an AMI ICD–CM diagnosis code on the anchor inpatient claim and whether the price MS–DRG is a CABG MS–DRG with major complication or comorbidity (231, 233, or 235) or a CABG MS–DRG without major complication or comorbidity (232, 234, or 236) (80 FR 73337 through 73358).

We propose that the CABG model-episode benchmark price for an episode would be the sum of the corresponding CABG anchor hospitalization benchmark price and the corresponding CABG post-anchor hospitalization benchmark price, as discussed in this section and in III.D.4.d.

The proposals to establish pricing for CABG model episodes are included in § 512.300(c)(7)(ii). We seek comment on our proposals to establish pricing for CABG model episodes.

(c) Adjustments for Certain AMI Model Episodes With CABG Readmissions

In section III.C.4.b of this proposed rule, we discuss AMI model episodes where a beneficiary is discharged from an AMI model participant under an AMI MS–DRG and is later readmitted for a CABG. In that section, we did not propose to cancel the AMI model episode altogether for a CABG readmission during the 90-day post-hospital discharge period or cancel the AMI model episode and initiate a CABG model episode because planned CABG readmission following an anchor hospitalization that initiates an AMI episode may be an appropriate clinical pathway for certain beneficiaries. For example, we noted that historically approximately 10 percent of those AMI beneficiaries who received CABGs during AMI episodes would receive the CABGs between 2 and 90 days post-discharge from the anchor hospitalization, and most of those readmissions did not occur through hospital emergency departments. Even though CABG readmissions are not excluded from AMI model episodes (because they are clinically-related to the AMI model episode), we propose to provide an adjusted AMI model-episode benchmark price in such circumstances so as not to financially penalize AMI model participants for relatively uncommon, costly, clinically-appropriate care patterns for AMI model beneficiaries. Accordingly, we are proposing to establish an adjusted CABG-readmission AMI model-benchmark episode price for AMI model episodes with a price MS–DRG of 280–282 or 246–251 that have readmission for a CABG MS–DRG 231–236.

Specifically, if a CABG readmission occurs during an AMI model episode with a price MS–DRG of 280–282 or 246–251, we propose to calculate a CABG-readmission AMI model-episode benchmark price equal to the sum of the standard AMI model-episode benchmark price corresponding to the price MS–DRG (AMI MS–DRGs 280–282 or PCI MS–DRGs 246–251) and the CABG anchor hospitalization benchmark price corresponding to the MS–DRG of the CABG readmission. Because the adjustment would be based on the anchor hospitalization benchmark price, which does not include costs associated with the post-discharge period for CABG, this adjustment approach would avoid ''double counting'' post-discharge costs. Because adjusting for spending that occurred during a CABG readmission accounts for most of the spending variation between AMI model episodes with a CABG readmission and AMI model episodes without a CABG readmission, we propose no additional adjustment to the price for AMI model episodes with a CABG readmission.

In the event of any other readmission other than CABG during an AMI model episode that is not excluded from the AMI model episode definition, we would apply the usual rules of EPM-episode pricing that would include the spending for the related readmission in the actual AMI model-episode spending, without other adjustments. Fewer than 3 percent of those AMI model beneficiaries who receive inpatient or outpatient PCIs during AMI episodes receive the PCIs between 2 and 90 days post-discharge from the anchor or chained anchor hospitalizations, and we do not propose to make a pricing adjustment for PCIs that occur later in the AMI model episodes after discharge from the anchor or chained anchor hospitalizations. Since a PCI for an AMI typically is provided during the anchor or chained anchor hospitalization and most PCIs later in an episode occur in the context of a beneficiary presenting through the emergency department, we believe that the beneficiary likely has experienced a complication of care resulting in a PCI that may potentially be avoided through care management during the AMI model episode. Given that our intention is to offer appropriate incentives for care quality and efficiency by holding AMI model participants accountable for readmissions that could be related to the quality of care provided prior to the readmission, we believe that an adjustment other than for a CABG readmission would not be appropriate.

The proposal for adjusting episodes involving CABG readmissions is included in § 512.300(c)(7)(iii). We seek comment on our proposal for adjusting episodes involving CABG readmissions.

(d) Potential Future Approaches to Setting Target Prices for AMI and Hip Fracture Episodes

As previously described, our proposed approach for pricing AMI and CABG model episodes for beneficiaries with AMI sets different episode target prices depending upon whether the beneficiary is managed medically, undergoes PCI, or undergoes CABG during the acute phase of the episode, as well as whether the episode involves a chained anchor hospitalization or CABG readmission. Similarly, the target price set for beneficiaries experiencing hip fracture would depend on whether the patient undergoes hip fixation (and therefore initiates a SHFFT model episode) or hip arthroplasty (and therefore initiates a CJR model episode). We believe that this is a prudent approach that both recognizes the resource costs of services provided while encouraging care redesign during the portions of these episodes that we believe present the greatest opportunities to improve the quality and efficiency of the care delivered.

However, we note that the general principle guiding our payment reform efforts is that the payment system should hold providers accountable for the overall quality and cost of the care their beneficiaries receive rather than setting their payment based on the specific services delivered or settings in which they are delivered. We believe that this approach gives providers maximum flexibility to redesign care in ways that both produce the best outcomes for patients and controls the growth in spending for these services.

For this reason, we are interested in exploring future approaches to episode payment that would set an inclusive target price for episodes for beneficiaries with AMI that does not depend on whether the beneficiary is managed medically or receives PCI or CABG during the acute portion of the episode and, similarly, future approaches that would set prices for episodes for beneficiaries with hip fracture that do not depend on whether the beneficiary undergoes hip fixation or hip arthroplasty. While we believe that the choice of treatment during the acute phase of these episodes may be determined predominantly by clinical factors such that financial factors may play a smaller role in shaping episode

care redesign than they do following hospital discharge, we nevertheless believe it would be valuable to consider testing an inclusive episode payment model. Providers may be able to redesign and implement care pathways that we might not have otherwise anticipated, especially as the evidence-base for AMI and hip fracture treatment continues to grow and evolve.

We seek comment on this type of approach to setting an inclusive episode target price and on any episode payment model design features that would be needed to make such an approach successful. In particular, we seek comment on potential approaches to risk-adjustment aimed at ensuring that providers are appropriately paid for caring for high-complexity episode beneficiaries in the context of this alternative approach. We would seek to ensure that all providers caring for these episode beneficiaries, including those providers for which we propose additional protections and those that serve a high percentage of potentially vulnerable populations of medically and socially complex patients as discussed in section III.D.7.c. of this proposed rule, would not bear undue financial risk and to mitigate any incentives to avoid caring for high-complexity patients. In addition, we seek comment on whether and how our methodology linking quality performance to payment under the proposed EPMs and the CJR model might need to be modified in the context of this alternative approach that would set an inclusive episode target price, in order to appropriately incentivize the delivery of high-quality care and discourage stinting on appropriate care.

(e) Summary of Pricing Methodologies for AMI, CABG, and SHFFT Model Episode Scenarios

Tables 8 through 10 summarize the standard pricing methodologies and the adjustments that would occur that are proposed in sections III.D.4.b.(1) and (2) of this proposed rule for AMI, CABG, and SHFFT model episodes.

TABLE 8—AMI MODEL PRICING SCENARIOS

AMI pricing scenario	Price
AMI Scenarios without Chained Anchor Hospitalization	
Single hospital AMI MS-DRG or PCI MS-DRG (with AMI diagnosis)	Episode benchmark price is standard episode benchmark price based on anchor MS-DRG (which is the price MS-DRG).
AMI Scenarios with Chained Anchor Hospitalizations	
A chained anchor hospitalization where the discharge from the first hospital is an AMI MS-DRG or PCI MS-DRG (with AMI diagnosis) that results in a final discharge from an AMI, PCI, or CABG MS-DRG (transfer PCI and CABG MS-DRGs not required to have AMI ICD-CM diagnosis code).	Episode benchmark price is the standard episode benchmark price or the CABG model episode benchmark price corresponding to price MS-DRG, assigned as the AMI, PCI, or CABG MS-DRG with highest IPPS weight. If the price MS-DRG is a CABG MS-DRG, the CABG model episode benchmark price is the sum of the CABG anchor hospitalization price for the MS-DRG and the CABG post-anchor hospitalization price based on with AMI ICD-CM diagnosis code and whether the CABG MS-DRG is w/MCC or not.
AMI Scenarios with Readmissions	
An AMI MS-DRG or PCI MS-DRG (with AMI diagnosis) anchored episode without a chained anchor hospitalization ongoing with CABG readmission.	Episode benchmark price is the sum of the standard episode benchmark price corresponding to the price MS-DRG and the CABG anchor hospitalization benchmark price corresponding to the CABG readmission MS-DRG.
AMI MS-DRG or PCI MS-DRG (with AMI diagnosis) anchored AMI episode with chained anchor hospitalization (not containing a CABG MS-DRG) ongoing with CABG readmission.	Episode benchmark price is the sum of the standard episode benchmark price for the price MS-DRG assigned to the chained anchor hospitalization and the CABG anchor hospitalization benchmark price corresponding to the CABG readmission MS-DRG.

TABLE 9—CABG MODEL PRICING SCENARIOS

CABG pricing scenario	Price
Single hospital CABG MS-DRG with AMI diagnosis	Episode benchmark price is the sum of the CABG anchor hospitalization benchmark price for the MS-DRG and the CABG post-anchor hospitalization benchmark price based on the presence of an AMI ICD-CM diagnosis code and whether the anchor MS-DRG is w/MCC or w/o MCC.
Single hospital CABG MS-DRG without AMI diagnosis	Episode benchmark price is the sum of the CABG anchor hospitalization benchmark price for the MS-DRG and the CABG post-anchor hospitalization benchmark price based on no AMI ICD-CM diagnosis code and whether the anchor MS-DRG is w/MCC or w/o MCC.

TABLE 10—SHFFT MODEL PRICING SCENARIOS

SHFFT Pricing scenario	Price
SHFFT MS-DRG	Episode benchmark price is standard episode benchmark price based on anchor MS-DRG (which is the price MS-DRG).

(3) Three Years of Historical Data

As was the case for the CJR model, we propose to use 3 years of historical EPM episodes for calculating EPM participants' EPM-episode benchmark prices, with each set of historical episodes updated every other year (80 FR 73340 through 73341). Under our proposal, each of the first 2 years of historical data would be trended to the most recent of the 3 years, based on national trend factors for each combination of price MS–DRGs and payments would be updated for each payment system (for example, IPPS, PFS, etc.) based on annual changes in input costs (see sections III.D.4.b(4) and III.D.4.b(5) of this proposed rule that immediately follow). Under our proposal, we would establish historical EPM-episode payments based on episodes that started between—

- January 1, 2013 and December 31, 2015 for performance years 1 and 2;
- January 1, 2015 and December 31, 2017 for performance years 3 and 4; and
- January 1, 2017 and December 31, 2019 for performance year 5.

We believe that 3 years of historical EPM-episode data should provide sufficient historical episode volume to reliably calculate EPM-episode benchmark prices, and that updating these data every other year would allow us to make the most current claims data available in a way that incorporates the effects of regular Medicare payment system updates and changes in utilization without creating uncertainty in pricing for EPM participants. We would further note that the effects of updating EPM-participant hospital-specific data on an EPM-episode's benchmark prices would diminish over time as the contribution of regional pricing on EPM benchmark prices will increase from one-third for performance years 1 and 2 to two-thirds in performance year 3, and 100 percent in performance years 4 and 5.

The proposal for 3 years of historical data updated every other year under the proposed EPMs is included in § 512.300(c)(1).

We seek comment on our proposal for 3 years of historical data updated every other year.

(4) Trending Historical Data to the Most Recent Year

We recognize that some payment variation could exist in the 3 years of historical EPM-episode data due to annual Medicare payment system updates (for example, IPPS, OPPS, IRF PPS, SNF PPS) and national changes in utilization patterns. Thus, EPM episodes in the third year of the 3 historical years might have higher average payments than those from the earlier 2 years, in part due to Medicare payment rate increases over the course of the 3-year period. Also, EPM-episode payments could change over time due to national trends reflecting changes in industry-wide practice patterns. For example, readmissions for all patients, including those in CABG model episodes, may decrease nationally due to improved industry-wide surgical protocols that reduce the chance of infections. We do not intend for the incentives under the EPMs to be affected by Medicare payment system rate changes that are beyond EPM participants' control or to provide reconciliation payments to (or require repayments from) EPM participants for achieving lower (or higher) Medicare expenditures solely because they followed national changes in practice patterns. Instead, we aim to incentivize EPM participants to improve care quality and efficiency based on their hospital-specific inpatient and post-discharge care practices under the EPMs.

To mitigate the effects of Medicare payment system updates and changes in national utilization practice patterns on the 3 years of historical episode data, we propose to apply a national trend factor to each of the years of historical EPM-episode payments as we do with the CJR model (80 FR 73341 through 73342). Specifically, we propose to inflate the 2 oldest years of historical EPM-episode payments for EPM episodes to the most recent year of the 3 historical years using changes in the national EPM-episode payments for each different type of EPM episode. That is, we propose to apply separate national trend factors for the following pricing scenarios:

- SHFFT model episodes, separately by each price MS–DRG in 480–482.
- AMI model episodes without CABG readmissions, separately by each price MS–DRG in 280–282 and 246–251; and
- The anchor hospitalization portion of CABG model episodes, separately by each price MS–DRG in 231–236.
- The post-anchor hospitalization portion of CABG model episodes, separately for:

++ With AMI ICD–CM diagnosis code on the anchor inpatient claim and CABG price MS–DRG with major complication or comorbidity (231, 233, or 235);

++ With AMI ICD–CM diagnosis code on the anchor inpatient claim and CABG price MS–DRG without major complication or comorbidity (232, 234, or 236);

++ Without AMI ICD–CM diagnosis code on the anchor inpatient claim and CABG price MS–DRG with major complication or comorbidity (231, 233, or 235); and

++ Without AMI ICD–CM diagnosis code on the anchor inpatient claim and CABG price MS–DRG without major complication or comorbidity (232, 234, or 236).

For example, when using Calendar Year (CY) 2013 through 2015 historical EPM-episode data to establish EPM-episode benchmark prices for performance years 1 and 2, we would calculate an aggregate national average SHFFT model episode payment in historical episodes with price MS–DRG 480 for each of the 3 historical years. To trend historical payments to the most recent year in an historical window, we would create a ratio based on national average historical EPM-episode payment for that episode type in a previous year and for the most recent year. Thus, in this example, we would create a ratio of national average SHFFT model historical episode payment with price MS–DRG 480 in CY 2015 as compared to that national average SHFFT model historical episode payment in CY 2013 in order to trend the CY 2013 historical SHFFT model episode payments to CY 2015. Similarly, we would determine the ratio of the national average SHFFT model historical episode payment for CY 2015 to national average SHFFT model historical episode payment in CY 2014 to trend 2014 SHFFT model episode payments to CY 2015. This process would be repeated for each pricing scenario previously listed.

We believe this method for trending data would capture updates in Medicare payment systems as well as national utilization pattern changes that might have occurred within that 3-year period. Moreover, as with the CJR model, we believe that adjusting for national rather than regional trends in utilization would be most appropriate as any Medicare payment system updates and significant changes in utilization practice patterns would not be region-specific but rather be reflected nationally.

The proposal for trending historical data is included in § 512.300(c)(11). We seek comment on our proposal for trending historical data.

(5) Update Historical EPM-Episode Payments To Account for Ongoing Payment System Updates

As previously mentioned, we propose to prospectively update the historical EPM-episode payments to account for ongoing updates to Medicare payment systems (for example, IPPS, OPPS, IRF PPS, SNF, PFS, etc.) in order to ensure we incentivize EPM participants based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond hospitals' control. Under our proposal, we would apply the same methodology developed for the CJR model to incorporate Medicare payment updates (80 FR 73342 through 73446).

Because Medicare payment systems rates are not updated at the same time during the year—for example, rates under the IPPS, IRF PPS, and SNF payment systems are updated effective October 1, while the hospital OPPS and MPFS rates are updated annually effective January 1—we propose to generally update historical EPM-episode payments and calculate EPM-episode benchmark prices separately for EPM episodes initiated between January 1 and September 30 versus October 1 and December 31 of each performance year, and at other intervals if determined necessary. The EPM-episode benchmark price in effect as of the day the EPM episode is initiated would be the EPM-episode benchmark price for the whole EPM episode. Note that for performance year 5, the second set of EPM-episode benchmark prices would be for EPM episodes that start and end between and including October 1 and December 31 because the fifth performance period of the SHFFT, CABG, and AMI models would end on December 31, 2021. Also, an EPM episode benchmark price for a given EPM performance year could be applied to EPM episodes included in another performance year. For example, an EPM episode initiated in November 2017, and ending in February 2018 would have an EPM-episode benchmark price based on the second set of 2017 EPM-episode benchmark prices (for EPM episodes initiated between October 1, 2017, and December 31, 2017), and it would be captured in the CY 2018 EPM performance year (performance year 2) because it ended between January 1, 2018, and December 31, 2018. We refer to section III.D.2.a. of this proposed rule for further discussion on the definition of EPM performance years.

We propose to update historical EPM-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 EPM participant's historical EPM-episode 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 EPM episodes each EPM performance year. The six update factors for each of the previously stated components would be EPM-participant hospital-specific and would be weighted by the percent of the Medicare payment for which each of the six components accounts in the EPM participant's historical EPM episodes. The weighted update factors would be applied to historical EPM-participant 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 EPM participant's historical EPM-episode payments the component represents, and summing together the results. Each of an EPM participant's six update factors would be based on how inputs have changed in the various Medicare payment systems for the specific EPM participant.

As an example, we will assume for purposes of this example that 50 percent of an EPM participant's historical EPM-episode payments were for inpatient acute care services, 15 percent were for physician services, 35 percent were for SNF services, and 0.0 percent were for the remaining services. We will also assume for purposes of 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 EPM participant in this example would have its historical average EPM-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 sections III.D.4.c through d. of this proposed rule. Also, as discussed further in sections III.D.4.c. through d. the update factors would vary by price MS–DRG. For example, in CABG model episodes, the update factors would be calculated separately for the anchor hospitalization portion of episodes and the post-anchor hospitalization portion of episodes, as described in section III.D.4.d.

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 EPM-participant hospital-specific update factors. Instead of using historical EPM episodes attributed to a specific hospital, region-specific update factors would be based on all historical EPM episodes initiated at any IPPS hospital within the region with historical EPM episodes, regardless of whether or not the MSAs in which the hospitals are located were selected for inclusion in the models. We refer to the CJR Final Rule for further discussion of our specific methodology and considerations for adopting this methodology for updating historical EPM-episode payments for ongoing payment system updates (80 FR 73342 through 73446).

The proposal for updating episode payments for ongoing annual Medicare payment updates is included in § 512.300(c)(10). We seek comment on our proposal for updating episodes payments for ongoing annual Medicare payment updates.

(6) Blend Hospital-Specific and Regional Historical Data

We propose to calculate EPM-episode benchmark prices using a blend of EPM-participant hospital-specific and regional historical average EPM-episode payments, including historical EPM-episode payments for all IPPS hospitals that are in the same U.S. Census division, which is discussed further in section III.D.4.b.(7) of this proposed rule. Specifically, we propose to blend two-thirds of the EPM-participant hospital-specific historical EPM-episode payments and one-third of the regional historical EPM-episode payments to set an EPM participant's EPM-episode benchmark prices for the first 2 performance years of the proposed EPMs (CYs 2017 and 2018). For performance year 3 of the EPMs (CY

2019), we propose to adjust the proportion of the EPM-participant hospital-specific and regional historical EPM-episode payments used to calculate the EPM-episode benchmark prices from two-thirds EPM-participant hospital-specific and one-third regional to one- third EPM-participant hospital-specific and two-thirds regional. Finally, we propose to use only regional historical EPM-episode payments for performance years 4 and 5 of the EPMs (CYs 2020 and 2021) to set an EPM participant's EPM episode-benchmark prices, rather than a blend between the hospital-specific and regional historical EPM episode payments.

Consistent with our methodology for the CJR model, we propose two exceptions. First, we propose to use only regional historical EPM-episode payments to calculate EPM episode-benchmark prices for EPM participants with low historic EPM-episode volume (80 FR 73544). For SHFFT model episodes, this exception applies to SHFFT model participants with fewer than 50 historical SHFFT model episodes in total across the 3 historical years. For AMI model episodes anchored by MS–DRGs 280–282, this exception applies to AMI model participants with fewer than 75 of these particular AMI model historical episodes in total across the 3 historical years. For AMI model episodes anchored by PCI MS–DRGs 246–251, this exception applies to AMI model participants with fewer than 125 of this particular AMI model historical episodes in total across the 3 historical years. For CABG model episodes, this exception applies to CABG model participants with fewer than 50 historical CABG model episodes in total across the 3 historical years. The proposed thresholds for low historic volume in this proposed rule are higher than the CJR model threshold for low historical LEJR episode volume of 20 episodes in total across the 3 historical years. The higher thresholds are based on the volume thresholds from the BPCI Model 2 Risk Track B for 90-day episodes, which increase when the ratio of within-hospital episode spending variation to between-hospital episode spending variation increases. That is, as EPM episode payment variation increases within a hospital relative to EPM-episode payment variation between hospitals, it is necessary to have more EPM episodes at that hospital to estimate a stable EPM- episode benchmark price using data from only that hospital. We propose to set higher thresholds for the SHFFT, AMI, and CABG models based on internal analysis from BPCI episode data that shows higher within-hospital episode spending variation relative to between-hospital episode spending variation for episodes anchored by the EPM MS–DRGs, compared to episodes anchored by MS–DRGs 469 and 470 included in the CJR model.[65]

Second, in the case of an EPM participant that has undergone a merger, consolidation, spin-off, or other reorganization that results in a new hospital entity without 3 full years of historical claims data, we propose that EPM participant hospital-specific historical EPM-episode payments would be determined using the historical EPM episode payments attributed to their predecessor(s), as in the CJR model (80 FR 73544).

The aforementioned proposals align with our method for blending EPM participant hospital-specific and regional data under the CJR model. We refer to the CJR model Final Rule for further discussion on alternatives to and reasons for adopting this methodology for the CJR model, which informs our proposal with respect to the proposed EPMs (80 FR 73346–73349).

The proposal for blending payments when establishing participants' benchmark and quality-adjusted targets and certain exceptions is included in § 512.300(c)(2), (3), and (4). We note that the specific order of steps, and how this step fits in with others, is discussed further in section III.D.4.c. of this proposed rule. We seek comment on our proposal for blending payments when establishing participants' benchmark and quality-adjusted targets as well as the proposed exceptions.

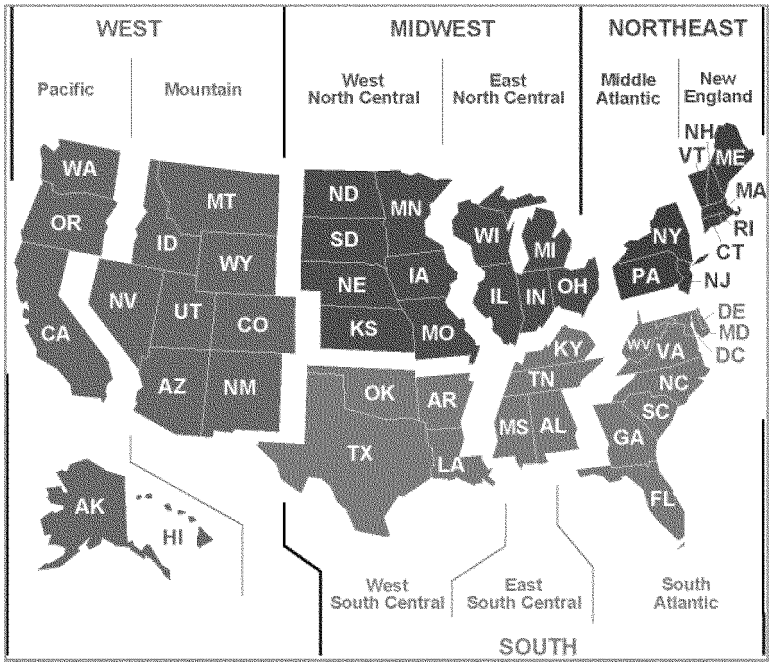
(7) Define Regions as U.S. Census Divisions

As we do for the CJR model, for all 5 performance years, we proposed to define ''region'' as one of the nine U.S. Census divisions[66] in Figure 1 (80 FR 73349 through 73350).

[65] BPCI Model 2 Baseline Price Common Template calculations for 90-day episodes in Risk Track B calculates BPCI volume thresholds based on the ratio of within-hospital episode spending variation and between-hospital episode spending variation for BPCI Clinical Episodes, based on episodes that met BPCI eligibility criteria and that began in July 1, 2009–June 30, 2012.

[66] 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.

FIGURE 1: U.S. CENSUS DIVISIONS[67]



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 clarify that we would ascribe the same regional component of EPM-episode benchmark prices for EPM participants in MSAs that span U.S. Census divisions. That is, selected MSAs that span U.S. Census divisions would be attributed to one U.S. Census division for purposes of calculating the regional component of an EPM-episode benchmark price. Specifically, we will attribute an MSA to the U.S. Census division in which the majority of people in the MSA reside.

The proposal to define a region as one of the nine U.S. Census divisions is included in § 512.300(c)(2). We seek comment on our proposal to define region in this manner.

(8) Normalize for Provider-Specific Wage Adjustment Variations

Some variation in historical EPM-episode payments across hospitals in a region may be due to wage adjustment differences in Medicare 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) that reflects the relative wage level in the geographic are of the facility or practitioner (or the beneficiary's 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 another hospital's EPM episode-benchmark price with a different level would introduce unintended pricing distortion not based on utilization pattern differences.

To preserve how wage levels affect provider payment amounts, while minimizing the distortions introduced when calculating the regional-component of blended EPM-episode benchmark prices, we propose to normalize for wage indices at the claim level for both historical EPM-episode payments and actual EPM-episode payments. As discussed in section III.D.3.b. of proposed rule, we propose to utilize the CMS Price (Payment) Standardization Detailed Methodology to calculate EPM-episode benchmark and quality-adjusted target prices and actual EPM-episode spending. This methodology removes wage level differences in calculating standardized payment amounts.

We believe it is important to reintroduce wage index variations near the end of the EPM-episode price-setting methodology and when calculating actual EPM-episode payments during an EPM performance year, to account for the differences in cost for care redesign across different geographic areas of the country. For example, hiring additional hospital staff to aid in patient follow-up during the post-discharge period of an AMI model episode would be significantly more costly in San Francisco than in rural Idaho. If we do not reintroduce wage index variations into EPM-episode benchmark price and actual EPM-episode payment calculations, we would calculate reconciliation and repayment amounts that would not capture labor cost variation throughout the country, and EPM participants in certain regions may see less opportunity and financial incentive to invest in care redesign. Thus, when setting EPM-episode benchmark prices and calculating actual EPM-episode payments, we propose to reintroduce the hospital-specific wage variations by multiplying EPM-episode payments by the wage normalization factor when calculating the EPM-episode benchmark prices and actual EPM -episode payments for each EPM participant, as described in section III.D.4.c. of the proposed rule.

We propose to use the following algorithm to create a wage normalization factor: 0.7 * IPPS wage index + 0.3. The 0.7 approximates the

[67] *http://www.eia.gov/consumption/commercial/census_maps.cfm.*

labor share in IPPS, IRF PPS, SNF, and HHA Medicare payments. The specific order of steps, and how this step fits in with others, is discussed further in section III.D.4.c. of the proposed rule. We refer to the CJR model Final Rule for more detailed information on our normalization process adopted for the CJR model (80 FR 73350 through 73352).

The proposal to normalize for provider-specific wage adjustment variations is included in § 512.300(c)(12). We seek comment on our proposal to normalize for these variations.

(9) Combining Episodes To Set Stable Benchmark and Quality-Adjusted Target Prices

For the purposes of having sufficient episode volume to set stable EPM-episode benchmark and quality-adjusted target prices, we propose generally to follow the process from the CJR model to calculate severity factors, EPM-participant hospital-specific weights, and region-specific weights that allow us to surmount issues of low volume for EPM episodes with particular characteristics by aggregating EPM episodes and portions of EPM episodes across dimensions that include anchor MS–DRGs, the presence of AMI ICD–CM diagnosis code on the anchor inpatient claim, and the presence of a major complication or comorbidity for anchor CABG MS–DRGs (80 FR 73352 through 73353). Where the CJR Final Rule refers to anchor factors, for the purposes of this proposed rule we refer to severity factors to avoid confusion when performing calculations pertaining to expenditures that occurred during the anchor hospitalization and after the anchor hospitalization in CABG model episodes.

For SHFFT model episodes, we propose to combine episodes with price MS–DRGs 480–482 to use a greater historical episode volume to set more stable SHFFT episode benchmark and quality-adjusted target prices. To do so, we propose to calculate severity factors for episodes with price MS–DRGs 480 and 481 equal to—

$$MS-DRG\ 480\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 480\ episode\ spend}{Natl.avg.\ MS-DRG\ 482\ episode\ spend}$$

$$MS-DRG\ 481\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 481\ episode\ spend}{Natl.avg.\ MS-DRG\ 482\ episode\ spend}$$

The national average would be based on SHFFT model episodes attributed to any IPPS hospital. The resulting severity factors would be the same for all SHFFT model participants. For each SHFFT model participant, a hospital weight would be calculated using the following formula, where SHFFT model episode counts are SHFFT-model-participant hospital-specific and based on the SHFFT model episodes in the 3 historical years used in SHFFT model episode benchmark and quality-adjusted target price calculations:

$$\frac{Count\ of\ episodes\ with\ price\ MS-DRG\ 480-482}{\begin{array}{c}MS-DRG\ 480\ episode\ count * MS-DRG\ 480\ severity\ factor + \\ MS-DRG\ 481\ episode\ count * MS-DRG\ 481\ severity\ factor + \\ MS-DRG\ 482\ episode\ count * 1\end{array}}$$

A SHFFT model participant's hospital-specific average episode payment would be calculated by multiplying such participant's hospital weight by its combined historical average episode payment (sum of historical episode payments for historical episodes with price MS–DRGs 480–482 divided by the number of historical episodes with price MS–DRGs 480–482). 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 episode with price MS–DRGs 480 and 481 as more than one episode (assuming episodes with price MS– DRGs 480 and 481 have higher average payments than episodes with price MS–DRG 482) so that the pooled historical average episode payment, and subsequently the SHFFT model episode benchmark and quality-adjusted target prices, are not skewed by the SHFFT model participant's relative breakdown of historical episodes with price MS–DRGs 480 and 481 versus historical episodes with price MS–DRG 482.

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 SHFFT model episodes that were attributed to any IPPS hospital located within the region. The hospital-specific and region-specific pooled historical average payments would be blended together as discussed in section III.D.4.b.(6) of the proposed rule. The specific order of steps, and how this step fits in with others, is discussed further in section III.D.4.c. of the proposed rule.

Afterwards, the blended pooled calculations would be ''unpooled'' by setting the episode benchmark price for episodes with price MS–DRG 482 to the resulting calculation, and by multiplying the resulting calculation by the severity factors to produce the episode benchmark prices for episodes with price MS–DRGs 480 and 481. Applying the discount factor as discussed in III.D.4.b.(10) and III.D.4.c. would result in the SHFFT model quality-adjusted target prices for episodes with price MS–DRGs 480–482.

For episodes in the AMI model with price MS–DRGs in 280–282 or 246–251

and without readmissions for CABG MS–DRGs, we propose to follow an analogous procedure to the SHFFT model with the following modifications. First we propose to group episodes with price MS–DRGs 280–282 separately from episodes with price MS–DRGs 246–251 for the calculations. Second, we propose to calculate severity factors for episodes with price MS–DRGs 280–282 as—

$$MS-DRG\ 280\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 280\ episode\ spend}{Natl.avg.\ MS-DRG\ 282\ episode\ spend}$$

$$MS-DRG\ 281\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 281\ episode\ spend}{Natl.avg.\ MS-DRG\ 282\ episode\ spend}$$

Third, we propose to calculate hospital-specific weights and region-specific weights for episodes with price MS–DRGs 280–282 as—

$$\frac{Count\ of\ episodes\ with\ price\ MS-DRG\ 280-282}{\begin{array}{c}MS-DRG\ 280\ episode\ count\ *\ MS-DRG\ 280\ severity\ factor\ + \\ MS-DRG\ 281\ episode\ count\ *\ MS-DRG\ 281\ severity\ factor\ + \\ MS-DRG\ 282\ episode\ count * 1\end{array}}$$

Fourth, we propose to calculate severity factors for episodes with price MS–DRG 246–251 as—

$$MS-DRG\ 246\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 246\ episode\ spend}{Natl.avg.\ MS-DRG\ 251\ episode\ spend}$$

$$MS-DRG\ 247\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 247\ episode\ spend}{Natl.avg.\ MS-DRG\ 251\ episode\ spend}$$

$$MS-DRG\ 248\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 248\ episode\ spend}{Natl.avg.\ MS-DRG\ 251\ episode\ spend}$$

$$MS-DRG\ 249\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 249\ episode\ spend}{Natl.avg.\ MS-DRG\ 251\ episode\ spend}$$

$$MS-DRG\ 250\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 250\ episode\ spend}{Natl.avg.\ MS-DRG\ 251\ episode\ spend}$$

Fifth, we propose to calculate hospital-specific weights and region-specific weights for episodes with price MS–DRG 246–251 as—

$$\frac{Count\ of\ episodes\ with\ price\ MS-DRG\ 246-251}{\begin{array}{c}MS-DRG\ 246\ episode\ count\ *\ MS-DRG\ 246\ severity\ factor\ + \\ MS-DRG\ 247\ episode\ count\ *\ MS-DRG\ 247\ severity\ factor\ + \\ MS-DRG\ 248\ episode\ count\ *\ MS-DRG\ 248\ severity\ factor\ + \\ MS-DRG\ 249\ episode\ count\ *\ MS-DRG\ 249\ severity\ factor\ + \\ MS-DRG\ 250\ episode\ count\ *\ MS-DRG\ 250\ severity\ factor\ + \\ MS-DRG\ 251\ episode\ count * 1\end{array}}$$

After blending historical and regional pooled episode payments for episodes with price MS–DRGs 280–282, the blended pooled calculations would be ''unpooled'' by setting the episode benchmark price for price MS–DRG 282 to the resulting calculation, and by multiplying the resulting calculation by the severity factors to produce the episode benchmark prices for price MS–DRGs 280 and 281.

After blending historical and regional pooled episode payments for episodes with price MS–DRGs 246–251, the blended pooled calculations would be ''unpooled'' by setting the episode benchmark price for price MS–DRG to the resulting calculation, and by multiplying the resulting calculation by the severity factors to produce the episode benchmark prices for price MS–DRGs 246–251.

Applying the discount factor as discussed in III.D.4.b.(10) and III.D.4.c would result in the quality-adjusted target prices for price MS–DRGs 280–282 and 246–251.

For episodes in the CABG model with price MS–DRGs in 231–236, we propose to calculate severity factors, hospital-specific weights, and region-specific weights separately for the anchor hospitalization portion of CABG model episodes and the post-anchor hospitalization portion of CABG model episodes.

For the anchor hospitalization portion of CABG model episodes, we propose to follow an analogous procedure to the SHFFT model with the anchor hospitalization portion of CABG model episodes grouped by the price MS–DRG. Specifically, we propose to calculate anchor hospitalization severity factors for price MS–DRGs 231–235 as—

$$MS-DRG\ 231\ anchor\ hosp.severity\ factor = \frac{Natl.avg.\ MS-DRG\ 231\ anchor\ hosp.spend}{Natl.avg.\ MS-DRG\ 236\ anchor\ hosp.spend}$$

$$MS-DRG\ 232\ anchor\ hosp.severity\ factor = \frac{Natl.avg.\ MS-DRG\ 232\ anchor\ hosp.spend}{Natl.avg.\ MS-DRG\ 236\ anchor\ hosp.spend}$$

$$MS-DRG\ 233\ anchor\ hosp.severity\ factor = \frac{Natl.avg.\ MS-DRG\ 233\ anchor\ hosp.spend}{Natl.avg.\ MS-DRG\ 236\ anchor\ hosp.spend}$$

$$MS-DRG\ 234\ anchor\ hosp.severity\ factor = \frac{Natl.avg.\ MS-DRG\ 234\ anchor\ hosp.spend}{Natl.avg.\ MS-DRG\ 236\ anchor\ hosp.spend}$$

$$MS-DRG\ 235\ anchor\ hosp.severity\ factor = \frac{Natl.avg.\ MS-DRG\ 235\ anchor\ hosp.spend}{Natl.avg.\ MS-DRG\ 236\ anchor\ hosp.spend}$$

We also propose to calculate hospital-specific weights and region-specific weights for the anchor hospitalization portion of CABG model episodes as—

$$\frac{Count\ of\ episodes\ with\ price\ MS-DRG\ 231-236}{\begin{array}{c}MS-DRG\ 231\ episode\ count\ *\ MS-DRG\ 231\ anchor\ hosp.severity\ factor\ +\\ MS-DRG\ 232\ episode\ count\ *\ MS-DRG\ 232\ anchor\ hosp.severity\ factor\ +\\ MS-DRG\ 233\ episode\ count\ *\ MS-DRG\ 233\ anchor\ hosp.severity\ factor\ +\\ MS-DRG\ 234\ episode\ count\ *\ MS-DRG\ 234\ anchor\ hosp.severity\ factor\ +\\ S-DRG\ 235\ episode\ count\ *\ MS-DRG\ 235\ anchor\ hosp.severity\ factor\ +\\ MS-DRG\ 236\ episode\ count\ *\ 1\end{array}}$$

After blending historical and regional pooled anchor hospitalization payments for the CABG model episodes, the blended pooled calculations would be ''unpooled'' by setting the price MS–DRG 236 anchor hospitalization benchmark price to the resulting calculation, and by multiplying the resulting calculation by the severity factors to produce the anchor hospitalization benchmark prices for price MS–DRGs 231–235.

For the post-anchor hospitalization portion of CABG model episodes, we propose to follow an analogous procedure to the SHFFT model with the post-anchor hospitalization portion of

CABG model episodes grouped in the following manner—

- With AMI diagnosis on the anchor inpatient claim and price MS–DRG with major complication or comorbidity (231, 233, or 235)
- With AMI diagnosis on the anchor inpatient claim and price MS–DRG without major complication or comorbidity (232, 234, or 236)
- Without AMI diagnosis on the anchor inpatient claim and price MS–DRG with major complication or comorbidity (231, 233, or 235)
- Without AMI diagnosis on the anchor inpatient claim and price MS–DRG without major complication or comorbidity (232, 234, or 236)

Specifically, we propose to calculate post-anchor hospitalization severity factors as—

$$w/AMI\ and\ MS-DRG\ w/MCC\ post-anchor\ hosp.severity\ factor = \frac{Natl.avg.\ w/AMI\ and\ MS-DRG\ w/MCC\ post-anchor\ hosp.spend}{Natl.avg.\ w/o\ AMI\ and\ MS-DRG\ w/o\ MCC\ post-anchor\ hosp.spend}$$

$$w/AMI\ and\ MS-DRG\ w/o\ MCC\ post-anchor\ hosp.severity\ factor = \frac{Natl.avg.\ w/AMI\ and\ MS-DRG\ w/o\ MCC\ post-anchor\ hosp.spend}{Natl.avg.\ w/o\ AMI\ and\ MS-DRG\ w/o\ MCC\ post-anchor\ hosp.spend}$$

$$w/o\ AMI\ and\ MS-DRG\ w/MCC\ post-anchor\ hosp.severity\ factor = \frac{Natl.avg.\ w/o\ AMI\ and\ MS-DRG\ w/\ MCC\ post-anchor\ hosp.spend}{Natl.avg.\ w/o\ AMI\ and\ MS-DRG\ w/o\ MCC\ post-anchor\ hosp.spend}$$

We also propose to calculate hospital-specific weights and region-specific weights for the post-anchor hospitalization portion of CABG model episodes as—

$$\frac{Count\ of\ episodes\ with\ price\ \ MS-DRG\ 231-236}{\begin{pmatrix} w/AMI\ and\ MS-DRG\ w/MCC\ \ episode\ count\ * \\ w/AMI\ and\ MS-DRG\ w/MCC\ post-anchor\ hosp.severity\ factor \end{pmatrix} + \begin{pmatrix} w/AMI\ and\ MS-DRG\ w/o\ MCC\ \ episode\ count\ * \\ w/AMI\ and\ MS-DRG\ w/o\ MCC\ post-anchor\ hosp.severity\ factor \end{pmatrix} + \begin{pmatrix} w/o\ AMI\ and\ MS-DRG\ w/MCC\ episode\ count\ * \\ w/o\ AMI\ and\ MS-DRG\ w/MCC\ post-anchor\ hosp.severity\ factor \end{pmatrix} + (w/o\ AMI\ and\ MS-DRG\ w/o\ MCC\ episode\ count\ *\ 1)}$$

After blending historical and regional pooled post-anchor hospitalization payments for the CABG model episodes, the blended pooled calculations would be ''unpooled'' by setting the without AMI ICD–CM diagnosis code on the anchor inpatient claim and price MS–DRG without major complication or comorbidity (232, 234, or 236) post-anchor hospitalization benchmark price to the resulting calculation, and by multiplying the resulting calculation by the severity factors to produce the post-anchor hospitalization benchmark prices for:

- With AMI diagnosis on the anchor inpatient claim and price MS–DRG with major complication or comorbidity (231, 233, or 235)
- With AMI diagnosis on the anchor inpatient claim and price MS–DRG without major complication or comorbidity (232, 234, or 236)
- Without AMI diagnosis on the anchor inpatient claim and price MS–DRG with major complication or comorbidity (231, 233, or 235)

We propose to calculate episode benchmark prices for CABG model episodes by summing combinations of CABG anchor hospitalization benchmark prices and CABG post-anchor hospitalization benchmark prices. Applying the discount factor as discussed in III.D.4.b.(10) and III.D.4.d of this proposed rule would result in the quality-adjusted target prices for CABG model episodes.

For episodes in the AMI model with CABG readmissions, we propose to perform no additional blending of hospital-specific and regional-specific episode payments. We propose to calculate the AMI model episode benchmark and quality-adjusted target prices for such episodes as described in section III.D.4.e. of this proposed rule.

The proposals to combine episodes to set stable benchmark and quality-adjusted target prices are included in § 512.300(c)(13). We seek comment on our proposals for combining episodes for these purposes.

(10) Effective Discount Factors

As discussed in section III.D.2.c. of this proposed rule, we propose to make EPM participants partly or fully accountable for EPM-episode payments in relationship to the EPM quality-adjusted target price. As part of this, in setting an episode quality-adjusted target price for an EPM participant, we propose to apply an effective discount factor to an EPM participant's hospital-

specific and regional blended historical EPM-episode payments for a performance period. We expect EPM participants to have a significant opportunity to improve the quality and efficiency of care furnished during episodes in comparison with historical practice, because the EPMs would facilitate the alignment of financial incentives among providers caring for EPM beneficiaries. Our proposed effective discount factors are intended to serve as Medicare's portion of reduced expenditures from an EPM episode with any EPM-episode expenditures below the quality-adjusted target price potentially available as reconciliation payments to the EPM participant where the anchor hospitalization occurred.

For the EPMs, we propose to establish a 3 percent effective discount factor to calculate the quality-adjusted target prices for EPM participants in the below acceptable and acceptable quality categories, as discussed in section III.E.3.f. of this proposed rule and similar to the CJR model (80 FR 73355). The effective discount factor to calculate the quality-adjusted target price for EPM participants in the good and excellent quality categories would be 2 percent and 1.5 percent, respectively.

Because of the proposed phase-in of repayment responsibility as discussed in section III.D.2.c. of this proposed rule, with no responsibility in either performance year 1 or performance year 2 (NDR) and only partial repayment responsibility in performance year 2 (DR) and all of performance year 3, an EPM participant with actual EPM-episode payments that exceed the quality-adjusted target prices multiplied by the EPM participant's number of EPM episodes to which each quality-adjusted target price would apply in performance year 2 (DR) and performance year 3 would owe Medicare less that would otherwise result from this calculation. As discussed in section III.E.3.f of this rule, an ''applicable discount factor'' applies to repayment amounts in performance years 2 and 3 while this repayment responsibility is being phased-in. We refer to section III.E.1. and specifically Tables 20 through 28 in this proposed rule for further illustration of the discount percentages that would apply for reconciliation payment and Medicare repayment over the 5 EPM performance years. We believe this methodology offers EPM participants an opportunity to create savings for themselves and Medicare, while also maintaining or improving quality of care for EPM model beneficiaries.

The proposal to establish discount factors that would apply to the quality categories is included in § 512.300(d). We seek comment on our proposal to establish discount factors that apply to the quality categories.

c. Approach To Combine Pricing Features for all SHFFT Model Episodes and AMI Model Episodes Without CABG Readmissions

The following presents our proposed methodology for combining the pricing features presented in section III.D.4.b. of this proposed rule with respect to SHFFT model episodes and AMI model episodes without a CABG readmission.

- Step 1—Calculate historical EPM-episode payments for episodes that were initiated during the 3-historical-years of each applicable EPM (that is, individually for each of the SHFFT and AMI models) (section III.D.4.b.(3) of this proposed rule) for all IPPS hospitals for all Medicare Part A and B services included in the EPM episodes. Limit the potential AMI model episodes to those episodes with price MS–DRGs in 280–282 or 246–251 and without readmissions for CABG MS–DRGs. We note that specific PBPM payments may be excluded from historical EPM-episode payment calculations as discussed in section III.D.6.d. of this proposed rule.
- Step 2—Remove the effects of special payment provisions (section III.D.3.b. of this proposed rule) and normalize for wage index differences (section III.D.4.b.(8) of this proposed rule) by standardizing Medicare FFS payments at the claim-level.
- Step 3—Prorate Medicare payments for included episode services that span a period of care that extends beyond the episode (section III.D.3.c. of this proposed rule.).
- Step 4—Trend forward the 2 oldest historical years of data to the most recent year of historical data (section III.D.4.b.(4) of this proposed rule). Separate national trend factors would be applied for each combination of price MS–DRGs.
- Step 5—Cap high episode payment episodes with a region- and price-MS–DRG-specific high payment ceiling (section III.D.3.d. of this proposed rule), using the episode output from the previous step.
- Step 6—Group episodes based on price MS–DRGs (SHFFT MS–DRGs 480–482; AMI MS–DRGs 280–282; PCI MS–DRGs 246–251). Within each group of episodes, calculate severity factors and EPM-participant hospital-specific weights (section III.D.4.b.(9) of this proposed rule) using the episode output from the previous step to pool together episodes in each group of price MS–DRGs, resulting in EPM-participant hospital-specific pooled historical average episode payments for each group of price MS–DRGs. Similarly, calculate region-specific weights to calculate region-specific pooled historical average episode payments for each group of price MS–DRGs.
- Step 7—Calculate EPM-participant hospital-specific and region-specific weighted update factors (section III.D.4.b.(5) of this proposed rule). Multiply each EPM-participant hospital-specific and region-specific pooled historical average episode payment by its corresponding EPM-participant hospital-specific and region-specific weighted update factors to calculate EPM-participant hospital-specific and region-specific updated, pooled, historical average episode payments.
- Step 8—Blend together each EPM-participant hospital-specific updated, pooled, historical average episode payment with the corresponding region-specific updated, pooled, historical average episode payment according to the proportions for the EPM performance year (III.D.4.b.(6) of this proposed rule). EPM participants 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.
- Step 9—Multiply the outputs of step (8) by the wage normalization factor described in section III.D.4.b.(8) of this proposed rule to reintroduce geographic variation. For purposes of this proposed rule, we will define the three outputs of this step as the standard episode benchmark price for—

++ SHFFT model episodes with price MS–DRG 482

++ AMI model episodes with price MS–DRG 282 without readmission for CABG, and

++ AMI model episodes with price MS–DRG 251 without readmission for CABG.

- Step 10—Multiply the output of step (9) by the appropriate severity factors (step (6) of this calculation process and detailed in section III.D.4.b.(9) of this proposed rule) to calculate the standard episode benchmark prices for—

++ SHFFT model episodes with price MS–DRGs 480–481

++ AMI model episodes with price MS–DRGs 280–281 without readmission for CABG

++ AMI model episodes with price MS–DRGs 246–250 without readmission for CABG

• Step 11—Multiply the outputs of step (9) and (10) by 1 minus the applicable effective discount factor based on the EPM participant's quality category as described in sections III.D.4.b.(10) and III.E.3.f. of this proposed rule. For purposes of this proposed rule, we will define the outputs of this step as the episode quality-adjusted target prices for:

++ SHFFT model episodes with price MS–DRGs 480–482

++ AMI model episodes with price MS–DRGs 280–282 without readmission for CABG, and

++ AMI model episodes with price MS–DRGs 246–251 without readmission for CABG

d. Approach To Combine Pricing Features for CABG Model Episodes

The following presents our proposed methodology for combining the pricing features presented in section III.D.4.b of this proposed rule with respect to CABG model episodes.

(1) Anchor Hospitalization Portion of CABG Model Episodes

• Step 1—Calculate historical episode payments that occurred during the anchor hospitalization of CABG model episodes that were initiated during the 3 historical years (section III.D.4.b.(2) of this proposed rule) for all IPPS hospitals for all Medicare Part A and B services included in the episodes. We note that specific PBPM payments may be excluded from historical episode payment calculations as discussed in section III.D.6. of this proposed rule.

• Step 2—Apply steps III.D.4.c.(2) through (4) to the results of step (1) with trend factors calculated based on the anchor hospitalization portion of CABG model episodes with price MS–DRGs 231–236.

• Step 3—Group the anchor hospitalization portion of episodes based on price MS–DRGs 231–236 and apply steps III.D.4.c.(6) through (10) to the anchor hospitalization portion of the CABG model episodes with severity factors, hospital-specific weighted update factors, and region-specific weighted update factors calculated to apply based only on the anchor hospitalization portion of CABG model episodes with price MS–DRGs 231–236. For purposes of this proposed rule, we will define the output of this step as CABG anchor hospitalization benchmark prices for CABG model episodes with price MS–DRGs 231–236.

(2) Approach To Combine Pricing Features for Post-Anchor Hospitalization Portion of CABG Model Episodes

• Step 1—Calculate historical episode payments that occurred after the anchor hospitalization for CABG model episodes that were initiated during the 3 historical years (section III.D.4.b.(2) of this proposed rule) for all IPPS hospitals for all Medicare Parts A and B services included in the episodes. We note that specific PBPM payments may be excluded from historical episode payment calculations as discussed in section III.D.6. of this proposed rule.

• Step 2—Apply steps III.D.4.c.(2) through (4) to the results of step (1) with trend factors calculated based on the post-anchor hospitalization portion of CABG model episodes with price MS–DRGs 231–236, as described in section III.D.4.b.(4) of this proposed rule.

• Step 3—Group the post-anchor hospitalization portion of episodes based on—

++ With AMI diagnosis on the anchor inpatient claim and price MS–DRG with major complication or comorbidity (231, 233, or 235)

++ With AMI diagnosis on the anchor inpatient claim and price MS–DRG without major complication or comorbidity (232, 234, or 236)

++ Without AMI diagnosis on the anchor inpatient claim and price MS–DRG with major complication or comorbidity (231, 233, or 235)

++ Without AMI diagnosis on the anchor inpatient claim and price MS–DRG without major complication or comorbidity (232, 234, or 236).

Then apply steps III.D.4.c.(6)–(10) to the post-anchor hospitalization portion of the CABG model episodes with severity factors, hospital-specific weights, and region-specific weights calculated to apply based on the groups previously described in this step. For purposes of this proposed rule, we will define the output of this step as CABG post-anchor hospitalization benchmark prices for CABG model episodes corresponding to the groups described in this step.

(3) Combine CABG Anchor Hospitalization Benchmark Price and CABG Post-Anchor Hospitalization Benchmark Price

• Step 1—Sum the CABG anchor hospitalization benchmark price corresponding to each price CABG MS–DRG and the CABG post-anchor hospitalization price corresponding to each of the post-anchor hospitalization groupings described in III.D.4.d.(2). For purposes of this proposed rule, we will define the outputs of those calculations to be CABG model episode benchmark prices for—

++ CABG model episodes with price MS–DRG 231 and with AMI diagnosis

++ CABG model episodes with price MS–DRG 232 and with AMI diagnosis

++ CABG model episodes with price MS–DRG 233 and with AMI diagnosis

++ CABG model episodes with price MS–DRG 234 and with AMI diagnosis

++ CABG model episodes with price MS–DRG 235 and with AMI diagnosis

++ CABG model episodes with price MS–DRG 236 and with AMI diagnosis

++ CABG model episodes with price MS–DRG 231 and without AMI diagnosis

++ CABG model episodes with price MS–DRG 232 and without AMI diagnosis

++ CABG model episodes with price MS–DRG 233 and without AMI diagnosis

++ CABG model episodes with price MS–DRG 234 and without AMI diagnosis

++ CABG model episodes with price MS–DRG 235 and without AMI diagnosis, and

++ CABG model episodes with price MS–DRG 236 and without AMI diagnosis

The CABG episode benchmark prices for each price CABG MS–DRG with AMI diagnosis would also apply as AMI model episode benchmark prices for AMI model episodes with price MS–DRGs 231–236.

• Step 2—Multiply the results of step 1 by the appropriate effective discount factor that reflects the EPM participant's quality category as described in sections III.D.4.b.(10) and III.E.3.f. of this proposed rule. For purposes of this proposed rule, we will define the outputs of this step to be CABG model episode quality-adjusted target prices for—

++ CABG model episodes with price MS–DRG 231 and with AMI diagnosis

++ CABG model episodes with price MS–DRG 232 and with AMI diagnosis

++ CABG model episodes with price MS–DRG 233 and with AMI diagnosis

++ CABG model episodes with price MS–DRG 234 and with AMI diagnosis

++ CABG model episodes with price MS–DRG 235 and with AMI diagnosis

++ CABG model episodes with price MS–DRG 236 and with AMI diagnosis

++ CABG model episodes with price MS–DRG 231 and without AMI diagnosis

++ CABG model episodes with price MS–DRG 232 and without AMI diagnosis

++ CABG model episodes with price MS–DRG 233 and without AMI diagnosis
++ CABG model episodes with price MS–DRG 234 and without AMI diagnosis
++ CABG model episodes with price MS–DRG 235 and without AMI diagnosis, and
++ CABG model episodes with price MS–DRG 236 and without AMI diagnosis

The episode quality-adjusted target prices for each anchor CABG MS–DRG with AMI diagnosis would also apply as AMI model episode quality-adjusted target prices for AMI model episodes with price MS–DRGs 231–236. The effective discount factor applied to calculate the AMI model episode quality-adjusted target prices for AMI model episodes with price MS–DRGs 231–236 could differ from the effective discount factor applied to calculate CABG model episode quality-adjusted target prices for CABG model episodes if the participant had different levels of quality performance on the AMI and CABG model composite quality scores that determine the discount factor for the quality-adjusted target prices.

e. Approach To Combine Pricing Features for AMI Model Episodes With CABG Readmissions

The following presents our proposed methodology for combining the pricing features presented in section III.D.4.b of this proposed rule with respect to AMI model episodes with a CABG readmission.

In general, the AMI model episode benchmark price for AMI model episodes with CABG readmission is the sum of the applicable standard AMI model episode benchmark price for an AMI episode without readmission corresponding to the AMI price MS–DRG and the applicable CABG anchor hospitalization benchmark price for a CABG model episode corresponding to the CABG readmission MS–DRG in the AMI model.

• Step 1—For each combination of AMI price MS–DRG and CABG readmission MS–DRG, sum the corresponding AMI model episode benchmark price and CABG anchor hospitalization benchmark price. This results in 54 possible CABG readmission AMI model episode benchmark prices, corresponding to—

++ Price MS–DRG 280; Readmission MS–DRG 231
++ Price MS–DRG 280; Readmission MS–DRG 232
++ Price MS–DRG 280; Readmission MS–DRG 233
++ Price MS–DRG 280; Readmission MS–DRG 234
++ Price MS–DRG 280; Readmission MS–DRG 235
++ Price MS–DRG 280; Readmission MS–DRG 236
++ Price MS–DRG 281; Readmission MS–DRG 231
++ Price MS–DRG 281; Readmission MS–DRG 232
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++ Price MS–DRG 281; Readmission MS–DRG 235
++ Price MS–DRG 281; Readmission MS–DRG 236
++ Price MS–DRG 282; Readmission MS–DRG 231
++ Price MS–DRG 282; Readmission MS–DRG 232
++ Price MS–DRG 282; Readmission MS–DRG 233
++ Price MS–DRG 282; Readmission MS–DRG 234
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++ Price MS–DRG 282; Readmission MS–DRG 236
++ Price MS–DRG 246; Readmission MS–DRG 231
++ Price MS–DRG 246; Readmission MS–DRG 232
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++ Price MS–DRG 250; Readmission MS–DRG 236
++ Price MS–DRG 251; Readmission MS–DRG 231
++ Price MS–DRG 251; Readmission MS–DRG 232
++ Price MS–DRG 251; Readmission MS–DRG 233
++ Price MS–DRG 251; Readmission MS–DRG 234
++ Price MS–DRG 251; Readmission MS–DRG 235, and
++ Price MS–DRG 251; Readmission MS–DRG 236

• Step 2—Multiply the results of step 1 by the effective discount factor that reflects the EPM participant's quality category, as described in sections III.D.4.b.(10) and III.E.3.f. of this proposed rule. For purposes of this proposed rule, we will define the outputs of this step to be AMI model episode quality-adjusted target prices for the same combinations of AMI price MS–DRG and readmission MS–DRG in step (1).

5. Process for Reconciliation

a. Net Payment Reconciliation Amount (NPRA)

Consistent with the CJR model, we propose to conduct reconciliation for each EPM by calculating an EPM-specific NPRA for each EPM participant (80 FR 73381 through 73383). After the completion of an EPM performance year, we propose to retrospectively calculate an EPM participant's actual EPM-episode payments based on the EPM episode definitions as discussed in sections III.C.3. and III.C.4. of this proposed rule and the payment policies applicable to calculating actual EPM-episode payments as discussed in the subsections of section III.D.3 of this proposed rule.

We propose to compare each EPM participant's actual EPM episode payments to its quality-adjusted target prices. We propose, as discussed in

section III.D.4. of this proposed rule, that an EPM participant would have multiple quality-adjusted target prices for EPM episodes ending in a given performance year, based on the anchor MS–DRG for the EPM episode, whether the EPM episode included a chained anchor hospitalization; whether the EPM episode included readmission for CABG MS–DRGs; whether the EPM episode included an AMI ICD–CM diagnosis code on the anchor inpatient claim; the performance year when the EPM episode was initiated; when the EPM 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 the potential effective discount factors. The difference between each EPM episode's actual EPM episode payment and the relevant quality-adjusted target price under the EPM (calculated as quality-adjusted target price subtracted by actual EPM episode payment) would be aggregated for all EPM episodes in each EPM for an EPM participant within the performance year, representing the NPRA. For performance year 2, we would perform two separate aggregations in order to create two NPRAs—one reflecting episodes that ended during performance year 2 (NDR), and a second for episodes that ended during performance year 2 (DR).

We propose to not include any reconciliation payments or repayments to Medicare under the EPMs for a given performance year when calculating actual episode spending and, therefore the NPRA for a subsequent performance year. We want to incentivize providers to provide high-quality and efficient care in all years of the EPMs. If reconciliation payments for a performance year were counted as Medicare expenditures in a subsequent performance year, an EPM participant 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 propose to not have the NPRA for a given performance year be impacted by EPM repayments or reconciliation payments made in a prior performance year. For example, if an EPM participant receives a $10,000 reconciliation payment in the second quarter of 2018 for achieving episode spending below the quality-adjusted target price for performance year 1, that $10,000 reconciliation payment amount would not be included in the performance year 2 calculations of actual EPM-episode payments.

The NPRA would be subject to the stop-loss and stop-gain limits described in section III.D.7.b. of this proposed rule.

b. Payment Reconciliation

We propose to retrospectively reconcile an EPM participant's actual EPM-episode payments against the quality-adjusted target prices 2 months after the end of the performance year. 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 an EPM reconciliation payment or hold hospitals responsible for repayment, as applicable, in quarter 2 of that calendar year.

We also propose that during the following performance year's reconciliation process, we would calculate the prior performance year's actual EPM episode payments a second time to account for final claims run-out and any canceled EPM episodes, due to overlap with other models or other reasons as specified in section III.C.4.b of this proposed rule. This calculation, termed the subsequent reconciliation, 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, as well as the post-episode spending and ACO overlap calculation in order to determine the amount of the payment Medicare would make to the EPM participant or such participant's repayment amount. We note that the subsequent reconciliation calculation would be combined with the previous calculation of NPRA for a performance year to ensure the stop-loss and stop-gain limits discussed in section III.D.7.b. of this proposed rule are not exceeded for a given performance year.

For the performance year 1 reconciliation process, we would calculate an EPM participant's NPRA as previously described, and if positive, such participant would receive the amount as a reconciliation payment from Medicare, subject to the stop-gain limit for performance year 1. If negative, the EPM participant would not be responsible for repayment to Medicare, consistent with our proposal to phase in financial responsibility beginning in the second quarter of performance year 2.

For the performance year 2 reconciliation process, we would calculate two separate NPRAs for an EPM participant—one for episodes that ended during performance year 2 (NDR) and a second for episodes that ended during performance year 2 (DR). While these NPRAs would be separately determined for each of these two periods, whether an EPM participant receives a Medicare reconciliation payment or makes a Medicare repayment in performance year 2 would be determined based on the sum of these two separately determined NPRAs. The NPRA for both performance year 2 (NDR) and performance year 2 (DR) would be subject to the same stop-gain limit of 5 percent, but because EPM participants would only have repayment responsibility for negative NPRA in performance year 2 (DR), the stop-loss limit of 5 percent would only apply to performance year 2 (DR). Thus, if an EPM participant's NPRA for the first quarter of performance year 2 is positive, that amount would be counted toward a reconciliation payment from Medicare, subject to the stop-gain limit for performance year 2. If negative, the EPM participant would not be responsible for repayment to Medicare of the amount determined for performance year 2 (NDR). If an EPM participant's NPRA is positive for episodes ending during performance year 2 (DR), that amount would be counted toward a reconciliation payment from Medicare, subject to the stop-gain limit for performance year 2. If negative, the EPM participant would be responsible for repayment to Medicare of the amount determined for episodes ending during performance year 2 (DR), subject to the stop loss limits for performance year 2 (DR).

During the subsequent reconciliation process for performance year 2, we would also calculate the prior performance year's actual EPM episode payments a second time separately for episodes that ended during performance year 2 (NDR) and for episodes that ended during performance year 2 (DR).

Also, starting with the EPM reconciliation process for performance year 2, in order to determine the reconciliation or repayment amount, the amount from the subsequent reconciliation calculation would be combined with the NPRA for that subsequent year. The result of the post-episode spending calculation for performance year 1, as proposed in section III.D.7.e., and the dollar amount of the EPM discount percentage that was paid out as shared savings to an ACO during the prior year as specified in section III.D.6.b. of this proposed rule, would also be added to the NPRA and subsequent reconciliation calculation in

order to create the reconciliation payment or repayment amount. If the amount is positive, and if the EPM participant is in the acceptable or better quality category for the EPM (discussed further in section III.E.3.f of this proposed rule), the EPM participant would receive the amount as a reconciliation payment from Medicare. If the amount is negative, Medicare would hold the EPM participant responsible for repaying the absolute value of the repayment amount following the rules and processes for all other Medicare debts. For example, when we conduct reconciliation for performance year 2 in early 2019, we would calculate the performance year 2 NPRA and the subsequent reconciliation calculation, post-episode spending, and ACO overlap calculation for performance year 1. These amounts would be added together to create the reconciliation payment or repayment amount.

Note that given our proposal to not hold EPM participants financially responsible for repayment for the first performance year, during the reconciliation process for performance year 2, the subsequent reconciliation 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. Likewise given our proposal to not hold EPM participants financially responsible for repayment for episodes ending during performance year 2 (NDR), during the reconciliation process for performance year 3, the subsequent reconciliation calculation amount for performance year 2 (NDR) would be compared against the performance year 2 (NDR) NPRA to ensure that the sum of the NPRA calculated for performance year 2 (NDR) and the subsequent reconciliation calculation for performance year 2 (NDR) is not less than zero.

For performance year 2 (DR) and performance years 3 through 5, though, we propose that Medicare would hold the participant responsible for repaying part or all of the absolute value of the repayment amount, as proposed in section III.D.2.c. of this proposed rule, following the rules and processes for all other Medicare debts. Table 11 illustrates a simplified example of how the subsequent reconciliation calculation may affect the following year's reconciliation payment. Note that this example assumes the EPM participant is not responsible for post-episode spending or ACO overlap for performance year 1.

TABLE 11—SAMPLE RECONCILIATION RESULTS

	Performance year 1 (2017) NPRA	Performance year 1 subsequent reconciliation calculation	Difference between PY1 subsequent reconciliation calculation and NPRA	Performance year 2 (2018) NPRA *	Reconciliation payment made to EPM participant in quarter 2 2019
Hospital A	$50,000	$40,000	($10,000)	$25,000	$15,000

* Note the calculation of NPRA for performance year 2 represents the combined amounts of the NPRA for performance year 2 (NDR) and performance year 2 (DR).

The second column represents the NPRA calculated for performance year 1, meaning that EPM participant Hospital A's aggregated episode payment was $50,000 below the sum of quality-adjusted target prices for all of Hospital A's EPM episodes. The third column represents the subsequent reconciliation calculation, indicating that when calculating actual EPM-episode payments during performance year 1 a second time, we determined that Hospital A's aggregated EPM-episode payment was $40,000 below the sum of quality-adjusted target prices for all of Hospital A's EPM episodes, due to claims run out, 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.

This reconciliation process would account for overlap between the CJR model and other CMS models and programs as discussed in section III.D.6.b of this proposed rule, and would also involve updating performance year EPM-episode claims data. We also note that in cases where an EPM participant has appealed one or more of its EPM quality measure results through the HIQR Program appeal process (which is not part of the proposed EPM appeals process), where such HIQR Program appeal findings would result in a different effective discount factor for the EPM participant to calculate the quality-adjusted target prices from EPM-episode benchmark prices, the subsequent reconciliation calculation would account for these changes as well.

For example, for performance year 1 for these EPMs in 2017, we would capture claims submitted by March 1, 2018, and reconcile payments for EPM participants approximately 6 months after the end of the performance year 1 in quarter 2 of calendar year 2018. We would carry out the subsequent reconciliation calculation in the following year in quarter 2 of calendar 2019, simultaneously with the reconciliation process for the second performance year, 2018. Table 12 displays the reconciliation timeframes for the EPMs.

TABLE 12—PROPOSED TIMEFRAME FOR RECONCILIATION FOR EPMS

EPM performance year	EPM performance period	Reconciliation claims submitted by	NPRA calculation	Second reconciliation, ACO overlap, and post-episode spending calculations	Calculation amounts included in reconciliation payment and repayment amounts
Year 1 *	Episodes beginning on or after July 1, 2016 and ending through December 31, 2017.	March 1, 2018	Q2 2018	March 1, 2019	Q2 2019

TABLE 12—PROPOSED TIMEFRAME FOR RECONCILIATION FOR EPMS—Continued

EPM performance year	EPM performance period	Reconciliation claims submitted by	NPRA calculation	Second reconciliation, ACO overlap, and post-episode spending calculations	Calculation amounts included in reconciliation payment and repayment amounts
Year 2	Episodes ending January 1, 2018 through December 31, 2018.	March 1, 2019	Q2 2019	March 1, 2020	Q2 2020
Year 3	Episodes ending January 1, 2019 through December 31, 2019.	March 1, 2020	Q2 2020	March 2, 2021	Q2 2021
Year 4	Episodes ending January 1, 2020 through December 31, 2020.	March 2, 2021	Q2 2021	March 1, 2021	Q2 2021
Year 5	Episodes ending January 1, 2021 through December 31, 2021.	March 1, 2022	Q2 2022	March 1, 2023	Q2 2023

*Note that the reconciliation for Year 1 would not include repayment responsibility from EPM participants.

We propose 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 EPM episodes. We believe that beginning to pull 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 EPM 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 recognize 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 believe that the 2 months of claims run-out would be an accurate reflection of EPM-episode payments and consistent with the claims run-out timeframes used for reconciliation in other payment models, such as BPCI Models 2 and 3 and the CJR model. 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 are concerned that this approach would significantly delay earned reconciliation payments under the EPMs.

However, we propose to conduct a subsequent reconciliation calculation 14 months after the end of a performance year to account for canceled episodes, post-episode spending, overlap with other CMS models and programs, and any remaining claims available at that time. The proposals for the annual reconciliation and subsequent reconciliation calculation are included in § 512.305 and § 512.307. We seek comment on these proposals for an annual reconciliation and subsequent calculation.

c. Reconciliation Report

For EPM participants to receive timely and meaningful feedback on their performance under the models as well as better understand the basis of their reconciliation payment or Medicare repayment for a given performance year, if any, we propose to annually issue to EPM participants a reconciliation report, similar to the CJR Reconciliation Report we make available to CJR participants (80 FR 73408). We propose that these reports would contain the following information:

- Information on the EPM participant's composite quality score described in section III.E.3.a. through III.E.3.e of this proposed rule.
- The total actual episode payments for the EPM participant.
- The NPRA.
- Whether the EPM participant is eligible for a reconciliation payment or must make a repayment to Medicare.
- The NPRA and subsequent reconciliation calculation amount for the previous performance year, as applicable.
- The post-episode spending amount and ACO overlap calculation for the previous performance year, as applicable.
- The reconciliation payment or repayment amount.

For performance year 2, we propose that the reconciliation report would include information separately for the performance year 2 (NDR) and performance year 2 (DR) portions of that year.

As discussed in section III.D.8 of this proposed rule, EPM participants would review their reconciliation report and would be required to provide written notice of any error, in a calculation error form that must be submitted in a form and manner specified by CMS. Unless the EPM participant provides such notice, the reconciliation report would be deemed final within 45 calendar days after it is issued, and CMS would proceed with payment or repayment. The proposal to issue a reconciliation report is included in § 512.305(f). We seek comments on our proposal to issue a reconciliation report to EPM participants and what other information, if any, would be helpful to include in this report.

6. Adjustments for Overlaps With Other Innovation Center Models and CMS Programs

a. Overview

Three issues may arise in overlap situations that must be addressed under EPM. First, we acknowledge that there may be circumstances where a hospital in a geographic area selected for the AMI, CABG or SHFFT model is also participating in BPCI for the same episode. We refer to this as ''provider overlap.'' Second, there may be situations where a Medicare beneficiary receives care that could potentially be counted under more than one episode or total cost of care payment model. We refer to this as ''beneficiary overlap.'' Finally, EPM reconciliation payments and Medicare repayments made under Parts 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 beneficiary's cost of care under Medicare. Therefore, a payment reconciliation policy is necessary in order to credit the entity that is closest to that care for the episode of care in terms of time, location, and care management responsibility.

We establish our proposal for provider overlap at § 512.100(b) and § 512.230(g). We establish our proposal for beneficiary overlap at § 512.230(f), § 512.230(h), and § 512.230(i). We establish our proposal for payment reconciliation at § 512.210 and

§ 512.305. We seek comment on our proposals to account for overlap between EPMs and other CMS models or programs.

b. Provider Overlap

(1) BPCI Participant Hospitals in Geographic Areas Selected for EPMs

Provider overlap exists when a hospital in a geographic area selected for the AMI, CABG or SHFFT model is also an episode initiator in BPCI for an episode anchored by that EPM's DRG. BPCI is an episode payment model testing AMI, CABG, SHFFT, and 45 other episodes in acute care, post-acute care, or both acute care and post-acute care settings.

Similar to CJR, we propose that in the geographic areas where the AMI, CABG and SHFFT models will be implemented, an acute care hospital participating in BPCI Model 2 or 4 will participate in an EPM for episodes anchored by EPM MS–DRGs that are not covered under the hospital's current BPCI agreement. If a BPCI hospital in an EPM-selected area withdraws from BPCI episodes anchored by EPM MS–DRGs, the BPCI hospital will participate in the EPMs for which it was previously excluded. This proposal promotes accountable care by ensuring beneficiary coverage by BPCI or an EPM in selected areas.

We establish the proposal for hospitals in geographic areas selected for EPMs that are also participating in BPCI episodes anchored by EPM DRGs at § 512.100(b). We seek comment on this proposal.

(2) BPCI Physician Group Practice (PGP) Episode Initiators in Hospitals Participating in EPMs

It is possible that a physician in a BPCI PGP may treat a Medicare beneficiary in a hospital participating in one or more EPM. We propose that if a beneficiary is admitted to an EPM participant for an episode anchored by EPM MS–DRGs covered under the PGP's BPCI agreement and the attending or operating physician on the admission's inpatient claim is a member of the BPCI PGP, the BPCI episode will take precedence over the EPM episode for which the hospital would otherwise be the accountable entity. In other words, if, for any portion of the EPM episode, a beneficiary would also be in a BPCI PGP episode, we will cancel or never initiate the EPM episode. For example—

- A beneficiary is admitted for a CABG to an EPM participant in the CABG model. The attending or operating physician on the inpatient claim for the admission is in a BPCI Model 2 PGP participating in CABG. The episode is initiated under BPCI; an EPM episode does not initiate.
- A beneficiary is admitted for an AMI to an EPM participant in the AMI model. The beneficiary receives a PCI while hospitalized. The attending or operating physician on the inpatient claim for the admission is in a BPCI Model 2 PGP participating in PCI episodes but not medical AMI episodes. A PCI episode is initiated under BPCI; an EPM episode does not initiate.
- A beneficiary is admitted for an AMI to an EPM participant in the AMI model. A PCI was not part of the beneficiary's treatment. The attending or operating physician on the inpatient claim for the admission is in a BPCI Model 2 PGP participating in PCI episodes only. The episode is initiated under the AMI model. A PCI episode under BPCI Model 2 would not initiate unless a PCI were performed on the beneficiary, and
- A beneficiary is admitted for an AMI to an EPM participant in the AMI model. A CABG was not part of the beneficiary's treatment. The attending or operating physician on the inpatient claim is in a BPCI Model 2 PGP participating in CABG episodes only. The episode is initiated under the AMI model. A CABG episode under BPCI Model 2 would not be initiated unless a CABG was performed on the beneficiary while hospitalized.

We establish the proposal for BPCI PGP episode initiators in hospitals participating in EPMs at § 512.230(g). We seek comment on this proposal.

(c) Beneficiary Overlap

(1) Beneficiary Overlap With BPCI

We also need to account for instances where a different model's episode could initiate during an ongoing EPM episode. We propose that any BPCI Model 2, 3 or 4 episode, regardless of its anchor DRG exclusion status from an EPM episode definition, takes precedence over an AMI, CABG or SHFFT episode such that it would cancel or prevent the initiation of an AMI, CABG or SHFFT episode. For example—

- If a beneficiary is in an ongoing AMI model episode and is treated for SHFFT by a hospital, PGP physician, or post-acute care provider participating in a BPCI SHFFT episode, the initial AMI model episode will be canceled. The second entity will initiate a new episode under BPCI subject to the payment rules under that model, and
- If a beneficiary is in an ongoing BPCI AMI episode and is readmitted for SHFFT to an EPM participant in the SHFFT model, the BPCI episode would continue and the SHFFT model episode would not initiate.

Participants in BPCI have an expectation that eligible episodes will be part of the BPCI model test, whereas based on our proposal EPM participants would be aware that episodes may be canceled when there is overlap with BPCI episodes. We aim to preserve the integrity of ongoing model tests without introducing major modifications that could make evaluation of existing models more challenging. Given the current scheduled end date for the BPCI, we are proposing to give precedence to episodes covered under BPCI Models 2, 3 and 4 initiated on or before September 30, 2018.

We acknowledge this BPCI–EPM overlap policy differs from the CJR beneficiary overlap policy, where a beneficiary may be in a CJR LEJR episode and a non-LEJR BPCI episode concurrently. However, in CJR this overlap is rare. Within the 90-day post-hospital discharge period, included readmissions occur for less than 1 percent of LEJR beneficiaries. In contrast, included readmissions occur for approximately 25 percent of AMI and CABG beneficiaries. The high incidence of included readmissions for AMI, CABG and SHFFT episodes necessitates a different policy to avoid double-paying savings and double-counting losses, as well as not initiating new episodes when the readmission is a complication of care during the first episode that could be managed.

We considered alternative options for dealing with situations in which a beneficiary in an EPM episode could also be in a BPCI episode, including allowing the first episode initiated to take precedence regardless of the model under which it occurred. This would encourage more accountable care, particularly with AMI, CABG, and SHFFT episodes that are more likely to involve readmissions for complications than generally occur with LEJR. However, preventing BPCI episodes from being initiated, particularly those initiated by post-acute care providers which, by definition, occur after an anchor hospitalization, could substantially reduce the number of such episodes and our ability to fully test BPCI. Moreover, operational challenges due to different timelines for payment reconciliation are of concern.

We establish the proposal for beneficiary overlap with BPCI at § 512.230(h). We seek comment on this proposal.

(2) Beneficiary Overlap With the CJR Model and Other EPMs

As discussed in section III.C.4. of this proposed rule, if a beneficiary is in a SHFFT, AMI or CABG model or CJR episode and has a hospital readmission that is not excluded from the ongoing episode definition and would otherwise initiate an episode in a different EPM or the CJR model, that hospital readmission will not initiate another episode or cancel the ongoing episode. If a beneficiary is in a SHFFT, AMI or CABG model episode or CJR episode and has a hospital readmission that is excluded from the ongoing episode definition and could initiate an episode in a different EPM or the CJR model, the subsequent EPM or CJR episode will initiate, the ongoing episode would continue, and both episodes will occur concurrently. For example—

- The CJR model episode definition does not exclude the MS–DRGs that would initiate a SHFFT model episode. If a beneficiary is in the CJR model and receives SHFFT at an EPM participant in the SHFFT model during the ongoing CJR episode, the CJR episode will continue and the SHFFT model episode will not initiate;
- SHFFT model episode definition does not exclude the MS–DRGs that would initiate a CJR LEJR episode. If a beneficiary is in the SHFFT model and receives an LEJR at a CJR hospital during the ongoing SHFFT episode, the SHFFT episode will continue and the CJR episode will not initiate;
- The SHFFT model episode definition does not exclude the MS–DRGs that would initiate an AMI model episode. If a beneficiary is in the SHFFT model and is readmitted for an AMI to an EPM participant in the AMI model during the ongoing SHFFT model episode, the SHFFT model episode will continue and the AMI model episode will not initiate;
- The AMI model episode definition does not exclude the MS–DRGs that would initiate a CABG model episode. If a beneficiary is in the AMI model and is readmitted for a CABG to the same or another EPM participant in the CABG model during the ongoing AMI model episode, the AMI model episode will continue and the CABG model episode will not initiate.

We believe that an overlap policy that gives precedence to the ongoing episode over subsequent episodes initiated during the post-hospital discharge period, except where the second admission is explicitly excluded, aligns with our stated goal of encouraging more accountable care. Moreover, this policy would establish an operationally straightforward policy for future EPMs.

We establish the proposal for beneficiary overlap with the CJR model and other EPMs at § 512.230(i). We seek comment on this proposal.

(3) Beneficiary Overlap With Shared Savings Models and Programs

We expect many beneficiaries in an AMI, CABG or SHFFT model episode will also be aligned or attributed to a Shared Savings Program participant or a participant in an ACO model initiated by the CMS Innovation Center. For the purposes of this discussion, the term ACO will be used generically to refer to either Shared Savings Program or Innovation Center ACO models. Shared savings payments to ACOs and shared savings losses repaid by ACOs to CMS have the potential to overlap with EPM reconciliation payments. As with CJR, we propose to attribute savings achieved during an EPM episode to the EPM participant, and include EPM reconciliation payments for ACO-aligned beneficiaries as ACO expenditures. In order to address comments received during rulemaking for CJR, we propose to test an alternative strategy to address ACO overlap. Specifically, we propose to exclude beneficiaries from EPMs who are aligned to ACOs in the Next Generation ACO model and End Stage Renal Disease (ESRD) Seamless Care Organizations (ESCOs) in the Comprehensive ESRD Care initiative in tracks with downside risk for financial losses. We do not propose to exclude beneficiaries aligned to Shared Savings Program ACOs in Tracks 1, 2, or 3 at this time. However, we seek comment on excluding beneficiaries from EPMs that are prospectively assigned to SSP Track 3 as well as to other financial risk tracks. The Shared Savings Program is a national program. We do not believe that testing a new approach to addressing overlap, which could potentially disrupt ACO investments, operations, and care redesign activities, would be appropriate at this time prior to a test with a smaller population. We plan to monitor and learn from the test of excluding beneficiaries prospectively assigned to an ACO from risk tracks and consider these results and comments in future rule-making.

Several strong considerations drive us to otherwise follow CJR precedent for addressing ACO overlap. First, CMS continues to avoid double payment of savings and double recoupment of losses, which is an important principle of successful payment reform. Second, in implementing the EPMs, there would be no additional operational effort due to consistency in ACO overlap policies across models. In this respect, we anticipate little to no difficulty in replicating prior policy as new episode payment models are introduced. Third, this would have no negative financial impact on EPM participants, an important consideration for future EPMs. The payment reconciliation for EPM participants is described in section III.D.5. of this proposed rule.

Therefore, we propose to follow the policy set forth in the CJR Final Rule for accounting for overlap between EPMs and the Shared Savings Program and ACO models other than the Next Generation ACO model and CEC listed previously.

Additionally, for programmatic consistency among ACO models and programs, given that our ACO models generally are tested for the purpose of informing future potential changes to the Shared Savings Program, we believe that the ACO model overlap adjustment policy should be aligned with the Shared Savings Program policy. Thus, we propose that under EPMs, we would make an adjustment to the reconciliation amount 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 an EPM hospital also participates in the ACO and the beneficiary in the EPM episode is also aligned to that ACO. This adjustment would be necessary to ensure that the applicable discount under the EPM is not reduced because a portion of that discount is paid out in shared savings to the ACO and thus, indirectly, back to the hospital.

However, we propose not to make an adjustment under EPMs when a beneficiary receives an AMI, SHFFT, or CABG at a hospital participating in the corresponding EPM and is aligned to an ACO in which the hospital is not participating. While this proposal would leave overlap unaccounted for in such situations, we do not believe it would be appropriate to hold responsible for repayment the hospital that managed the beneficiary during the episode through an EPM adjustment, given that the participant may have engaged in care redesign and reduced spending during the EPM episode. The participant may be unaware that the beneficiary is also aligned to an ACO. However, we recognize that as proposed this policy would allow an unrelated ACO full credit for the Medicare savings achieved during the episode. The evaluation of each of the EPMs, as discussed in section IV. of this proposed rule, would examine overlap in such

situations and the potential effect on Medicare savings.

We note that our proposed policy as outlined in this proposed rule would entail CMS reclaiming from the EPM participant any discount percentage paid out as shared savings for the Shared Savings Program or ACO models only when the hospital is an ACO participant and the beneficiary is aligned with that ACO, while other total cost of care models such as the Comprehensive Primary Care Plus initiative (CPC+) would adjust for the discount percentage in their calculations. We believe that other ACO models in testing that share operating principles with the Shared Savings Program should follow the same policies as the EPM 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.

However, there are circumstances when an alternative option may be appropriate to consider. Therefore, we are also considering an EPM–ACO overlap policy that would exclude from EPMs beneficiaries who are aligned to ACOs in the Next Generation ACO model and ESCOs in the Comprehensive ESRD Care Initiative in tracks with downside risk for financial losses. Some ACOs have successfully managed acute care and post-acute care expenditures below regional or national mean costs, and expressed that the current CJR and BPCI ACO overlap policies deprives them of a key source of savings. We are aware of situations in certain markets that seem to reduce opportunities for ACOs to achieve savings given historic experience that indicates these particular ACOs are able to manage the care within episodes as successfully as EPM participants. Attributing savings to participants in episode payment models, such as CJR participants and EPM participants under this proposed rule, creates a problem where the ACO is accountable for coordinating a beneficiary's care over a performance year but is not able to benefit from savings achieved from episodes completed during the performance year. Data shows that post-acute care spending is among the most significant sources of savings for ACOs currently, and where they focus significant investments.[68] [69]

Certain considerations weigh against exclusion of all ACO-aligned beneficiaries from participation in EPM episodes. Such a blanket exclusion would remove a large proportion of Medicare FFS beneficiaries from the EPMs, many of whom would inevitably receive care at EPM participants. This would dilute the power of the EPM test and generalizability of EPM findings. Additionally, differences between ACO beneficiary alignment algorithms do not support a blanket exclusion. It is more operationally feasible to identify and exclude beneficiaries who are prospectively aligned to ACOs. In retrospective alignment models, beneficiaries may be aligned to an ACO at the end of the performance year, before the performance year, or preliminarily aligned to one ACO before the performance year and subsequently aligned to a different ACO after all qualifying services are considered. In retrospective alignment, there will be significant numbers of beneficiaries aligned at final reconciliation to a given ACO who were not identified as preliminarily aligned to that ACO prior to the performance year. That is, they were identified either as unaligned to any ACO or aligned to a different ACO. In prospective alignment models and tracks, the list of aligned beneficiaries is available prior to the start of the performance year and a beneficiary's alignment does not change on the basis of his or her utilization in the performance year (subject to various exclusions made on a quarterly basis, such as a beneficiary's election into a Medicare Advantage plan).

Because ACOs in two-sided risk arrangements have stronger incentives than those in one-sided risk arrangements to reduce total cost of care, especially given the possibility of paying CMS shared losses, we believe that ACOs in two-sided risk arrangements may be best positioned to assume the risk associated with EPM episodes, while ACOs in one-sided risk arrangements may be less well-positioned to do so. ACOs in one-sided risk arrangements, such as those in the Shared Savings Program Track 1, do not bear the risk of owing losses to CMS. In contrast, ACOs in two-sided risk arrangements, such as the Next Generation ACO model, are held to as much as 80 percent to 100 percent of first dollar losses. Thus, we believe that pursuing a blanket exclusion from EPMs of aligned beneficiaries from all ACOs would inappropriately disadvantage EPM participants that carry significant financial risk under EPM.

This proposed ACO overlap policy would grant ACOs in models and tracks with the highest levels of downside risk for financial losses—the Next Generation ACO model and tracks of the Comprehensive ESRD Care Initiative with downside risk for financial losses—paramount financial opportunity in exchange for accepting total cost of care responsibility for their beneficiaries. EPM participants may still realize opportunities to save by partnering with ACOs, but outside of the EPM arrangement. Specifically, we refer to section IIII.I. of this proposed rule which describes opportunities for gainsharing allowed under these models.

This policy tests the effects of such an ACO-aligned beneficiary exclusion policy within a broader test of the effectiveness of EPMs. We can learn its impact on EPM participants and ACOs that have beneficiaries excluded from EPMs, as well as ACOs that do not have beneficiaries excluded from EPMs. This will improve our understanding about the appropriate entity to hold accountable for the costs within the episode. For this reason we are recommending this test be limited to the AMI, CABG, and SHFF, and CJR models, and ACO models being conducted under CMS' Innovation Center, and are not proposing to implement the policy more broadly to other ACOs, such as those in the Shared Savings Program. In proposing the exclusion of beneficiaries in only a limited number of ACO initiatives we attempt to balance the desire to build a new payment reform initiative while mitigating the potential challenges to existing shared savings models and programs. We seek comment on this proposal as well as input on extending the proposal to CJR and other ACOs accepting two-sided risk, such as those ACOs in the Shared Savings Program Track 3.

We have investigated CMS data related to the services under consideration in the AMI, CABG and SHFFT models. A small fraction of total beneficiaries aligned to ACOs qualifying for this exclusion in fact have relevant anchor hospitalizations that would initiate an EPM in a given calendar year. For instance, from 2013 through 2015, about 2.4 percent of beneficiaries aligned to Pioneer ACO model participants had an anchor hospitalization that would have

[68] McWilliams J, Michael Laura A, Hatfield Michael E, Chernew Bruce E, Landon and Aaron L Schwartz. ''Early Performance of Accountable Care Organizations in Medicare—NEJM.'' N Engl J Med. Massachusetts Medical Society, 13 Apr. 2016. Web. 02 May 2016. *http://www.ncbi.nlm.nih.gov/pubmed/27075832.*

[69] McWilliams J, Michael Michael E. Chernew, Bruce E Landon and Aaron L Schwartz. ''Performance Differences in Year 1 of Pioneer Accountable Care Organizations.'' N Engl J Med. (2015); 372(20): 1927–936. Massachusetts Medical Society, 15 Apr. 2015. Web. 02 May 2016. *http://www.ncbi.nlm.nih.gov/pubmed/25875195.*

initiated an AMI, CABG or SHFFT model.

We have considered several additional options to account for EPM–ACO beneficiary overlap prior to proposing the strategy outlined previously. We considered whether to split the risk, including at an equal sharing rate, at the time of financial reconciliation between EPM participants and ACOs when episodes included overlapping beneficiaries. This has the advantage of mitigating the supposed ''carve out'' of ACO expenditures, but requires CMS to arbitrarily declare a level of risk sharing. We are also concerned about the operational feasibility of such calculations, given that reconciliation would have to occur in tandem, resulting in long delays in payments or recoupments for both EPM participants and ACOs. We also considered whether to attribute to ACOs the more favorable of either the episode-specific target price or the actual expenditures incurred by the beneficiary during the episode time period. However, this policy would result in significant losses to the Medicare Trust Fund, as the double payment of savings/losses would be a certainty.

We establish the proposal to exclude from the EPMs beneficiaries who are aligned to an ACO in the Next Generation ACO Model or Comprehensive ESRD Care Initiative at § 512.230(f). We establish the proposal to attribute savings achieved during an EPM episode to the EPM participant, and include EPM reconciliation payments for other ACO-aligned beneficiaries as ACO expenditures at § 512.305 and § 512.307. We seek comment on our proposals to account for beneficiary overlap with shared savings models and programs.

d. Payment Reconciliation of Overlap With Non-ACO CMS Models and Programs

In general, Per-Beneficiary Per-Month (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 an EPM, but the clinical relationship between the services paid by the PBPM payments and the EPM will vary. For purposes of this proposed rule, we consider clinically related those services paid by PBPM payments that are for the purpose of care coordination and care management of any beneficiary diagnosis or hospital admission not excluded from an EPM's episode definition, as discussed in section III.C. of this proposed rule.

As with CJR, we propose to include PBPM payments for new and enhanced services in EPM reconciliation calculations if we determine, on a model by model basis, that the services paid by PBPM payments are (1) not excluded from an EPM model's episode definition; (2) rendered during the episode; and (3) paid for from the Medicare Part A or Part B Trust Funds. 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.C. of this proposed rule. The PBPM payments for clinically related services would not be excluded from the EPMs' historical episodes used to calculate target prices when the PBPM payments are made from the Part A or Part B Trust Fund, and they would not be excluded from calculation of actual episode expenditures during an EPM's 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 EPMs, as discussed in section III.C. of this proposed rule) would not be the only mechanism for exclusion of a service from an EPM. All such PBPM model payments we determine are clinically unrelated would be excluded as discussed in this proposed rule. Finally, all services paid by PBPM payments funded through the Innovation Center's appropriation under section 1115A of the Act would be excluded from the EPMs, without a specific determination of their clinical relationship to an EPM. We believe 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 EPMs. In addition, because these services are not paid for from the Medicare Parts A or B Trust Funds, we are not confident that they would be covered by Medicare under existing law. Therefore, we believe the services paid by these PBPM payments are most appropriately excluded from the EPMs. Our proposal for the treatment of services paid by PBPM payments in the EPMs would pertain to all existing models with PBPM payments, as well as future models and programs that incorporate PBPM payments. We believe that this proposal is fully consistent with our goal of including all related Part A and Part B services in the EPMs, as discussed in section III.C. of this proposed rule.

As with CJR, the OCM and MCCM services and conditions are excluded from the AMI, CABG, and SHFFT episode definitions and thus their payments are excluded from EPM reconciliation (listed on the CMS Web page at *https://innovation.cms.gov/Files/x/cjr-pbpmexclusions.xlsx*). While the OCM will pay for new or enhanced services through PBPM payments funded by the Medicare Part B Trust Fund, we do not believe these services are clinically related to the EPMs. The OCM incorporates episode-based payment initiated by chemotherapy treatment, a service generally reported with ICD–9–CM and ICD–10–CM codes that will be excluded from the AMI, CABG, and SHFFT episode definition in section III.C. of this proposed rule. We believe 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 AMI, CABG and SHFFT model episodes. Therefore, we propose that services paid by PBPM payments under the OCM be excluded from the AMI, CABG and SHFFT models. Similarly, we propose to exclude services paid by PBPM payments under the MCCM. 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 will not include such

payments in the AMI, CABG and SHFFT models' episode spending calculations. In addition, unlike the regular hospice benefits, which are furnished to beneficiaries in lieu of curative care and which therefore can be coordinated during an AMI, CABG or SHFFT model episode, the services furnished under the MCCM will be in addition to curative services. We note that we are including such curative services in the EPM episode, as they are consistent with our episode definition described in III.C. of this proposed 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.

We acknowledge there may be new models 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 EPM episodes through the same sub regulatory approach that we are proposing to use to update the episode definitions (excluded MS–DRGs and ICD–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 in the EPMs based on the standards we propose to use to update EPM episode definitions that are discussed in section III.C. of this proposed rule.

If we determine that a PBPM payment would primarily be used to pay for services to manage an excluded clinical condition, we would exclude the PBPM payment from the EPM 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 EPM 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 EPM episode definitions discussed in section III.C. of this 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.

The payment reconciliation is described in section III.D.5. of this proposed rule. As with CJR, 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 EPM-related reconciliation payments and repayments as described in section III.D.5. of this proposed rule, for beneficiaries who are also in EPM episodes.

We establish the proposal for accounting for non-ACO services and payments in the EPM reconciliation process at § 512.210. We seek comment on this proposal.

7. Limits or Adjustments to EPM Participants' Financial Responsibility

a. Overview

We recognize that hospitals that would be designated for participation in the proposed EPMs currently vary with respect to their readiness to function under an EPM with regard to their organizational and systems capacity and structure, as well as their beneficiary population served. Some EPM participants may be more quickly able to demonstrate high quality performance and savings than others, even though we proposed that the EPM-episode benchmark prices be based predominantly on the hospital's own historical EPM-episode utilization in the early years of the EPMs. We also note that providers may be incentivized to excessively reduce or shift utilization outside of an EPM's episode by the proposed payment policies of the EPMs. In order to mitigate any excessive repayment responsibility for EPM participants or reduction or shifting of care outside an EPM episode, especially beginning in performance year 2 of the EPMs when we propose to begin to phase in responsibility for repaying Medicare for excess EPM-episode payments, we propose several specific policies as follows.

b. Limit on Actual EPM-Episode Payment Contribution to Repayment Amounts and Reconciliation Payments

(1) Limit on Actual EPM-Episode Payment Contribution to Repayment Amounts

As discussed in section III.D.3.d. of this proposed rule regarding our proposed pricing adjustment for high payment EPM episodes, EPM participants would not bear financial responsibility for actual EPM-episode payments greater than a ceiling set at 2 standard deviations above the mean regional EPM-episode payment. Nevertheless, EPM participants would begin to bear repayment responsibility beginning performance year 2 (DR) for those EPM episodes where actual EPM-episode payments are greater than the EPM quality-adjusted target prices up to the level of the regional EPM-episode ceiling. When aggregated across all EPM episodes in a model, the total money owed to Medicare by an EPM participant for actual EPM-episode payments above the applicable EPM quality-adjusted target price could be substantial if a hospital's EPM episodes generally had high payments. As an extreme example, if a hospital had all of its EPM episodes paid at 2 standard deviations above the mean regional EPM-episode payment, the EPM participant would need to repay Medicare a large amount of money, especially if the number of EPM episodes was large.

To limit a hospital's overall repayment responsibility for actual EPM-episode payments under the EPMs, (hereafter called a ''stop-loss limit''), we propose to establish the same stop-loss limits that were adopted for the CJR model (80 FR 73401); except, that they would apply beginning in the second rather than first quarter of performance year 2. Specifically, we propose a 5 percent stop-loss limit in performance year 2 (DR), a 10 percent stop-loss limit in performance year 3, and a 20 percent stop-loss limit for performance years 4 and 5 for each EPM. That is, beginning in the second quarter of performance year 2 as we phase in repayment responsibility, the EPM participant would owe Medicare under each proposed EPM no more than 5 percent of the sum of the EPM quality-adjusted target prices for all of the EPM participant's EPM episodes during performance year 2 (DR). This responsibility gradually phases up to 20 percent by performance year 4.

For performance year 2, the comparison against the stop loss limit would only apply for NPRA attributable to episodes ending in performance year 2 (DR). When we calculate the NPRA for performance year 2 as described in section III.D.5. of this proposed rule, we would ensure the NPRA attributable to episodes ending during performance year 2 (NDR) is not less than zero and that NPRA attributable to episodes ending during performance year 2 (DR) does not exceed the stop-loss limit of 5

percent of the sum of quality-adjusted target prices for episodes that ended during performance year 2 (DR).

Similarly, when we conduct the subsequent reconciliation calculation to reassess actual EPM-episode payments for performance year 2 (which will occur concurrently with the reconciliation for performance year 3), we would combine the performance year 2 (NDR) NPRA and the result of the subsequent reconciliation calculation for performance year 2 (NDR) to ensure the result is not less than zero. Also, we would combine the performance year 2 (DR) NPRA and the result of the subsequent reconciliation calculation for performance year 2 (DR) to ensure the stop-loss limit is not exceeded.

For performance years 3 through 5, it would not be necessary to split the performance years to ensure that the stop-loss limit is not exceeded as a single stop-loss limit would apply in each year. For example, when we calculate the NPRA for performance year 3, as described in section III.D.5. of this proposed rule, we would ensure the NPRA does not exceed the stop-loss limit of 10 percent of the sum of quality-adjusted target prices. Similarly when we conduct the subsequent reconciliation calculation to reassess actual EPM-episode payments for performance year 3 (which will occur concurrently with the reconciliation for performance year 4), we would combine the performance year 3 NPRA and the result of the subsequent reconciliation calculation for performance year 3 to ensure the stop-loss limit is not exceeded.

Note that, as described in sections III.D.5.b. and III.D.7.e., the result of the post-episode spending calculation and ACO overlap calculation that would occur concurrently with the subsequent reconciliation calculation for a given performance year would not be subject to the stop-loss limit. The result of these calculations will be added to the NPRA and subsequent reconciliation calculation to create the repayment amount or reconciliation payment. We believe that these limits both offer EPM participants reasonable protections while maintaining incentives to improve care quality and efficiency. We would note that in addition to the CJR model, we apply a similar ultimate 20 percent stop-loss limit to payments under the BPCI initiative.

The proposal to limit hospitals' overall payment responsibility under the models is included in § 512.305(c)(2)(iii)(A). We seek comment on our proposal to limit hospitals' overall payment responsibility.

(2) Limitation on Reconciliation Payments

We believe limits on reconciliation payments made under the proposed EPMs would also be appropriate for several reasons. Under our proposal, in performance year 1, EPM participants have no repayment responsibility for excess EPM episode spending above the EPM quality-adjusted target price. CMS bears full financial responsibility for Medicare actual EPM-episode payments for an EPM episode that exceeds the EPM quality-adjusted target price, and we believe our responsibility should have judicious limits. Therefore, we believe it would be reasonable to cap an EPM participant's reconciliation payment due to actual EPM-episode payments for a given performance year as a percentage of EPM-episode payment on the basis of responsible stewardship of CMS resources. In addition, we note that beginning in performance year 1, EPM participants would be eligible for reconciliation payments due to the NPRA if actual EPM-episode payments are less than the quality-adjusted target prices. This proposal for reconciliation payments due to the NPRA provides a financial incentive to EPM participants from the beginning of the model to manage and coordinate care throughout the EPM episode with a focus on ensuring that EPM beneficiaries receive the lowest intensity, medically appropriate care throughout the EPM episode that results in high quality outcomes. Therefore, we also believe it would be reasonable to cap an EPM participant's reconciliation payment resulting from actual EPM-episode payments based on concerns about potential excessive reductions in utilization under the proposed EPMs that could lead to beneficiary harm.

In determining what would constitute an appropriate reconciliation payment limit due to actual episode spending (hereafter called a ''stop-gain limit''), we believe it should provide significant opportunity for EPM participants to receive reconciliation payments for greater episode efficiency that includes achievement of quality care and actual EPM-episode payment reductions below the quality-adjusted target price, while avoiding the creation of significant incentives to sharply reduce utilization that could be harmful to EPM beneficiaries. We also believe that establishing parallel stop-gain and stop-loss limits is important to provide proportionately similar protections to CMS and EPM participants for their financial responsibilities under the EPMs as well as to protect the health of beneficiaries. Accordingly, we propose to establish symmetrical stop-gain limits. Specifically, we propose a 5 percent stop-gain limit in performance years 1 and 2, a 10 percent stop-gain limit in performance year 3, and a 20 percent stop-gain limit for performance years 4 and 5 for each EPM. That is, in performance year 1 as we phase in the stop-gain limits, the reconciliation payment that the EPM participant would be eligible to receive under each proposed EPM would be no more than 5 percent of the sum of the EPM quality-adjusted target prices for all of the EPM participant's EPM episodes during the performance year. This limit gradually phases up to 20 percent by performance year 4. As indicated in the CJR Final Rule, we want to ensure that any savings achieved by EPM participants in the early years of the EPM are not due to random variation, and that changes undertaken to improve efficiency include achievement in care quality and not sharp decreases in utilization that could be harmful to beneficiaries (80 FR 73402).

We clarify that, as with the stop-loss limit as discussed in this section, we propose that we would determine whether an EPM participant has met the stop-gain limit by assessing the NPRA and subsequent reconciliation for a given performance year, if any. We believe this approach aligns with our goal to place limits on the amount a participant may earn as a reconciliation payment due to reduced actual EPM-episode payments.

We would also 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 EPM-episode services. We refer to section III.G. of this proposed rule for our proposals on monitoring and addressing hospital performance under the proposed EPMs.

The proposal to establish a cap on an EPM participant's reconciliation payment due to actual EPM-episode payments for a given performance year as a percentage of EPM-episode payment is included in § 512.305(c)(2)(iii)(B). We seek comment on this proposed cap.

c. Additional Protections for Certain EPM Participants

(1) Proposed Policies for Certain EPM Participants to Further Limit Repayment Responsibility

While the aforementioned proposals generally provide additional safeguards to ensure that EPM participants would have limited repayment responsibility due to the raw NPRA, we are proposing

additional protections for certain groups of EPM participants that may have a lower risk tolerance and less infrastructure and support to achieve efficiencies for high-payment EPM 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.

For the purpose of these models, we propose 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.

We propose to define a Sole Community Hospital as it is defined in § 412.92. That is, 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.

We propose to define a Medicare Dependent Hospital (MDH) as it is defined in § 412.108. That is, an MDH is 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.

We propose to define a Rural Referral Center as it is defined in § 412.96. Specifically, 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 these criteria, 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 at least 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.

Additional information on these hospitals can be found in the CJR Final Rule at 80 FR 73403 through 73405.

In the CJR Final Rule, we established the same stop-gain limits for these hospitals as for hospitals in general (that is, 5 percent in performance years 1 and 2, 10 percent in performance year 3, and 20 percent in performance years 4 and 5); however, we limited losses for rural hospitals, SCHs, Medicare Dependent Hospitals and RRCs to 3 percent in performance year 2, and 5 percent in performance years 3 through 5 (80 FR 73406). In that Final Rule, we noted that these hospitals can face unique challenges that do not exist for most other hospitals. For example, these hospitals may be the only source of healthcare services for beneficiaries or certain beneficiaries living in rural areas, and may be in areas with fewer providers including fewer physicians and post-acute care facilities. Further, these hospitals may have more limited options in coordinating care and reducing spending while maintaining quality of care. We continue to believe that urban hospitals may not have similar concerns as they are often in areas with many other providers and have a greater opportunity to develop efficiencies under the EPMs. Given these circumstances, for the CJR model we determined that we should have a more protective stop-loss limit policy for these hospitals. Given the similarity between the CJR model and the proposed EPMs, we have similar concerns, which we believe should be addressed by establishing greater protections for these hospitals when they are EPM participants. Accordingly, we are proposing the same stop-loss thresholds for these hospitals participating in the proposed EPMs as were adopted for the CJR model except that the thresholds would begin in performance year 2 (DR)—specifically, 3 percent in performance year 2 (DR), and 5 percent for performance years 3 through 5 for each EPM.

The proposal to establish separate financial loss limits for certain hospitals that could be less able to tolerate risk is included in § 512.305(c)(2)(iii)(C). We seek comment on our proposed limit on financial loss for these hospitals.

(2) Considerations for Hospitals Serving a High Percentage of Potentially Vulnerable Populations

In addition to the aforementioned hospitals, we recognize that other EPM participants, for which we do not propose additional protections, could also face factors affecting their ability to achieve savings under the proposed EPMs, and that these factors could be unrelated to their practice patterns but instead could reflect the EPM participants' responsibilities for a relatively high percentage of potentially vulnerable populations with higher than average historical spending and/or less opportunities for efficiencies. For example, this could include hospitals that serve a relatively high percentage of beneficiaries that are dually eligible for both Medicare and Medicaid or whose total Medicare payments include a relatively high proportion of disproportionate share hospital payments under 1886(d) (5) (F) of the Act. Some of these hospitals are located in rural areas and would thus likely be

classified as a type of hospital for which we propose additional protections. However, most hospitals that serve a relatively high percentage of beneficiaries that are dually eligible for both Medicare and Medicaid or whose total Medicare payments include a relatively high proportion of disproportionate share hospital payments are located in urban areas, and very few are classified as a rural hospital, RRC, MDH, or SCH that would be subject to the additional protections we propose. For the first 2 performance years of the EPMs, where quality-adjusted target prices are set predominantly based on EPM-participant hospital-specific data, factors affecting these hospitals may be of less concern than in the final 3 performance years of the EPMs where pricing is either predominantly or totally based on regional data.

The potential challenges posed by these kinds of factors is highlighted in Section 2(d) of the Improving Medicare Post-Acute Care Transformation ''IMPACT'' Act of 2014 (Pub. L. 113–183). Specifically, Section 2(d) requires the Secretary to conduct a study that examines the effect of individuals' socioeconomic status, including their Medicaid eligibility, on quality measures and resource use and other measures for individuals under the Medicare program, in recognition that less healthy individuals may require more intensive interventions. The Secretary is required to submit a report on the results of this study within 2 years of enactment of the IMPACT Act. The IMPACT Act also requires the Secretary to conduct a second study that examines the impact of various risk factors, as well as race, health literacy, limited English proficiency (LEP), and Medicare beneficiary activation, on quality measures and resource use and other measures under the Medicare program in order to recognize that less healthy individuals may require more intensive interventions. The Secretary must submit a report on the results of this study within 5 years of enactment of the IMPACT Act.

If these studies find a relationship between the factors examined in the studies and quality measures and resource use and other measures, then the Secretary shall provide recommendations for, among other things, how CMS should account for such factors in quality measures, resource use measures, and other measures under Medicare; and in determining payment adjustments based on such measures in other applicable provisions related to the program. Likewise, taking into account these studies and their recommendations as well as other relevant information, the Secretary is required to routinely, as determined appropriate and based on an individual's health status and other factors, assess appropriate adjustments to quality measures, resource use measures, and other measures under the Medicare program; and assess and implement appropriate adjustments to Medicare payments based on these measures. The Assistant Secretary for Planning and Evaluation is responsible for these studies and a report on the results of the first one is forthcoming. Upon issuance of these studies' reports, we plan to consider their results as we implement the proposed EPMs. We also plan to monitor the influence of beneficiary characteristics such as socioeconomic status on EPM participants' performance during our implementation and evaluation of the EPMs. Given that the performance of EPM participants would be compared largely against their own historical episode cost performance data for the first 2 years of the models, we do not anticipate that the aforementioned factors should materially affect participants' ability to achieve savings. However, as we increasingly begin to rely more on regional cost performance data to determine episode benchmarks and quality-adjusted target prices in performance year 3, these factors could become more germane. Thus, in the event we identify the need for adjustments, we could consider proposing additional policies through subsequent rulemaking. Additionally, we plan to use information collected as part of our efforts to monitor beneficiary access to care and quality of care as discussed in sections III.G.4. and III.G.5. of this proposed rule to inform if potential adjustments would be needed in future years of the model.

Protections for EPM participants are discussed in section III.D.7.b.(1) of this proposed rule. We seek comment about all issues specific to hospitals serving a high percentage of potentially vulnerable populations and their opportunities to advance the goals of the EPMs. In particular, we seek comment, including data analysis, about approaches to identifying these hospitals; their opportunities to achieve high quality episode performance; specific considerations about their opportunities to achieve efficient care for the clinical conditions included in the AMI, CABG, and SHFFT models; potential approaches to risk adjustment as elaborated upon in section III.D.4.b.(2)(d) of this proposed rule; potential approaches to additional protections that could be considered for the future modeled after our proposals in section III.D.7.b.(1) of this proposed rule for certain other EPM participants or other alternatives; and evaluation methodologies to ensure that we include appropriate comparison groups and monitor and evaluate the most relevant outcomes.

d. Application of Stop-Gain and Stop-Loss Limits

Because hospitals could be participating in the proposed AMI, CABG, and SHFFT models concurrently with the CJR model, an additional consideration concerns the level at which the stop-loss and stop-gain thresholds would be applied, for example, at the hospital level, as is currently the case for the CJR model, or at some other level, for example, at the model level. Our intention is to establish appropriate incentives and protections for hospitals under the proposed EPMs and the CJR model without creating unnecessary administrative complexity. This issue becomes especially relevant to the proposed EPMs and CJR model given that the CJR model and proposed EPMs would be operating at different points within their performance periods. That is, episodes under the proposed EPMs would always lag 1 performance year behind those in the CJR model. Thus, SHFFT model participants that would begin the first SHFFT model performance year in 2017 would already be participating in their second performance year under the CJR model. Consequently, in this example, a stop-loss limit could apply to the performance year 2 episodes under the CJR model but not to the performance year 1 SHFFT model episodes under the SHFFT model as SHFFT model participants would not have repayment responsibility in SHFFT model performance year 1 under our proposal. In contrast, for this example, the stop-gain limits would be the same for both the SHFFT and CJR model since the limit for both performance year 1 and 2 would be 5 percent.

Continuing with this example for a later performance year (performance year 4 for the CJR model and performance year 3 for the SHFFT model), any stop-loss limits that applied would be different. That is, the stop-loss limits for the CJR model episodes in performance year 4 would be 20 percent in contrast to the 10 percent stop-loss limit that would apply to the SHFFT model episodes in performance year 3. The proposed stop-gain limits would likewise diverge in this example as they

are proposed to be symmetrical with the stop-loss limits.

Given these differences, we considered two options for setting stop-gain and stop-loss limits for hospitals participating in more than one of the AMI, CABG, SHFFT, and CJR models. Under the first option, we would determine stop-loss and stop-gain limits, in total, at the participant level based on weighted thresholds. Specifically, CMS would calculate a single weighted stop-loss/gain threshold based on the total spending under each model. Thus, using the aforementioned example where CJR model episodes would be in performance year 4 of their model and SHFFT model episodes would be in performance year 3, assuming 50 percent of total spending under the CJR and SHFFT models is for CJR model episodes and the remaining 50 percent is for SHFFT model episodes, the weighted stop-loss limit for the two models at the hospital level would be 15 percent: (0.50×0.20 for CJR model episodes) + (0.5×0.10 for SHFFT model episodes) = 0.15. Although this option would allow the application of a single stop-loss threshold to a hospital's total repayment under the models, we are concerned that computing a single limit such as this could either dilute or magnify the intended protections of the stop-loss limit under each model. As such, a hospital that would have been protected from repayment exceeding 10 percent of its SHFFT model quality-adjusted target prices multiplied by the number of SHFFT model episodes for performance year 3 would only be protected for costs above the higher 15 percent level. Conversely, a hospital that would have been protected only for repayment above 20 percent of its CJR model quality-adjusted target prices multiple by the number of CJR model episodes for performance year 3 would be protected against repayment above the lower 15 percent threshold.

Alternatively, we considered establishing stop-loss and stop-gain thresholds at the model level; that is, separately for each of the AMI, CABG, and SHFFT models, in addition to the limits that already exist for the CJR model. Under this option, we would separately apply the CJR-applicable stop-loss and stop-gain limits to CJR model episodes, the AMI-applicable limits to AMI model episodes, and so forth. Thus, considering the aforementioned example, the stop-loss limit for CJR model episodes in performance year 4 would be 20 percent for the hospital's CJR model episodes, while the stop-loss limit for SHFFT model episodes for performance year 3 would be 10 percent. While we might choose to aggregate these amounts to conduct a single financial transaction with a hospital participating in more than one model, we believe this option that would apply stop-loss and stop-gain limits at the model level for hospitals participating in more than one model is superior to first option in that it better maintains appropriate incentives and protections under each of the models.

The proposal to establish stop-gain and stop-loss limits at the model level is included in § 512.305(c)(2)(iii)(D). We seek comment on our proposal to establish stop-gain and stop-loss limits at the model level.

e. EPM Participant Responsibility for Increased Post-Episode Payments

We note that while episodes under the proposed EPMs would extend 90 days post-discharge from the anchor or chained anchor hospitalization, some EPM participants may have an incentive to withhold or delay medically-necessary care until after an EPM episode ends to reduce its actual EPM-episode payments. This inappropriate shifting could include both those services that are related to the episode (for which the hospital would bear financial responsibility as such services would be included in the actual EPM-episode payment calculation) and those that are unrelated (which would not be included in the actual EPM-episode payment calculation), because an EPM participant engaged in shifting of medically-necessary services outside the EPM episode for potential financial reward may be unlikely to clearly distinguish whether the services were related to the EPM episode or not in the hospital's decisions.

We believe that this inappropriate shifting would not be typical, especially given the relatively long EPM episode duration. However, in order to identify and address inappropriate shifting of care, we propose to calculate for each EPM performance year the total Medicare Parts A and B expenditures in the 30-day period following completion of each EPM episode for all services covered under Medicare Parts A and B, regardless of whether the services are included in the proposed EPM episode definition (sections III.C.3. and III.C.4 of this proposed rule). This proposal is consistent with our processes for BPCI Model 2 and the CJR model (80 FR 73407 through 73408).

We propose that the post-episode spending calculation for a performance year would occur at the same time we perform the subsequent reconciliation calculation for that same year. We believe this timeframe will allow sufficient time for claims run out in order to set a reliable regional threshold for determining the post-episode spending. For example, we would conduct reconciliation for performance year 1 in the spring of 2018. The post-episode spending calculation for performance year 1 would occur during the next reconciliation process (spring 2019), when we conduct the subsequent reconciliation calculation for performance year 1 and account for overlap with other models and programs.

Our proposed calculation would include prorated payments for services that extend beyond the EPM episode as discussed in section III.D.3.c. of this proposed rule. Specifically, we would identify whether the average 30-day post-episode spending for an EPM participant in any given EPM performance year is greater than 3 standard deviations above the regional average 30-day post-episode spending, based on the 30-day post-episode spending for episodes attributed to all regional hospitals participating in the EPM in the same region as the EPM participant. We propose that if the EPM participant's average post-episode spending exceeds this threshold, the EPM participant would repay Medicare for the amount that exceeds such threshold. We note that an EPM participant's responsibility for post-episode spending would not be subject to the stop-loss and stop-gain limits proposed in section III.D.7.b. of this proposed rule. Although we believe cases in which an EPM participant would be responsible for repayment of post-episode spending that exceed the threshold would be rare, our intention is to identify and hold EPM participants responsible for situations in which those participants have significantly increased spending on services in the 30 days following the end of an EPM episode in order to inappropriately shift services out of EPM episodes. We do not believe such behavior should be subject to stop-loss limits. This policy is consistent with our proposal for the CJR model in section V.D.1. of this proposed rule.

Based on our experience with BPCI, we have not found that this proposal, including our proposal to include all Medicare Parts A and B expenditures to measure 30-day post-episode spending, would inappropriately penalize EPM participants. To that end, however, we believe our proposed threshold of 3 standard deviations above the regional average is a high threshold, and we only propose that an EPM participant would repay Medicare for the amount that

exceeds such threshold. We further note that those EPM participants that are eligible for reconciliation payments in an EPM performance year and also have average 30-day post-episode spending that is higher than 3 standard deviations above the regional average 30-day post-episode spending would have their reconciliation payments reduced by the amount by which spending exceeds 3 standard deviations.

The proposals to determine if a participant's post-episode spending 30 days after the end of an episode exceeds 3 standard deviations of average spending in their region for that period, and require those participants exceeding that threshold to repay Medicare for the amounts in excess of 3 standard deviations are included in § 512.307(c). We seek comment on our proposals to determine if a participant exceeds this threshold and to repay amounts in excess of the threshold.

8. Appeals Process

a. Overview

Consistent with the BPCI initiative and CJR model, we propose to institute appeals processes for the EPMs that would allow EPM participants to appeal matters related to payment, CR incentive payments, reconciliation amounts, repayment amounts, determinations associated with quality measures affecting payment, as well as non-payment related issues, such as enforcement matters. These matters are discussed throughout section III.D. and III.F. respectively.

We seek comment on the proposal to institute appeals processes, in the following discussion, for the EPMs.

b. Notice of Calculation Error (First Level Appeal)

We propose the following calculation error process for EPM participants to contest matters related to payment or reconciliation, of which the following is a non-exhaustive list: The calculation of the EPM participant's reconciliation amount or repayment amount as reflected in the reconciliation report; the calculation of the EPM participant's CR incentive payment as reflected in the CR incentive payment 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. EPM participants would review their reconciliation report and CR incentive payment report and be required to provide written notice of any error, in a calculation error form that must be submitted in a form and manner specified by CMS. Unless the EPM participant provides such notice, the reconciliation report and CR incentive report would be deemed final within 45 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. We propose that if an EPM participant does not submit timely notice of a calculation error, that is notice within 45 calendar days of the issuance of the reconciliation report and CR incentive payment report the EPM participant would be precluded from later contesting any of the following matters contained in the reconciliation report or CR incentive payment report for that performance year; any matter involving the calculation of the EPM participant's reconciliation amount or repayment amount as reflected in the reconciliation report; any matter involving the calculation of the EPM participant's CR incentive payment as reflected in the CR incentive payment 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. Given that EPM participants bear the financial risk in the EPM model, only EPM participants may use the dispute resolution process described in this section.

In summary, we propose the following requirements in § 512.310 (a) for notice of calculation error:

- Subject to the limitations on review in subpart D of this part, if an EPM participant wishes to dispute the calculation that involves a matter related to payment, a CR incentive payment, reconciliation amounts, repayment amounts, or determinations associated with quality measures affecting payment, the EPM participant is required to provide timely written notice of the error, in a form and manner specified by CMS.
- Unless the EPM participant provides such notice, CMS deems final the reconciliation report and CR incentive payment report 45 calendar days after the reconciliation report or CR incentive payment report is issued and proceeds with the payment or repayment processes as applicable.
- If CMS receives a notice of a calculation error within 45 calendar days of the issuance of the reconciliation report or CR incentive payment report, 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 EPM participant.
- Only EPM participants may use the notice of calculation error process described in this part.

We seek comment on the proposed notice of calculation error requirements.

c. Dispute Resolution Process (Second Level of Appeal)

We propose the following dispute resolution process. First, we propose that only an EPM participant may utilize the dispute resolution process. Second, in order to access the dispute resolution process a participant must have timely submitted a calculation error form, as previously discussed, for any matters related to payment. We propose these matters would include any amount or calculation indicated on a reconciliation report or CR incentive payment report, including calculations not specifically reflected on a reconciliation report or CR incentive payment report but which generated figures or amounts reflected on a reconciliation report or a CR incentive payment report. The following is a non-exhaustive list of the matters we propose would need to be first adjudicated by the calculation error process as previously detailed: Calculations of reconciliation or repayment amounts; calculation of CR incentive payment amounts; calculations of NPRA; and any calculations or percentile distribution involving quality measures that we propose could affect reconciliation or repayment amounts. If an EPM participant wants to engage in the dispute resolution process with regard to one of these matters, we propose it would first need to submit a calculation error form. Where the EPM participant does not timely submit a calculation error form, we propose the dispute resolution process would not be available to the EPM participant with regard to those matters for the reconciliation report or CR incentive payment report for that performance year.

If the EPM participant did timely submit a calculation error form and the EPM participant is dissatisfied with CMS's response to the EPM participant's notice of calculation error, the EPM participant 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 EPM participant's assertion that CMS or its representatives did not accurately calculate the NPRA, the CR incentive payment, or post-episode spending amount in accordance with EPM rules. The following is a non-exhaustive list of representative payment matters:

- Calculations of NPRA, calculations of the CR incentive payment, post-episode spending amount, target prices or any items listed on a reconciliation report or CR incentive payment 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 EPM participant need not submit a calculation error form. We propose to require the EPM participant 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 propose CMS would process the request as discussed later in this section.

We propose 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 EPM participant in writing within 15 calendar days of receiving the EPM participant'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 days after the date of the Scheduling Notice. The provisions at § 425.804(b), (c), and (e) (as in effect on the publication date of this proposed rule) would apply to reviews conducted pursuant to the reconsideration review process for EPM. 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 solicit comment on our proposals related to appeals rights under this model. The two-step appeal process for payment matters—(1) calculation error form, and (2) reconsideration review—is used broadly in other CMS models. We seek 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.F. of this proposed rule, and if so, whether the process for such appeals should differ from the processes proposed here.

In summary, we propose the following requirements in § 512.310(b) for the reconsideration process:

- If the EPM participant is dissatisfied with CMS's response to the notice of a calculation error, the EPM participant may request a reconsideration review in a form and manner as specified by CMS.
- The reconsideration request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the EPM participant's assertion that CMS or its representatives did not accurately calculate the NPRA, the reconciliation payment, the CR incentive payment or the repayment amount in accordance with subpart d of this part.
- If CMS does not receive a request for reconsideration from the EPM participant within 10 calendar days of the issue date of CMS's response to the EPM participant'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 § 512.305.
- The CMS reconsideration official notifies the EPM participant in writing within 15 calendar days of receiving the EPM participant's review request of the following:

++ The date, time, and location of the review.

++ The issues in dispute.

++ The review procedures.

++ The procedures (including format and deadlines) for submission of evidence.

- 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 notification.
- 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 the EPM.
- The CMS reconsideration official issues a written determination within 30 days of the review. The determination is final and binding.

Only EPM participants may utilize the dispute resolution process described in this subpart. We seek comment on the proposed reconsideration process for the EPMs.

d. Exception to the Notice of Calculation Error Process and Notice of Termination

Similar to the CJR model and BPCI initiative, if the EPM participant contests a matter that does not involve an issue contained in, or a calculation which contributes to, an EPM reconciliation report or a CR incentive report, a notice of calculation error is not required. Consistent with III.D.8(c) in this proposed rule, in instances where a notice of calculation error is not required, for example an EPM participant's termination from the EPM, we propose the EPM participant provide a written notice to CMS requesting review within 10 calendar days of the notice. CMS has 30 days to respond to the EPM participant's request for review. If the EPM participant fails to notify CMS, the decision is deemed final.

In summary, we propose the following requirements in § 512.310(c) for an exception to the notice of calculation error process.

- If the EPM participant contests a matter that does not involve an issue contained in, or a calculation which contributes to, a reconciliation report or CR incentive payment report, a notice of calculation error is not required. In these instances, if CMS does not receive a request for reconsideration from the EPM participant within 10 calendar days of the notice of the initial determination, the initial determination is deemed final and CMS proceeds with the action indicated in the initial determination.

In summary, we propose the following requirements in § 512.310(d) for notice of termination:

- If an EPM participant receives notification that it has been terminated from the EPM and wishes to appeal such termination, it must provide a written notice to CMS requesting review of the termination within 10 calendar days of the notice. CMS has 30 days to respond to the EPM participant's request for review. If the participant fails to notify CMS, the termination is deemed final.

We seek comment on the proposed exception to the notice of calculation error process and notice of termination.

e. Limitations on Review

In summary, we propose the following requirements in § 512.310(e) for 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:

++ 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 section 1115A(b)(3) of Act.

++ The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of Act.

++ Decisions to expand 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 (e)(1) or (2) of this section.

We seek comment on the proposed limitations on review.

III. Provisions of the Proposed Regulations

E. EPM Quality Measures, Public Display, and Use of Quality Measures in the EPM Payment Methodology

1. Background

As discussed in the CJR model final rule, Medicare payment policy has moved away from FFS payments unlinked to quality and towards payments that are linked to quality of care (80 FR 73358). Through the Medicare Modernization Act and the Affordable Care Act, we have implemented specific IPPS programs like the HIQR Program (section 1886(b)(3)(B) of the Act), the HVBP Program (subsection (o) of section 1886), the Hospital Acquired Condition Reduction Program (HACRP) (subsection (q) of section 1886), and the Hospital Readmissions Reduction Program (HRRP) (subsection (p) of section 1886), where quality of care is linked to payment. We have also implemented the Shared Savings Program, an ACO program that links shared savings payment to quality performance. The CJR model similarly incorporates pay-for-performance through the potential for financial reward to participants based on the hospital's level of quality performance, while also including an incentive for quality improvement if the hospital's current level of quality is relatively low (80 FR 73374).

We propose pay-for-performance methodologies similar to the CJR model for the proposed EPMs. Specifically, we propose to financially reward higher quality in an EPM episode by reducing the effective discount factor used to calculate EPM quality-adjusted target prices at reconciliation. We would establish the effective discount factor based on the EPM participant's overall quality performance and improvement on the EPM's quality measures as reflected in the EPM participant's EPM composite quality score. We would calculate the EPM participant's composite quality score for each EPM performance year at the time of reconciliation. The EPM composite quality score would also determine whether an EPM participant is eligible for a reconciliation payment if savings are achieved beyond the EPM quality-adjusted target price by setting a minimum EPM composite quality score for reconciliation payment eligibility.

We note that we continue to believe that EPMs should include pay-for-performance methodologies that incentivize improvements in patient outcomes while simultaneously lowering health care spending (80 FR 73465). We believe that improved quality of care, specifically achieved through coordination and communication among providers in conjunction with patients and their caregivers, can favorably influence performance on patient outcomes. Like the CJR model, we also believe that the proposed three new EPMs would provide the opportunity for EPM participants to improve the quality of care based on timely reported patient experience, including communications with doctors and nurses, and responsiveness of hospital staff (80 FR 73465). Finally, we strive to align as many measures as possible in CMS's proposed new EPMs with those in ongoing models and programs. Our goal is to focus provider improvement efforts and minimize burden on EPM participants in needing to become familiar with and report new measures, while still allowing us to appropriately capture meaningful quality data and use it in the EPMs' pay-for-performance methodologies.

More specifically, similar to our final decision for the CJR model, we are not proposing to use any readmissions measures that could apply to clinical conditions in these EPMs but that are already in place or have been finalized for the HRRP, specifically the Hospital 30-day all-cause risk-standardized readmission rate (RSRR) following AMI hospitalization (NQF #0505) and the Hospital 30-day all-cause, unplanned, RSRR following CABG surgery (NQF #2515), due to the incentives, already in place by the HRRP, for hospitals to lower excess readmission rates (80 FR 73479). While we consider these readmissions measure rates to be important metrics for providing information about AMI and CABG hospital performance in the HRRP and HIQR Program for payment and public reporting, respectively, other proposed measures for the AMI and CABG models support the intent of these models to reduce actual payments in an EPM episode while ensuring that quality of care for AMI and CABG model beneficiaries is improved.

Furthermore, while we recognize the lack of complete alignment between EPM beneficiaries and the proposed cohorts for the EPM quality measures, we believe the proposed measures provide meaningful information about EPM participant quality performance and improvement that are relevant to EPM beneficiaries. For the AMI and CABG models in particular, beneficiaries included in the proposed episode-specific measures would significantly overlap with beneficiaries in AMI and CABG model episodes. We note that for purposes of the EPMs where we need to identify episodes that are included in the EPMs, we use the terms anchor and chained anchor hospitalization to identify hospitalizations that initiate EPM episodes for beneficiaries whose care is included in the EPMs. In describing the quality measures in detail in section III.E.4. of this proposed rule, we use the term index hospitalization to identify hospitalizations of beneficiaries whose outcomes are included in the measures. Thus, anchor hospitalizations and index hospitalizations would have varying degrees of overlap depending on the specific quality measure.

Moreover, we note that hospitals are the unit of analysis for the EPMs and that the proposed measures are hospital-centric measures, both because these are currently available measures that are aligned with those in other CMS programs and because one of the major goals of the EPMs is to encourage collaboration among different types of providers in order to achieve better care and reduced expenditures, while holding acute care hospitals financially responsible. For further discussion of our proposal that hospitals be

accountable for EPM episodes, we refer to section III.B.3. of this proposed rule.

We recognize that there are also some gaps in the current proposed measures relative to other settings in which patients receive care post-hospital discharge during EPM episodes, as well as around important complications of care for clinical conditions included in the three models. However, we believe that these hospital-level measures reasonably assess how well EPM participants provide care for EPM beneficiaries since the measures, depending on the EPM, assess—(1) important patient outcomes, including mortality as well as complications and days of acute care following discharge from the index hospitalization which can be costly; and (2) patients' perspectives on their hospital experience, which include patient feedback on communication with doctors, communication with nurses, responsiveness of hospital staff, communication about medicines, discharge information, cleanliness of the hospital environment, quietness of the hospital environment, and transition to post-hospital care. As we gain more experience with the EPMs, as well as the CJR model currently in testing, and future EPMs, we plan to work to create a more robust set of episode quality measures for these and future models. We will continue to assess the evolving inventory of measures and will continue to refine quality measures for potential future rulemaking based on public comments, changes to the EPMs' payment methodologies, recommendations from EPM participants and their collaborators, and new CMS episode measure development activities as we learn more about the impact of EPMs on quality improvement and episode efficiency. We refer to section III.E.4.e. of this proposed rule for a discussion of potential future EPM episode measures.

2. Selection of Proposed Quality Measures for the EPMs

a. Overview of Quality Measure Selection

The outcome and patient experience measures proposed for the EPMs were selected in order to: (1) Promote alignment with the financial and quality goals of the EPMs; (2) leverage hospitals' familiarity with the measures due to their use in other CMS hospital quality programs, including programs that tie payment to performance such as the HVBP Program; (3) streamline EPM measures for EPM participants testing more than one EPM; and (4) ensure consistency with CMS's priorities to reduce AMI and CABG mortality and complications while improving patient experience, as well as with CMS's priorities to reduce major LEJR surgery complications while improving patient experience for SHFFT model beneficiaries, like those in the CJR model.

b. AMI Model Quality Measures

In order to encourage care collaboration among multiple providers of AMI model beneficiaries, we propose three required measures and one measure that relies on voluntary data submission, in order to determine AMI model participant episode quality performance and improvement that would be linked to the AMI model payment methodology as discussed in section III.E.3.f.(2) of this proposed rule. We propose the following measures for the AMI model:

- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (NQF #0230) (MORT–30–AMI).
- Excess Days in Acute Care after Hospitalization for AMI (AMI Excess Days).
- HCAHPS Survey (NQF #0166).
- Voluntary Hybrid Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #2473) (Hybrid AMI Mortality) data submission.

We refer to sections III.E.4.a. and d. of this proposed rule for a detailed discussion of our proposals regarding these measures for the AMI model, including their importance as measures of the quality-of-care for beneficiaries treated for AMI. The proposals for the AMI model measures are included in § 512.411, and the proposals for reporting the measures are included in § 512.400. We seek comment on our proposals for AMI model quality measures.

c. CABG Model Quality Measures

In order to encourage care collaboration among multiple providers of CABG model beneficiaries, we propose two required measures, in order to determine CABG model participant episode quality performance and improvement that would be linked to the CABG model payment methodology as discussed in section III.E.3.f.(3) of this proposed rule. We propose the following measures for the CABG model:

- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558) (MORT–30–CABG).
- HCAHPS Survey (NQF #0166).

We refer to sections III.E.4.b. and d. of this proposed rule for a detailed discussion of our proposals regarding these measures for the CABG model, including their importance as measures of the quality-of-care for beneficiaries treated with CABG.

The proposals for the CABG model measures are included in § 512.412., and the proposals for reporting the measures are included in § 512.400. We seek comment on our proposals for CABG model quality measures.

d. SHFFT Model Quality Measures

In order to encourage care collaboration among multiple providers of SHFFT model beneficiaries, we propose two required measures and one measure that relies on voluntary data submission, in order to determine SHFFT model participant episode quality performance and improvement that would be linked to the SHFFT model payment methodology as discussed in section III.E.3.f.(4) of this proposed rule. While we recognize that none of the proposed measures specifically target the care of SHFFT model beneficiaries, these measures are the same as those used for the CJR model because SHFFT model episodes will be tested along with the LEJR episodes in the CJR model (80 FR 73501 and 73507) at mostly the same hospitals. In addition, as discussed further in section III.E.3.e.(3) of this proposed rule, we propose to calculate a hospital-level composite quality score that would apply to episode payment for both the CJR and SHFFT models, consistent with our proposal of the same measures for the two models. We believe that due to the inclusion of beneficiaries with hip fracture in both the CJR and SHFFT models and our desire to streamline EPM participant measure reporting, as well as the focus of both models on major lower extremity orthopedic surgery, the same set of quality measures can be used for both models to incentivize quality improvement in lower extremity orthopedic surgery care and episode efficiency. We are also considering future measure development focused specifically on hip and femur fracture patients. We expect that many of the physicians and other providers collaborating with participant hospitals in the SHFFT and CJR models will be the same, such that certain care pathways and episode efficiencies may be coordinated for SHFFT and CJR model beneficiaries regardless of the model, potentially resulting in quality improvement for beneficiaries in both models. We propose the following measures for the SHFFT model:

- Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550) (Hip/Knee Complications).
- HCAHPS Survey (NQF #0166).
- Total Hip Arthroplasty (THA)/Total Knee Arthroplasty (TKA) voluntary patient-reported outcome (PRO) and limited risk variable data submission (Patient-reported outcomes and limited risk variable data following elective primary THA/TKA).

We considered an alternative approach to the required quality measures for the SHFFT model given that the proposed measures do not specifically target the SHFFT model beneficiaries. This alternative approach would not account for any hip-specific measures (such as, Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550) (Hip/Knee Complications)) and would instead only measure patient experience through the HCAHPS Survey (NQF #0166). Although there may be some rationale for excluding measures that do not specifically target SHFFT model beneficiaries, we do not propose this approach to SHFFT model quality measures because we believe that it is critical to include a measure of both clinical and patient experience outcomes in the setting of lower extremity orthopedic surgery episodes. Additionally, we believe that using quality measures for SHFFT model episodes that do not align with those in the CJR model could generate confusion at CJR model participant hospitals where we propose that the SHFFT model be tested as discussed in section III.B.4. of this proposed rule.

We refer to sections III.E.4.c. and d. of this proposed rule for a detailed discussion of our proposals regarding these measures for the SHFFT model, including their importance as measures of the quality-of-care for beneficiaries undergoing major lower extremity joint replacement surgery.

The proposals for the SHFFT model measures are included in § 512.413, and the proposals for reporting the measures are included in § 512.400. We seek comment on our proposals for SHFFT model quality measures.

3. Proposed Use of Quality Measures in the EPM Payment Methodologies

a. Overview of EPM Composite Quality Score Methodology

We believe that the proposed EPMs provide another mechanism for hospitals to improve quality of care, while also achieving cost efficiency. Incentivizing high-value care through episode payments for AMI, CABG, and hip fracture care is a primary objective of these proposed EPMs. Therefore, incorporating quality performance into the episode payment structure is an essential component of the proposed EPMs, just as it is for the CJR model (80 FR 73370). For the reasons stated previously, we believe it is important for the AMI, CABG, and SHFFT models to link the financial reward opportunity with performance and improvement in the quality of care for Medicare beneficiaries treated for AMI, CABG, and hip fracture.

As discussed in section III.D.4.a. of this proposed rule, which outlines the pricing methodologies for EPM episodes, for each EPM participant we propose to set an EPM-episode benchmark price for each EPM episode. We would apply the EPM participant's effective discount factor based on the participant's quality performance and improvement for the EPM performance year to the EPM-episode benchmark episode price to calculate the quality-adjusted target price for each EPM episode. We refer to section III.E.3.f. of this proposed rule for further discussion of the relationship between an EPM participant's quality performance and improvement and the effective discount factor. Each EPM episode includes an anchor hospitalization for either AMI (AMI MS–DRG or PCI MS–DRG with AMI ICD–10–CM diagnosis code in the principal or secondary diagnosis code position), CABG (CABG MS–DRG), or SHFFT (SHFFT MS–DRG) and a 90-day period after discharge from the anchor or chained anchor hospitalization. As discussed in section III.C.4.a.(5) of this proposed rule, a chained anchor hospitalization is an anchor hospitalization that initiates an AMI model episode and has at least one subsequent inpatient-to-inpatient transfer. An EPM quality-adjusted target price would represent expected spending on all related Part A and Part B items and services furnished during EPM episodes based on historical EPM episodes, and would incorporate the EPM participant's effective discount factor for the EPM performance year. Participants that achieve actual EPM-episode payments below the quality-adjusted target price for a given performance year may be eligible for a reconciliation payment from CMS, subject to the proposed stop-gain limit policy as discussed in section III.D.7.b. of this proposed rule. Participants that achieve actual EPM-episode payments that exceed the quality-adjusted target price for a given performance year may be required to repay Medicare a portion or all of the excess EPM-episode spending.

We propose an EPM composite quality score methodology for linking quality and payment in the EPMs that is similar to that methodology finalized for the CJR model (80 FR 73363 to 73381). Similar to the CJR model, the EPM-specific composite quality score methodology would allow both performance and improvement on each EPM's required quality measure to be meaningfully valued in the EPMs' pay-for-performance methodology, incentivizing and rewarding cost savings in relation to the quality of episode care provided by the EPM participant (80 FR 73374 and 73370). Specifically, the EPM composite quality score is made up of the composite performance score (which includes both patient experience and outcome measures, including points for voluntarily reported measures) and an improvement score.

We believe the actual level of quality performance achieved should be most highly valued in the EPM composite quality score to reward those EPM participants furnishing high quality care to EPM beneficiaries, with a smaller contribution to the EPM composite quality score made by improvement points if measure result improvement is achieved. We acknowledge that substantial improvement on a quality measure result is not the sole indicator that an EPM episode-of-care is high quality; yet, the improvement spurred by the hospital's participation in the EPM deserves to be valued as the EPM participant's performance is moving in a direction that is good for the health of beneficiaries. Like the CJR model, the EPMs involve a wide range of participants that must participate if they are located in the selected MSAs, and the participants would be starting from many different current levels of quality performance. We note that the Shared Savings Program utilizes a similar scoring and weighting methodology, which is described in detail in the CY 2011 Shared Savings Program Final Rule (see § 425.502). The HVBP Program and the HACRP 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). Despite the small number of quality measures proposed for the EPMs, the measures represent both clinical outcomes and patient experience, and each carries substantial value in the EPM composite quality score.

Although performance and improvement on each measure would be valued in the EPM composite quality score methodology, it is the EPM participant's overall quality

performance under the EPM that would be considered in the pay-for-performance approach, rather than performance on each quality measure individually determining the financial opportunity under the EPM. The EPM composite score methodology also provides a framework for incorporating additional measures of meaningful outcomes for EPM episodes in the future. Finally, while we believe that high performance on all of the quality measures represents goals of clinical care that should be achievable by all EPM participants that heighten their focus on these measures, we appreciate that many participants have room for significant improvement in their current measure performance. The EPM composite score methodology would provide the potential for financial reward for more EPM participants that reach overall acceptable or better quality performance, thus incentivizing their continued efforts to improve the quality and efficiency of EPM episodes.

We seek comment on our proposal to use an EPM-specific composite quality score in the pay-for-performance methodologies of the AMI, CABG, and SHFFT models.

b. Determining Quality Measure Performance

Similar to our reasoning in the CJR model, we believe that relative measure performance for the EPM measures would be the most appropriate way to incorporate quality performance into the EPMs because we do not have sufficient information about participant performance to set and use an absolute performance result on each measure (80 FR 73371). Moreover, we believe that participants nationally are currently working to improve their performance on the quality measures proposed for the EPMs on an ongoing basis as these are included in other CMS programs such as the HIQR and HVBP Programs. Therefore, while we expect that EPM participants would have a heightened focus on performance on these measures as a result of the financial incentives resulting from the EPM payment methodology, we are not yet certain what performance outcomes can be achieved under best practices.

Thus, at the time of reconciliation for an EPM performance year, we propose to assign each EPM participant's measure point estimate from the most recent year as discussed in section III.E.5. of this proposed rule to a performance percentile based on the national distribution of measure results for subsection (d) hospitals that are eligible for payment under the IPPS reporting the measure that meet the minimum patient case or survey count. This proposal applies to the MORT–30–AMI (NQF #0230) and AMI Excess Days measure results for the AMI model; the MORT–30–CABG (NQF #2558) measure result for the CABG model; the Hip/Knee Complications (NQF #1550) measure result for the SHFFT model; and the HCAHPS Survey (NQF #0166) measure result for all of the EPMs.

The measure-specific parameters that would apply to developing the national distributions are displayed in Table 13.

TABLE 13—REQUIREMENTS FOR USE OF SUBSECTION (d) HOSPITALS THAT ARE ELIGIBLE FOR PAYMENT UNDER THE IPPS MEASURE RESULTS IN DEVELOPING NATIONAL DISTRIBUTION OF REQUIRED MEASURES FOR EPMS

Measure	Requirements for use in national distribution
MORT–30–AMI (NQF #0230)	At least 25 patient cases in the 3-year measure performance period.
AMI Excess Days	At least 25 patient cases in the 3-year measure performance period.
MORT–30–CABG (NQF #2558)	At least 25 patient cases in the 3-year measure performance period.
Hip/Knee Complications (NQF #1550)	At least 25 patient cases in the 3-year measure performance period.
HCAHPS Survey (#0166)	At least 100 completed surveys in the 4-quarter reporting period.

We would assign any low volume EPM participant without a reportable value for the measure, new hospitals that are identified as EPM participants, or EPM participants where CMS has suppressed the measure value due to an error in the data used to calculate the measure to the 50th performance percentile of the measure result, so as not to disadvantage an EPM participant based on its low volume or lack of applicable cases because that participant may in actuality provide high quality care. We believe that relative measures of quality performance are most appropriate for the EPMs as participants continue to make progress nationally on improving patient outcomes and experience. Proposed measure-specific assignment of points in the EPMs' composite quality scores based on relative quality measure performance are discussed in sections III.E.3.e.(1), (2), and (3) of this proposed rule.

We seek comment on our proposed overall approach to determining quality measure performance based on assigning the EPM participant's measure point estimate to a measure performance percentile based on the national distribution of measure results from subsection (d) hospitals eligible for payment under the IPPS.

c. Determining Quality Measure Improvement

Consistent with our reasoning for the CJR model, we believe it would be important in the EPMs to directly reward EPM participants for quality improvement, similar to the pay-for-performance policies under other programs such as the HVBP Program and the Shared Savings Program, in order to provide a significant incentive for quality improvement for EPM participants at all current levels of quality performance (70 FR 73379). For the CJR model, we adopted a refinement to the composite quality score methodology that would supplement the composite quality score's valuing of quality performance in the pay-for-performance methodology of the CJR model (80 FR 73379). As in the CJR model, we believe the heightened focus on EPM episode cost and quality performance by participants in the EPMs may lead to substantial year-over-year quality measure improvement over the EPM performance years. Nevertheless, we believe that the actual level of quality performance achieved in the EPMs should be most highly valued in the EPM composite quality score to reward those participants furnishing high-quality care to EPM beneficiaries, with a small contribution to the composite quality score made by improvement points if measure result improvement is achieved. Thus, we propose adding into the EPM-specific composite quality score up to 10 percent of the maximum value for each EPM quality measure to which improvement could apply (excluding the voluntary data submission measures) for those EPM participants that demonstrate substantial improvement from the prior year's measure performance on that measure (80 FR 73379 through 73380). The maximum EPM composite quality score would be capped at 20 points

under this proposal. Proposed measure-specific assignment of points for improvement in the EPMs' composite quality scores are discussed in sections III.E.3.e.(1), (2), and (3).

For the AMI and CABG models, we propose to define measure improvement differently than in the CJR model, using an approach that is more similar to the methodologies of other CMS programs such as the HVBP Program. The CJR model defined measure improvement for model participants relative to a national performance distribution (80 FR 73380). In contrast, we propose to define measure improvement as any improvement in an AMI or CABG model participant's own measure point estimate from the previous year, regardless of the participant's measure point estimate starting and ending values, if the AMI or CABG model participant falls into the top 10 percent of participants based on the national distribution of measure improvement over the 2 years for subsection (d) hospitals that are eligible for payment under the IPPS reporting the measure that meet the minimum patient case or survey count. We propose this approach because it represents the greatest confidence that we are capturing meaningful improvement on a measure by an AMI or CABG model participant in comparison with performance changes of other hospitals yet, unlike the CJR and proposed SHFFT model methodologies, is founded on an AMI or CABG model participant's own measure performance change from year-to-year. We believe that moving toward incorporating a model participant's own measure performance improvement in the pay-for-performance methodologies for EPMs strengthens the incentives in the models for quality improvement, especially for EPM participants at the lower end of current measure performance.

For the SHFFT model, we propose to modify the definition of improvement used in the CJR model in two ways (80 FR 73379 through 73380). First, we propose to define measure improvement as improving 2 deciles or more in comparison to the national distribution of measure results from the prior year, based on a comparison of relative quality measure performance over the most recent 2 years of available quality measure result data. This is the same methodology as finalized for the CJR model, except that it reduces the threshold for improvement from 3 deciles to 2 deciles in order to reward a broader range of improvement. Second, we propose to award up to 10 percent of the maximum measure performance score on the outcome and patient experience measures described in III.E.3.e.(3) of this proposed rule, with a cap of the SHFFT model composite quality score at 20 points. This alters the CJR model methodology, which calculates the measure performance score, voluntary reporting points, and measure improvement score separately for a total potential maximum score of 22. Taken together, these two changes bring calculation of the SHFFT model composite quality score into greater alignment with existing CMS programs, such as the HVBP Program, by expanding the number of SHFFT model participants eligible for quality improvement points but reducing the number of participants who receive both the highest quality performance score on a measure and points for measure improvement simultaneously.

In section V.E. of this proposed rule, we propose changes to the CJR model composite quality score calculation consistent with the SHFFT model methodology described here, allowing use of the same definition of quality improvement for the SHFFT and CJR models, because these models would be tested in mostly the same hospitals. We believe this approach would provide SHFFT model participants at all current levels of quality performance, including those historically lagging, with significant incentives to achieve improvement quality of care under the SHFFT model. Using a common approach to measuring quality improvement for the SHFFT and CJR models would provide a single participant-level composite quality score that can be applied at reconciliation for each model to determine the payment policies that would apply to the participant for the CJR and SHFFT model episodes, taking into consideration the different model performance years.

The proposals to determine quality measure improvement for the AMI, CABG, and SHFFT models are included in § 512.315(b)(3), (c)(3), and (d)(3), respectively. We seek comment on our proposals to determine quality measure improvement for the AMI, CABG, and SHFFT models.

d. Determining Successful Submission of Voluntary Data for AMI and SHFFT Models (1) Hybrid AMI Mortality (NQF #2473) Voluntary Data

Similar to the CJR model, we propose that AMI model participants that successfully submit the Hybrid AMI Mortality (NQF #2473) measure voluntary data would be eligible for points in the AMI model composite quality score (80 FR 73375, 73381). Encouraging collection and submission of the Hybrid AMI Mortality (NQF #2473) measure voluntary data through the AMI model would increase hospital familiarity with submitting hybrid quality measures based on claims data and data submitted from electronic health records; further develop an outcome measure that provides meaningful information on outcomes for AMI hospitalizations that are commonly experienced by Medicare beneficiaries; provide another quality measure that may be incorporated into the AMI model pay-for-performance methodology in future years, pending successful implementation testing of the measure; and inform the quality strategy of future payment models.

The proposed requirements for determining successful submission of Hybrid AMI Mortality (NQF #2473) measure voluntary data are included in § 512.411(b)(2) and discussed in detail in section III.E.4.a.(3)(vii) of this proposed rule. We seek comment on our proposals for determining successful submission of voluntary data for each AMI model performance year.

(2) Patient-Reported Outcomes and Limited Risk Variable Voluntary Data Following Elective Primary THA/TKA

Like the CJR model, we propose that SHFFT model participants that successfully submit Patient-reported outcomes and limited risk variable voluntary data following elective primary THA/TKA be eligible for points in the SHFFT model composite quality score (80 FR 73375, 73381). We note that SHFFT model participants that are also participating in the CJR model would not need to submit data twice to satisfy the successful submission requirements of both models. If those hospitals successfully submit voluntary data for the CJR model they would be credited with successful submission under the SHFFT model.

The proposed requirements for determining successful submission of Patient-reported outcomes and limited risk variable voluntary data following elective primary THA/TKA are included in § 512.13(b)(2) and discussed in detail in section III.E.4.c.(2)(viii) of this proposed rule. We seek comment on our proposals for determining successful submission of voluntary data for each SHFFT model performance year.

e. Calculation of the EPM-Specific Composite Quality Score

(1) AMI Model Composite Quality Score

We propose to assign each participant an AMI model composite quality score, calculated as the sum of the individual quality measure performance scores

(including successful submission of Hybrid AMI Mortality (NQF #2473) measure voluntary data if applicable) and improvement scores. The quality measure performance scores would be set to reflect the intended weights for each of the quality measures and the successful submission of the Hybrid AMI Mortality (NQF #2473) voluntary data in the AMI model composite quality score. Each quality measure performance would be assigned a weight in the AMI model composite quality score, and possible scores for the measures would be set to reflect those weights. We would weight AMI model participant performance on each of the three required measures and successful submission of Hybrid AMI Mortality (NQF #2473) voluntary data according to the measure weights displayed in Table 14.

TABLE 14—MEASURES AND ASSOCIATED PERFORMANCE WEIGHTS IN AMI MODEL COMPOSITE QUALITY SCORE

Quality measure	Weight in composite quality score	Quality domain/weight
MORT-30-AMI (NQF #0230)	50%	Outcome/80%.
AMI Excess Days	20%	
Hybrid AMI Mortality (NQF #2473) Voluntary Data	10%	
HCAHPS Survey (NQF #0166)	20%	Patient Experience/20%.

We would assign the lowest weight of 10 percent to the submission of Hybrid AMI Mortality (NQF #2473) measure voluntary data because these data represent an AMI model participant's meaningful participation in advancing the quality measurement of AMI outcomes in keeping with our goal to move toward the use of electronic health records (EHRs) for measures, and in response to stakeholder feedback to include clinical data in outcome measures. Given the importance of AMI mortality as an extremely serious AMI outcome, we propose to assign the highest individual measure weight of 50 percent to the MORT–30–AMI (NQF #0230) measure. We propose to assign another 20 percent of the weight to the AMI Excess Days measure that is also included in the outcome quality domain. The remaining 20 percent of the AMI model composite quality score weight would be assigned to the HCAHPS Survey (NQF #0166) measure because we believe that incorporating this quality measure, which reflects performance regarding patients' perspectives on care, including communication, care transitions, and discharge information, is a meaningful patient experience measure of AMI model episode quality. This proposal of weights for the outcome and patient experience quality domains for the AMI model composite quality score is similar to the proposal of weights for the CABG model composite quality score described later in this section. We would assign the highest overall weight to the outcome quality domain (consisting of two measures and voluntary data submission) because the measures in this quality domain are specific to meaningful outcomes for AMI model beneficiaries. We do not propose to assign the HCAHPS survey (NQF #0166) measure the highest weight of the quality and patient experience domains, as the measure is not specific to AMI model episodes, but rather to all clinical conditions treated by AMI model participants. Unlike the CJR model where the quality measure weights in the CJR model composite quality score relatively evenly balance the outcome and patient experience quality domains, we would assign the highest weight in the AMI model to the outcome quality domain (consisting of two measures and voluntary data submission) because the measures in this quality domain are specific to meaningful, serious outcomes for AMI model beneficiaries, especially mortality which is not an outcome measure used in the CJR model composite quality score (80 FR 73375).

Under such an approach, we would first score individually each AMI model participant on the MORT–30–AMI (NQF #0230) measure; AMI Excess Days measure; and HCAHPS Survey (NQF #0166) measure based on the AMI model participant's performance percentile as compared to the national distribution of subsection (d) hospitals that are eligible for payment under the IPPS measure performance, assigning scores according to the point values displayed in Table 15. These individual measure scores have been set to reflect the measure weights included in Table 14 so they can ultimately be summed without adjustment in calculating the AMI model composite quality score. We note that in a chained anchor hospitalization where we propose in section III.C.4.a.(5) of this proposed rule that once an AMI model episode is initiated at a participant hospital, the AMI model episode would continue under the responsibility of that participant hospital, the transfer hospital's quality measure performance would not be included in assessing the AMI model participant's measure performance for the AMI model composite quality score. However, because the MORT–30–AMI (NQF #0230) measure attributes deaths to the initial hospital that admitted the beneficiary as an inpatient for AMI treatment in a transfer scenario, AMI model beneficiaries who die following treatment at a transfer hospital would be included in the AMI model participant's measure result and, therefore, their care represented in this quality measure.

TABLE 15—INDIVIDUAL MEASURE PERFORMANCE SCORING FOR THREE REQUIRED AMI QUALITY MEASURES

Performance percentile	MORT–30–AMI (points)	AMI excess days (points)	HCAHPS survey (points)
≥90th	10.00	4.00	4.00
≥80th and <90th	9.25	3.70	3.70
≥70th and <80th	8.50	3.40	3.40
≥60th and <70th	7.75	3.10	3.10
≥50th and <60th	7.00	2.80	2.80
≥40th and <50th	6.25	2.50	2.50

TABLE 15—INDIVIDUAL MEASURE PERFORMANCE SCORING FOR THREE REQUIRED AMI QUALITY MEASURES—Continued

Performance percentile	MORT–30–AMI (points)	AMI excess days (points)	HCAHPS survey (points)
≥30th and <40th	5.50	2.20	2.20
<30th	0.00	0.00	0.00

Given the current national distribution of subsection (d) hospitals eligible for payment under the IPPS performance on these measures, we believe 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 AMI model composite quality score. These three measures are well-established measures in use under CMS hospital programs, so we do not believe that scores below the 30th percentile reflect quality performance such that they should be assigned any individual quality measure score points under the AMI model.

Additionally, we would assign a measure quality score of 2 points for AMI model participants that successfully submit Hybrid AMI Mortality (NQF #2473) measure voluntary data and 0 points for participants that do not successfully submit these data. Because we would not use the actual Hybrid AMI Mortality (NQF #2473) measure result as an outcome measure in assessing AMI episode quality performance under the AMI model, we propose this straightforward binary approach to scoring the submission of Hybrid AMI Mortality (NQF #2473) measure voluntary data for hybrid outcome measure testing.

CMS may, in future regulations, require hospitals to report additional data elements from EHRs and propose additional hybrid measures in this and other models and programs, such as the HIQR Program. If, in future regulations, hospitals are required to report these same five data elements (age; heart rate; systolic blood pressure; troponin, creatinine) and six linking variables (CMS Certification Number (CCN), Medicare Health Insurance Claim (HIC) Number, date of birth, sex, admission date, and discharge date) that are included in the Hybrid AMI Mortality (NQF #2473) measure to support measurement through another CMS program, such as the HIQR Program, CMS may propose changes to the AMI model measures and the methodology for assigning the AMI model composite quality score.

Finally, we would award improvement scores on a measure-by-measure basis to those AMI model participants that demonstrate improvement on the measure; improvement points would be awarded for up to 10 percent of the maximum measure performance points available, with the total AMI model composite quality score capped at 20. Thus, improvement scores would be up to 1.0 points for the MORT–30–AMI (NQF #0230) measure; up to 0.4 points for the AMI Excess Days measure; and up to 0.4 points for the HCAHPS Survey (NQF #0166) measure.

We would sum the performance and improvement scores on the three quality measures and the score on successful submission of Hybrid AMI Mortality (NQF #2473) measure voluntary data to calculate an AMI composite quality score for each AMI model participant.

The proposal for the methodology to calculate the AMI model composite quality score is included in § 512.315(b)(1)–(4). We seek comment on our proposed methodology to calculate the AMI model composite quality score.

(2) CABG Model Composite Quality Score

We propose to assign each participant a CABG model composite quality score, calculated as the sum of the individual quality measure performance and improvement scores. The quality measure performance scores would be set to reflect the intended weights for each of the quality measures. Each quality measure performance would be assigned a weight in the CABG model composite quality score and possible scores for the measures would be set to reflect those weights. We would weight CABG model participant performance on each of the two required measures according to the measure weights displayed in Table 16.

TABLE 16—MEASURES AND ASSOCIATED PERFORMANCE WEIGHTS IN CABG MODEL COMPOSITE QUALITY SCORE

Quality measure	Weight in composite quality score	Quality domain/weight
MORT–30–CABG (NQF #2558)	75%	Outcome/75%.
HCAHPS Survey (NQF #0166)	25%	Patient Experience/25%.

We propose to assign 75 percent of the weight in the CABG model composite quality score to the outcome quality domain, assigning all weight to the MORT–30–CABG (NQF #2558) measure, and the remaining 25 percent of the CABG model composite quality score weight to the HCAHPS Survey (NQF #0166) measure representing the patient experience quality domain. This proposal of weights for the outcome and patient experience quality domains for the CABG model composite quality score is similar to the proposal of weights for the AMI model composite quality score described previously in this section. CABG mortality is an extremely serious outcome and, like our proposal for the Mort–30–AMI (NQF #230) measure in the AMI model composite quality score, we propose that the MORT–30–CABG (NQF #2558) measure would have the highest individual measure weight in the CABG model composite quality score. We would assign 25 percent of the weight to the HCAHPS survey measure (NQF #0166) because we believe that incorporating this quality measure, which reflects performance regarding patients' perspectives on care, including communication, care transitions, and discharge information, is a meaningful

patient experience measure of CABG model episode quality. We would assign the highest overall weight to the outcome quality domain (consisting of one measure) because it is specific to meaningful outcomes for CABG surgery for CABG model beneficiaries. We do not propose to assign the HCAHPS survey (NQF #0166) measure the highest weight of the quality and patient experience quality domains, as the measure is not specific to CABG model episodes, but rather to all clinical conditions treated by CABG model participants. Unlike the CJR model where the measure weights in the CJR model composite quality score relatively evenly balance the outcome and patient experience quality domains, CABG mortality representing the outcome quality domain is a serious outcome specific to CABG model beneficiaries such that we believe it deserves a high weight in the proposed CABG model composite quality score (80 FR 73375).

Under such an approach, we would first score individually each CABG model participant on the MORT–30–CABG (NQF #2558) measure; and HCAHPS Survey (NQF #0166) measure based on the participant's performance percentile as compared to the national distribution of subsection (d) hospitals that are eligible for payment under the IPPS measure performance, assigning scores according to the point values displayed in Table 17. These individual measure scores have been set to reflect the measure weights included in Table 16 so they can ultimately be summed without adjustment in calculating the CABG model composite quality score.

TABLE 17—INDIVIDUAL SCORING FOR TWO REQUIRED CABG QUALITY MEASURES

Performance percentile	MORT–30–CABG (points)	HCAHPS survey (points)
≥90th	15.00	5.00
≥80th and <90th	13.88	4.63
≥70th and <80th	12.75	4.25
≥60th and <70th	11.63	3.88
≥50th and <60th	10.50	3.50
≥40th and <50th	9.38	3.13
≥30th and <40th	8.25	2.75
<30th	0.00	0.00

Given the current national distribution of subsection (d) hospitals that are eligible for payment under the IPPS performance on these measures, we believe 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 two measures reflect the intended weight of the measure in the CABG model composite quality score. These two measures are well-established measures in use under CMS hospital programs, so we do not believe that scores below the 30th percentile reflect quality performance such that they should be assigned any individual quality measure score points under the CABG model.

Finally, we would award improvement scores on a measure-by-measure basis to those CABG model participants that demonstrate improvement on the measure; improvement points would be awarded for up to 10 percent of the maximum measure performance points available, with the total CABG model composite quality score capped at 20. Thus, improvement scores would be up to 1.5 points for the MORT–30–CABG (NQF #2558) measure; and up to 0.5 points for the HCAHPS Survey (NQF #0166) measure.

We would sum the performance and improvement scores on the two quality measures to calculate a CABG model composite quality score for each CABG model participant.

The proposal for the methodology to calculate the CABG model composite quality score is included in § 512.315(c)(1) through (4). We seek comment on our proposed methodology to calculate the CABG model composite quality score.

(3) SHFFT Model Composite Quality Score

We propose to adopt the same calculation of the SHFFT model composite quality score as the CJR model, including the proposed changes to the CJR model composite quality score methodology described in section V.E. of this proposed rule. For those participants in both SHFFT and CJR models, the SHFFT model composite quality score calculated each year would be the same as the CJR model composite quality score (80 73370 through 73381). We propose to assign each SHFFT model participant a SHFFT model composite quality score, capped at 20 points and calculated as the sum of the individual quality measure and improvement scores as well as successful submission of THA/TKA voluntary PRO and limited risk variable data if applicable. The quality measure performance scores would be set to reflect the intended weights for each of the quality measures. Each quality measure performance would be assigned a weight in the SHFFT model composite quality score and possible scores for the measures would be set to reflect those weights. We would weight SHFFT model participant performance on each of the two required measures and successful submission of THA/TKA voluntary PRO and limited risk variable data according to the measure weights displayed in Table 30.

TABLE 18—MEASURES AND ASSOCIATED PERFORMANCE WEIGHTS IN SHFFT MODEL COMPOSITE QUALITY SCORE

Quality measure	Weight in composite quality score	Quality domain/weight
Hip/Knee Complications (NQF #1550	50%	Outcome/50%.
THA/TKA voluntary PRO and limited risk variable submission	10%	Patient Experience/50%.
HCAHPS Survey (NQF #0166)	40%	

Consistent with the CJR model, we propose to assign 50 percent of the weight in the SHFFT model composite quality score to the outcome quality domain, assigning 50 percent of the weight to the Hip/Knee Complications (NQF #1550) measure. We propose to assign 50 percent of the weight to the patient experience quality domain, specifically 10 percent of the weight in that quality domain to the THA/TKA voluntary PRO and limited risk variable submission. We would assign 40 percent of the weight to the HCAHPS survey measure (NQF #0166) representing the patient experience (80 FR 73375). We would assign 40 percent to the HCAHPS survey measure (NQF #0166) because we believe 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 SHFFT episode quality under the SHFFT model, and because doing so ensures that there is a consistent methodology for linking quality performance and improvement to payment for SHFFT model participants that are also participating in the CJR model. As in the CJR model, we believe this weighting appropriately balances patient experience with meaningful health outcomes for beneficiaries (80 FR 73375).

Under such an approach, we would first score individually each SHFFT model participant on the Hip/Knee Complications (NQF #1550) measure; and HCAHPS Survey (NQF #0166) measure based on the participant's performance percentile as compared to the national distribution of subsection (d) hospitals that are eligible for payment under the IPPS measure performance, assigning scores according to the point values displayed in Table 19. These individual measure scores have been set to reflect the measure weights included in Table D6 so they can ultimately be summed without adjustment in calculating the SHFFT model composite quality score. We note that the point score for each decile for the two measures for the SHFFT model is the same as that used for other CJR model.

TABLE 19—INDIVIDUAL SCORING FOR TWO REQUIRED SHFFT QUALITY MEASURES

Performance percentile	Hip/knee complications (points)	HCAHPS survey quality score (points)
≥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

Given the current national distribution of subsection (d) hospitals that are eligible for payment under the IPPS performance on these measures, we believe 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 SHFFT model composite quality score. These two measures are well-established measures in use under CMS hospital programs, so we do not believe that scores below the 30th percentile reflect quality performance such that they should be assigned any individual quality measure score points under the SHFFT model.

As in the CJR model, we propose to assign a measure quality score of 2 points for SHFFT model participants that successfully submit THA/TKA voluntary PRO and limited risk variable data and 0 points for participants that do not successfully submit these data (80 FR 73376).

Finally, we would award improvement scores on a measure-by-measure basis to those SHFFT model participants that demonstrate improvement on the measure (defined as year-over-year improvement of 2 or more deciles in the performance distribution); improvement points would be awarded for up to 10 percent of the maximum measure performance points available, with the total SHFFT model composite quality score capped at 20. Thus, improvement scores would be up to 1.0 points for the Hip/Knee Complications (NQF #1550) measure; and up to 0.8 points for the HCAHPS Survey (NQF #0166) measure.

We would sum the performance and improvement scores on the two required quality measures and the score on successful submission of THA/TKA voluntary PRO and limited risk variable data to calculate a SHFFT model composite quality score for each SHFFT model participant. For those CJR model participants (the majority of SHFFT model participants), the SHFFT model composite quality score would be the same as the participant's score for the CJR model.

The proposal for the methodology to calculate the SHFFT model composite quality score is included in § 512.315(d)(1) through (4). We seek comment on our proposed methodology to calculate the SHFFT model composite quality score.

f. EPM Pay-for-Performance Methodologies To Link Quality and Payment

(1) Overview of Pay-for-Performance Proposals Applicable to the EPMs

As in the CJR model, we propose that the maximum effective discount factor for all EPM participants that could be incorporated in quality-adjusted target prices would be 3.0 percent (80 FR 733760). We refer to section III.D.4.b.(10) of this proposed rule for further discussion of the application of the effective discount factor to EPM-episode benchmark prices in calculating quality-adjusted target prices. EPM participants that provide high-quality episode care would have the opportunity to reduce the effective discount factor used to calculate their quality-adjusted prices at reconciliation. The effective discount factors are displayed in tables in the following EPM-specific sections, based on the EPM-specific composite quality score that would place each EPM participant into one of four quality categories, specifically ''Below Acceptable,'' ''Acceptable,'' ''Good,'' and ''Excellent,'' for each EPM performance year. Three tables are required to display the proposed effective discount factor and applicable discount factor (the discount

factor that represents the phase-in of repayment responsibility in performance years 2 (DR) and 3) for each quality category due to the phase-in of EPM participant repayment responsibility from no responsibility in performance year 1 and performance year 2 (NDR), to partial responsibility in performance years 2 (DR) and 3, and finally full responsibility in performance years 4 and 5 as discussed in section III.D.2.c. Note that the applicable discount factor only applies to EPM performance years 2 (DR) and 3.

(2) AMI and CABG Model Pay-for-Performance Methodologies

(a) AMI Model Pay-for-Performance Methodology

We propose to incorporate the AMI model composite quality score in the AMI model payment methodology by (1) requiring a minimum AMI model composite quality score for reconciliation payment eligibility if the AMI model participant's actual episode payments are less than the quality-adjusted target price and (2) determining the effective discount factor included in the quality-adjusted target price experienced by the AMI model participant in the reconciliation process. The payment policies we would apply are displayed in Tables 20, 21, and 22 for the performance years of the AMI model. Under the AMI model as proposed, there is no AMI model participant repayment responsibility in performance year 1 and performance year 2 (NDR) and this responsibility begins to be phased-in in performance year 2 (DR), with full implementation in performance year 4. Because repayment responsibility is phased-in, in performance years 2 (DR) and 3, repayment responsibility only applies to a portion of the amount of excess AMI model episode spending that results from the quality-adjusted target prices that include the AMI model participant's effective discount factor. We, therefore, refer in the repayment column to the applicable discount factor for repayment amount in performance years 2 (DR) and 3. The effective discount factor applies to both the reconciliation payment and the repayment amount in performance years 4 and 5. We note that the average Medicare payment for historical AMI episodes beginning in CYs 2012 to 2014 was $24,200.[70]

TABLE 20—PERFORMANCE YEAR 1 AND PERFORMANCE YEAR 2 (NDR): RELATIONSHIP OF AMI MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

AMI model composite quality score	Eligible for reconciliation payment	Effective discount factor for reconciliation payment %	Effective discount factor for repayment amount
<3.6	No	3.0	Not applicable,
>=3.6 and <6.9	Yes	3.0	Not applicable.
>=6.9 and <=14.8	Yes	2.0	Not applicable.
>14.8	Yes	1.5	Not applicable.

TABLE 21—PERFORMANCE YEARS 2 (DR) AND 3: RELATIONSHIP OF AMI MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

AMI model composite quality score	Eligible for reconciliation payment	Effective discount factor for reconciliation payment %	Applicable discount factor for repayment amount* %
<3.6	No	3.0	2.0
>=3.6 and <6.9	Yes	3.0	2.0
>=6.9 and <=14.8	Yes	2.0	1.0
>14.8	Yes	1.5	0.5

*The applicable discount factor for the repayment amount only applies in performance years 2 (DR) and 3 when repayment responsibility is being phased-in.

TABLE 22—PERFORMANCE YEARS 4 AND 5: RELATIONSHIP OF AMI MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

AMI model composite quality score	Eligible for reconciliation payment	Effective discount factor for reconciliation payment	Effective discount factor for repayment amount
<3.6	No	3.0	3.0
>=3.6 and <6.9	Yes	3.0	3.0
>=6.9 and <=14.8	Yes	2.0	2.0
>14.8	Yes	1.5	1.5

[70] Episodes for AMI beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CYs 2012–2014.

Under this approach, the maximum AMI model effective discount factor included in the quality-adjusted target price would be 3.0 percent, consistent with the CJR model (80 FR 73365). We believe that a maximum effective discount factor of 3.0 percent 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 BPCI participants are testing AMI episodes subject to the 3.0 percent discount factor. AMI model participants that provide high quality episode care would have the opportunity for a lower effective discount factor to be included in their quality-adjusted target prices at reconciliation as displayed in Tables 20, 21, and 22.

Under this methodology, we would require AMI model participants to achieve a minimum AMI model composite quality score of >=3.6 to be eligible for a reconciliation payment if actual episode payments were less than the quality-adjusted target price based on the 3.0 percent maximum effective discount factor. Participants with below acceptable quality performance reflected in an AMI model composite quality score <3.6 would not be eligible for a reconciliation payment if actual AMI model episode payments were less than the quality-adjusted target price. A level of quality performance that is below acceptable would not affect AMI model participants' repayment responsibility if actual AMI model episode payments exceed the quality-adjusted target price. We believe that excessive reductions in utilization that lead to low actual AMI model episode payments and that could result from the financial incentives of an EPM would be limited by a requirement that this minimum level of AMI model episode quality be achieved for reconciliation payments to be made. This policy would encourage AMI model participants to focus on appropriate reductions or changes in utilization to achieve high quality care in a more efficient manner. Therefore, these participants would be ineligible to receive a reconciliation payment if actual AMI model episode payments were less than the quality-adjusted target price.

AMI model participants with an acceptable AMI model composite quality score of >=3.6 and <6.9 would be eligible for a reconciliation payment if actual AMI model episode payments were less than the quality-adjusted target price based on a 3.0 percent effective discount factor because their quality performance was at the acceptable level established for the AMI model. Therefore, these AMI model participants would be eligible to receive a reconciliation payment if actual AMI model episode payments were less than the quality-adjusted target price.

AMI model participants with a good AMI model composite quality score of >=6.9 and <=14.8 would be eligible for a reconciliation payment if actual AMI model episode payments were less than the quality-adjusted target price based on a 2.0 percent effective discount factor that reflects their good quality performance. Thus, participants achieving this level of quality for AMI episodes under the AMI model would either have less repayment responsibility (that is, the reduced effective discount factor would offset a portion of their repayment responsibility) or receive a higher reconciliation payment (that is, the reduced effective discount factor would increase the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual AMI model episode payments to quality-adjusted target prices that include the maximum 3.0 percent effective discount factor.

Finally, AMI model participants with an excellent AMI model composite score quality score of >=14.8 would be eligible to receive a reconciliation payment if actual AMI model episode payments were less than the quality-adjusted target price based on a 1.5 percent effective discount factor that reflects their excellent performance. Thus, participants achieving this level of quality for AMI episodes under the AMI model would either have less repayment responsibility (that is, the reduced effective discount factor would offset a portion of their repayment responsibility) or receive a higher reconciliation payment (that is, the reduced effective discount factor would increase the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual AMI model episode payments to quality-adjusted target prices that include the maximum 3.0 percent effective discount factor.

Under this methodology, the proposed stop-loss and stop-gain limits discussed in section III.D.7.b. of this proposed rule would not change. We believe this approach to quality incentive payments based on the AMI model composite quality score could have the effect of increasing the alignment of the financial and quality performance incentives under the AMI model to the potential benefit of AMI model participants and their collaborators as well as CMS, and would be consistent with the CJR model methodology linking quality and payment.

The proposal to link quality to payment in the AMI model pay-for-performance methodology is included in § 512.315(b)(5). We seek comment on our proposal to link quality to payment in the AMI model pay-for-performance methodology.

(b) CABG Model Pay-for-Performance Methodology

We propose to incorporate the CABG model composite quality score in the CABG model payment methodology by—(1) requiring a minimum CABG model composite quality score for reconciliation payment eligibility if the CABG model participant's actual episode payments are less than the quality-adjusted target price; and (2) determining the effective discount factor included in the quality-adjusted target price experienced by the CABG model participant in the reconciliation process. The payment policies we would apply are displayed in Tables 23, 24, and 25 for the performance years of the CABG model. Under the CABG model as proposed, there is no CABG model participant repayment responsibility in performance year 1 and performance year 2 (NDR) and this responsibility begins to be phased-in in performance year 2 (DR), with full implementation in performance year 4. Because repayment responsibility is phased-in, in performance years 2 (DR) and 3, repayment responsibility only applies to a portion of the amount of excess CABG model episode spending that results from the quality-adjusted target prices that include the CABG model participant's effective discount factor. We, therefore, refer in the repayment column to the applicable discount factor for repayment amount in performance years 2 (DR) and 3. The effective discount factor applies to both the reconciliation payment and the repayment amount in performance years 4 and 5. We note that the average Medicare payment for historical CABG episodes beginning in CYs 2012 to 2014 was $47,000.[71]

[71] Episodes for CABG beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CYs 2012–2014.

TABLE 23—PERFORMANCE YEAR 1 AND PERFORMANCE YEAR 2 (NDR): RELATIONSHIP OF CABG MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

CABG model composite quality score	Eligible for reconciliation payment	Effective discount factor for reconciliation payment %	Effective discount factor for repayment amount %
<2.8	No	3.0	Not applicable.
>=2.8 and <4.8	Yes	3.0	Not applicable.
>=4.8 and <=17.5	Yes	2.0	Not applicable.
>17.5	Yes	1.5	Not applicable.

TABLE 24—PERFORMANCE YEARS 2 (DR) AND 3: RELATIONSHIP OF CABG MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

CABG model composite quality score	Eligible for reconciliation payment	Effective discount factor for reconciliation payment %	Applicable discount factor for repayment amount * %
<2.8	No	3.0	2.0
>=2.8 and <4.8	Yes	3.0	2.0
>=4.8 and <=17.5	Yes	2.0	1.0
>17.5	Yes	1.5	0.5

* The applicable discount factor for the repayment amount only applies in performance years (DR) and 3 when repayment responsibility is being phased-in.

TABLE 25—PERFORMANCE YEARS 4 AND 5: RELATIONSHIP OF CABG MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

CABG model composite quality score	Eligible for reconciliation payment	Effective discount factor for reconciliation payment %	Effective discount factor for repayment amount %
<2.8	No	3.0	3.0
>=2.8 and <4.8	Yes	3.0	3.0
>=4.8 and <=17.5	Yes	2.0	2.0
>17.5	Yes	1.5	1.5

Under this approach, the maximum CABG model effective discount factor included in the quality-adjusted target price would be 3.0 percent, consistent with the CJR model (80 FR 73365). We believe that a maximum effective discount factor of 3.0 percent is reasonable as it is within the range of discount percentages included in the Medicare Acute Care Episode (ACE) demonstration and it is the Model 2 BPCI discount factor for 30 and 60 day episodes, where BPCI participants are testing CABG episodes subject to the 3.0 percent discount factor. CABG model participants that provide high quality episode care would have the opportunity for a lower effective discount factor to be included in their quality-adjusted target prices at reconciliation as displayed in Tables 23, 24, and 25.

Under this methodology, we would require CABG model participants to achieve a minimum CABG model composite quality score of >=2.8 to be eligible for a reconciliation payment if actual episode payments were less than the quality-adjusted target price based on the 3.0 percent maximum effective discount factor. Participants with below acceptable quality performance reflected in an CABG model composite quality score <2.8 would not be eligible for a reconciliation payment if actual CABG model episode payments were less than the quality-adjusted target price. A level of quality performance that is below acceptable would not affect participants' repayment responsibility if actual CABG model episode payments exceed the quality-adjusted target price. We believe that excessive reductions in utilization that lead to low actual CABG model episode payments and that could result from the financial incentives of an EPM would be limited by a requirement that this minimum level of CABG model episode quality be achieved for reconciliation payments to be made. This policy would encourage CABG model participants to focus on appropriate reductions or changes in utilization to achieve high quality care in a more efficient manner. Therefore, these participants would be ineligible to receive a reconciliation payment if actual CABG model episode payments were less than the quality-adjusted target price.

CABG model participants with an acceptable CABG model composite quality score of >=2.8 and <4.8 would be eligible for a reconciliation payment if actual CABG model episode payments were less than the quality-adjusted target price based on a 3.0 percent effective discount factor because their quality performance was at the acceptable level established for the CABG model. Therefore, these CABG model participants would be eligible to

receive a reconciliation payment if actual CABG model episode payments were less than the quality-adjusted target price.

CABG model participants with a good CABG model composite quality score >=4.8 and <=17.5 would be eligible for a reconciliation payment if actual CABG model episode payments were less than the quality-adjusted target price based on a 2.0 percent effective discount factor that reflects their good quality performance. Thus, participants achieving this level of quality for CABG episodes under the CABG model would either have less repayment responsibility (that is, the reduced effective discount factor would offset a portion of their repayment responsibility) or receive a higher reconciliation payment (that is, the reduced effective discount factor would increase the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual CABG model episode payments to quality-adjusted target prices that include the maximum 3.0 percent effective discount factor.

Finally, CABG model participants with an excellent CABG model composite score quality score of >17.5 would be eligible to receive a reconciliation payment if actual CABG model episode payments were less than the quality-adjusted target price based on a 1.5 percent effective discount factor that reflects their excellent performance. Thus, participants achieving this level of quality for CABG model episodes would either have less repayment responsibility (that is, the reduced effective discount factor would offset a portion of their repayment responsibility) or receive a higher reconciliation payment (that is, the reduced effective discount factor would increase the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual CABG model episode payments to quality-adjusted target prices that include the maximum 3.0 percent effective discount factor.

Under this methodology, the proposed stop-loss and stop-gain limits discussed in section III.D.7.b. of this proposed rule would not change. We believe this approach to quality incentive payments based on the CABG model composite quality score could have the effect of increasing the alignment of the financial and quality performance incentives under the CABG model to the potential benefit of CABG model participants and their collaborators as well as CMS, and would be consistent with the CJR model methodology linking quality and payment.

The proposal to link quality to payment in the CABG model pay-for-performance methodology is included in § 512.315(c)(5). We seek comment on our proposal to link quality to payment in the CABG model pay-for-performance methodology.

(c) Alignment Between the AMI and CABG Model Methodologies

The AMI and CABG models are closely related, given that they both are based on a significant event or procedure for a beneficiary with CAD. As discussed in sections III.D.2.b. and c. of this proposed rule, we propose the use of a 30-day mortality measure in both models, specifically MORT–30–AMI (NQF #0230) with a weight of 50 percent in the AMI model composite quality score and MORT–30–CABG (NQF #2558) with a weight of 75 percent in the CABG model quality score. The beneficiaries included in the measure have some overlap, because some beneficiaries with AMI will have a CABG during their hospitalization that begins an episode. Analysis of both the MORT–30–AMI (NQF #0230) and MORT–30–CABG (NQF #2558) measure national distributions suggests that improving from the 25th percentile to 75th percentile represents roughly a 1 percentage point decrease in mortality rates for both measures.

In addition, we note that for historical episodes beginning in 2012 to 2014, the average Medicare spending for an AMI episode that extends 90 days post-hospital discharge was approximately $24,200 and for a CABG episode was approximately $47,000.[72] However, because we propose the same 1.5 percent to 3.0 percent effective discount factor range based on quality performance and improvement for the AMI and CABG models (and, to a lesser degree, because of the modestly lower weight assigned to the mortality measure under the AMI model), the absolute dollar amounts tied to changes in AMI or CABG mortality rates are different in the two models. A larger absolute financial incentive is associated with improvement in CABG mortality than AMI mortality under our proposal. We recognize that mortality is a serious outcome for beneficiaries with CAD who have a significant event or procedure, and we considered setting a wider effective discount factor range based on quality in the AMI model than the CABG model to align the absolute financial incentives to improve mortality under both models. For example, to create a more similar absolute financial incentive between the lowest and highest effective discount percentages in the AMI and CABG models, we could set the effective discount factor range for the AMI model at 0.75 percent to 3.75 percent and the CABG model range at 1.5 percent to 3 percent. Alternatively, we could set the AMI model effective discount factor range at 1.5 percent to 3 percent and compress the CABG effective discount factor range. While we do not propose different effective discount factor ranges for the AMI and CABG models in order to retain consistency with the CJR model and the BPCI initiative, we seek comments about the potential benefits and drawbacks of establishing the same absolute dollar incentive for similar improvements in quality across different models that have similar measures but vary in average episode cost. This feedback will be useful as we consider future episode payment models and candidate quality measures for potential new and existing models, as well as consider future refinements to the pay-for-performance methodologies under the models. Our goal in all of our episode payment models is to create strong financial incentives for quality performance and improvement for participants at all level of current quality performance and to rationalize the strength of the financial incentives in the context of the specificity and importance of the quality measures used under the models.

(3) SHFFT Model Pay-for-Performance Methodology

We propose to incorporate the SHFFT model composite quality score in the SHFFT model payment methodology by (1) requiring a minimum SHFFT model composite quality score for reconciliation payment eligibility if the SHFFT model participant's actual episode payments are less than the quality-adjusted target price and (2) determining the effective discount factor included in the quality-adjusted target price experienced by the SHFFT model participant in the reconciliation process. The payment policies we would apply are displayed in Tables 26, 27, and 28 for the performance years of the SHFFT model. Under the SHFFT model as proposed, there is no SHFFT model participant repayment responsibility in performance year 1 and performance year 2 (NDR) and this responsibility begins to be phased-in in performance year 2 (DR), with full implementation in performance year 4. Because repayment

[72] Episodes for AMI and CABG beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CYs 2012–2014.

responsibility is phased-in, in performance years 2 (DR) and 3, repayment responsibility only applies to a portion of the amount of excess SHFFT model episode spending that results from the quality-adjusted target prices that include the SHFFT model participant's effective discount factor. We, therefore, refer in the repayment column to the applicable discount factor for repayment amount in performance years 2 (DR) and 3. The effective discount factor applies to both the reconciliation payment and the repayment amount in performance years 4 and 5. We note that the average Medicare payment for historical SHFFT episodes beginning in CYs 2012 to 2014 was $43,000.[73]

We refer to section V.E. of this proposed rule for discussion of the correction to the composite quality score ranges for the four quality categories from what was presented in the CJR final rule (80 FR 73378). The SHFFT model composite quality score ranges displayed in Tables 26 through 28 are the corrected ranges that also apply to the CJR model.

TABLE 26—PERFORMANCE YEAR 1 AND PERFORMANCE YEAR 2 (NDR): RELATIONSHIP OF SHFFT MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

SHFFT model composite quality score	Eligible for reconciliation payment	Effective discount factor for reconciliation payment %	Effective discount factor for repayment amount
<5.0	No	3.0	Not applicable.
>=5.0 and <6.9	Yes	3.0	Not applicable.
>=6.9 and <=15.0	Yes	2.0	Not applicable.
>15.0	Yes	1.5	Not applicable.

TABLE 27—PERFORMANCE YEARS 2 (DR) AND 3: RELATIONSHIP OF SHFFT MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

SHFFT Model Composite Quality Score	Eligible for Reconciliation Payment	Effective Discount Factor for Reconciliation Payment %	Applicable Discount Factor for Repayment Amount* %
<5.0	No	3.0	2.0
>=5.0 and <6.9	Yes	3.0	2.0
>=6.9 and <=15.0	Yes	2.0	1.0
>15.0	Yes	1.5	0.5

*The applicable discount factor for the repayment amount only applies in performance years 2 (DR) and 3 when repayment responsibility is being phased-in.

TABLE 28—PERFORMANCE YEARS 4 AND 5: RELATIONSHIP OF SHFFT MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

SHFFT model composite quality score	Eligible for reconciliation payment	Effective discount factor for reconciliation payment %	Effective discount factor for repayment amount %
<5.0	No	3.0	3.0
>=5.0 and <6.9	Yes	3.0	3.0
>=6.9 and <=15.0	Yes	2.0	2.0
>15.0	Yes	1.5	1.5

Under this methodology, we would require SHFFT model participants to achieve a minimum SHFFT model composite quality score of >=5.0 to be eligible for a reconciliation payment if actual episode payments were less than the quality-adjusted target price based on the 3.0 percent maximum effective discount factor. Participants with below acceptable quality performance reflected in a SHFFT model composite quality score <5.0 would not be eligible for a reconciliation payment if actual SHFFT model episode payments were less than the quality-adjusted target price. A level of quality performance that is below acceptable would not affect participants' repayment responsibility if actual SHFFT model episode payments exceed the quality-adjusted target price. We believe that excessive reductions in utilization that lead to low actual SHFFT model episode payments and that could result from the financial incentives of an EPM would be limited by a requirement that this minimum level of SHFFT model episode quality be achieved for reconciliation payments to be made. This policy would encourage SHFFT model participants to

[73] Episodes for SHFFT beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CYs 2012–2014.

focus on appropriate reductions or changes in utilization to achieve high quality care in a more efficient manner. Therefore, these participants would be ineligible to receive a reconciliation payment if actual SHFFT model episode payments were less than the quality-adjusted target price.

SHFFT model participants with an acceptable SHFFT model composite quality score of >=5.0 and <6.9 would be eligible for a reconciliation payment if actual SHFFT model episode payments were less than the quality-adjusted target price based on a 3.0 percent effective discount factor because their quality performance was at the acceptable level established for the SHFFT model. Therefore, these SHFFT model participants would be eligible to receive a reconciliation payment if actual SHFFT model episode payments were less than the quality-adjusted target price.

SHFFT model participants with a good SHFFT model composite quality score of >=6.9 and <=15.0 would be eligible for a reconciliation payment if actual SHFFT model episode payments were less than the quality-adjusted target price based on a 2.0 percent effective discount factor that reflects their good quality performance. Thus, participants achieving this level of quality for SHFFT model episodes under the SHFFT model would either have less repayment responsibility (that is, the reduced effective discount factor would offset a portion of their repayment responsibility) or receive a higher reconciliation payment (that is, the reduced effective discount factor would increase the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual SHFFT model episode payments to quality-adjusted target prices that include the maximum 3.0 percent effective discount factor.

Finally, SHFFT model participants with an excellent SHFFT model composite score quality score of >15.0 would be eligible to receive a reconciliation payment if actual SHFFT model episode spending was less than the quality-adjusted target price based on a 1.5 percent effective discount factor that reflects their excellent performance. Thus, participants achieving this level of quality for SHFFT model episodes would either have less repayment responsibility (that is, the reduced effective discount factor would offset a portion of their repayment responsibility) or receive a higher reconciliation payment (that is, the reduced effective discount factor would increase the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual SHFFT model episode payments to quality-adjusted target prices that include the maximum 3.0 percent effective discount factor.

Under this methodology, the proposed stop-loss and stop-gain limits discussed in section III.D.7.b. of this proposed rule would not change. We believe this approach to quality incentive payments based on the SHFFT model composite quality score could have the effect of increasing the alignment of the financial and quality performance incentives under the SHFFT model to the potential benefit of SHFFT model participants and their collaborators as well as CMS, and would be consistent with the CJR model methodology linking quality and payment.

The proposal to link quality to payment in the SHFFT model pay-for-performance methodology is included in § 512.315(d)(5). We seek comment on our proposal to link quality to payment in the SHFFT model pay-for-performance methodology.

4. Details on Quality Measures for the EPMs

a. AMI Model-Specific Measures

(1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230) (MORT–30–AMI)

(a) Background

AMI is one of the most common principal hospital discharge diagnoses among older adults and is associated with high mortality. AMI was the tenth most common principal discharge diagnosis among patients with Medicare in 2012.[74] Each year, over 600,000 Americans will experience an AMI. Despite improvements in treatments, 30-day mortality rates following AMI exceed 7 percent. CMS pays approximately $11.7 billion annually for in-hospital costs for Medicare beneficiaries with coronary heart disease, of which AMI is a major contributor. The high prevalence and considerable morbidity and mortality associated with AMI create an economic burden on the healthcare system.[75]

Hospital mortality is an outcome that is likely attributable to care processes and is an important outcome for patients. 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, all contribute to patient outcomes. Many current hospital interventions are known to decrease the risk of death within 30 days of hospital admission.[76] [77] We believe it is important to assess the quality of care provided to Medicare beneficiaries who are hospitalized for AMI.

The measure developed by CMS, and currently implemented in the HIQR and HVBP Programs, assesses a hospital's risk-standardized mortality rate, which is the rate of death after admission to a hospital with a principal diagnosis of AMI. The measure outcome is the rate of mortality occurring after admission with a principal diagnosis of AMI for patients 65 and older during a 30-day period that begins with the date of the index admission for the specific hospital. An index admission is the hospitalization which is included in the measure cohort because it meets all inclusion criteria and does not meet any exclusion criteria. The index admission is the hospitalization to which the mortality outcome is attributed. The median hospital-level risk-standardized mortality rate for 2016 public reporting on Hospital Compare was 14.2 percent, with a interquartile range from 13.7 percent to 14.6 percent in hospitals. The variation in mortality rates suggests that important differences in the quality of care delivered across hospitals exist, and there is room for quality improvement.

We developed the measure of hospital-level risk-standardized mortality rate (RSMR) following AMI hospitalization, which was later endorsed by the NQF (NQF #0230). The measure has been publicly reported on Hospital Compare since FY 2007, and was incorporated into what is now the HIQR Program since FY 2008 (FY 2008 IPPS/LTCH final rule 71 FR 67960), and the HVBP Program since FY 2014 (FY 2011 IPPS/LTCH final rule 76 FR 26510).

(b) Data Sources

We propose to use Medicare Part A and Part B FFS claims submitted by the

[74] Agency for Healthcare Research and Quality (AHRQ). Healthcare Cost and Utilization Project (HCUP) *http://hcupnet.ahrq.gov/*.

[75] American Heart Association. Heart Disease and Stroke Statistics—2010 Update. Dallas, Texas: American Heart Association; 2010. c2010, American Heart Association.

[76] Jha AK, Orav EJ, Li Z, Epstein AM. The inverse relationship between mortality rates and performance in the Hospital Quality Alliance measures. Health Aff (Millwood). 2007 Jul–Aug; 26(4):1104–10.

[77] Rathore SS, Curtis JP, Chen J, Wang Y, Nallamothu BK, Epstein AJ, Krumholz HM. National Cardiovascular Data Registry. Association of door-to-balloon time and mortality in patients admitted to hospital with ST elevation myocardial infarction: National cohort study. BMJ. 2009 May 19; 338:b1807.

AMI model participant as the data source for calculation of the MORT–30–AMI (NQF #0230) measure. Index admission diagnoses and in-hospital comorbidities are assessed using Medicare Part A claims. Additional comorbidities prior to the index admission are assessed as Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to the index (initial) admission. Enrollment and post-discharge mortality status are obtained from Medicare's enrollment database which contains beneficiary demographics, benefits/coverage, and vital status information.

(c) Cohort

The MORT–30–AMI (NQF #0230) measure includes Medicare FFS beneficiaries, aged 65 years or older, discharged from non-federal acute care hospitals with a principal discharge diagnosis of AMI and with a complete claims history for the 12 months prior to admission. Eligible hospitalizations are defined using the following ICD–10–CM codes: I2109, I2119, I2111, I2119, I2129, I214, and I213.

We propose that the measure will include index admissions to all non-federal acute care hospitals, which includes all AMI model participants. Hospital performance will only be publically reported for hospitals with 25 or more index admissions in the 3-year measurement period. The AMI model cohort would differ from the hospital cohort that is currently captured in the measure through the HIQR Program. Although performance on the measure will not be publically reported for hospitals with fewer than 25 cases, they will receive information about their performance. We refer readers to section III.B.5. of this proposed rule for participant selection for the AMI model. For eligible hospitalizations defined using ICD–9–CM codes, we refer readers to the CMS Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(d) Inclusion and Exclusion Criteria

We propose that an index admission is the hospitalization to which the mortality outcome is attributed. We note that for purposes of the EPMs where we need to identify episodes that are included in the EPMs, we use the terms anchor and chained anchor hospitalization to identify hospitalizations that initiate EPM episodes for beneficiaries whose care is included in the EPMs. In describing the quality measures themselves in detail in section III.E.4. of this proposed rule, we use the term index hospitalization to identify hospitalizations of beneficiaries whose outcomes are included in the measures. Thus, anchor hospitalizations and index hospitalizations would have varying degrees of overlap depending on the specific quality measure. The measure includes the following index admissions for patients:

- Having a principal discharge diagnosis of AMI.
- Enrolled in Medicare FFS.
- Aged 65 or over.
- Not transferred from another acute care facility.
- Enrolled in Medicare Part A and Part B for the 12 months prior to the date of index admission, and enrolled in Part A during the index admission.

This measure excludes the following index admissions for patients:

- Discharged alive on the day of admission or the following day who were not transferred to another acute care facility.
- With inconsistent or unknown vital status or other unreliable demographic (age and gender) data;
- Enrolled in the Medicare hospice program any time in the 12 months prior to the index admission, including the first day of the index admission;
- Discharged against medical advice American Medical Association (AMA); or
- Without at least 30 days of post-discharge enrollment in FFS Medicare as the 30-day mortality outcome cannot be assessed for these patients.

Finally, 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, only one index admission for AMI per beneficiary is randomly selected for inclusion in the cohort.

(e) Risk-Adjustment

We note that this measure is aligned with the risk-adjustment methodologies adopted for the MORT–30–AMI (NQF #0230) measure under the HIQR Program in accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act, as finalized in FY 2008 IPPS/LTCH final rule (2008 IPPS/LTCH final rule 71 FR 67960). We also note that the measure risk adjustment takes into account patient age, sex, and comorbidities to allow a fair assessment of hospital performance. The measure defines the patient risk factors for mortality using diagnosis codes collected from all patient claims 1 year prior to patient index hospitalization for AMI. As previously noted in the MORT–30–AMI measure (NQF #0230), ICD–10–CM codes on Medicare Parts A and B administrative claims are used to inform the risk prediction for each patient; diagnostic codes from post-acute care 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. Use of Parts A and B data does not mean the measure is applicable to post-acute care settings, only that it uses comprehensive data to predict the risk of the outcome and adjust for hospital patient case mix. We note that the patient diagnosis codes are grouped using Hierarchical Condition Categories (HCCs), which are clinically relevant diagnostic groups of codes. The CCs used in the risk-adjustment model for this measure are provided on the CMS QualityNet Web site at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069856694*.

In summary, age, sex, and comorbidities present at the time of admission are adjusted for differences in hospital case mix (patient risk factors). The measure uses the hierarchical logistic regression model (HLM) statistical methodology for risk adjustment.

(f) Calculating the Risk-Standardized Mortality Ratio (RSMR) and Performance Period

We propose to calculate hospital 30-day, all-cause, risk-standardized mortality rates consistent with the methodology used to risk standardize all readmission and mortality measures used in CMS hospital quality programs. Using HLM, we calculate the hospital-level risk-standardized mortality rate following AMI hospitalization by producing a ratio of the number of ''predicted'' deaths (that is, the adjusted number of deaths at a specific hospital) to the number of ''expected'' deaths (that is, the number of deaths if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw mortality rate.

A 3-year rolling period for calculating measure results would be consistent with the time frame used for the HIQR Program (FY 2008 IPPS/LTCH final rule 71 FR 67960). Section III.E.5. of this proposed rule, Form, Manner, and Timing of Quality Measure Submission, summarizes the proposed measure performance periods for AMI model performance years 1 through 5. We note that, for each performance year, improvement on the MORT–30–AMI (NQF #0230) measure would be determined by comparing measure results from that performance year to results in the 3-year rolling

measurement period immediately preceding each AMI model performance year to results from the 3-year period from July 1, 2014 through June 30, 2017, for performance year 2 by comparing measure results in this year to results from the 3-year period from July 1, 2015 through June 30, 2018, in performance year 3 by comparing measure results in this year to results from the 3-year period from July 1, 2016 and June 30, 2019, in performance year 4 by comparing measure results in this year to results from the 3-year period from July 1, 2017 and June 30, 2020, and in performance year 5 by comparing measure results in this year to results from the 3-year period from July 1, 2018 and June 30 2021.

The proposal to include Hospital-level 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following AMI hospitalization (NQF #0230) measure in the AMI model is included in § 512.411(a)(1). We seek comment on this proposal to include Hospital-level 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following AMI hospitalization (NQF #0230) measure in the AMI model to assess quality performance.

(2) Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (AMI Excess Days)

(a) Background

The Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (AMI) measure (AMI Excess Days) is a risk-standardized outcome measure that compares the number of days that patients are predicted to spend in acute care across the full spectrum of possible acute care events (hospital readmissions, observation stays, and ED visits) after discharge from a hospital for AMI, to the days patients are expected to spend in acute care based on their degree of illness.

Some of the costs for AMI can be attributed to high acute care utilization for post-discharge AMI patients in the form of readmissions, observation stays, and emergency department (ED) visits. We note that patients admitted for AMI have disproportionately high readmission rates, and that readmission rates following discharge for AMI are highly variable across hospitals in the United States.[78,79]

For the previously adopted HIQR Program measure, Hospital 30-Day, All-Cause Risk- Standardized Readmission Rate (RSRR) following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505) (CY 2009 OPPS/ASC final rule with comment period; 73 FR 68780 through 68781), publicly reported 30-day risk-standardized readmission rates for AMI ranged from 17.5 percent to 30.3 percent for the time period between July 2011 and June 2012.[80] However, in addition to an increased risk of requiring readmission in the post-discharge period, patients are also at risk of returning to the hospital for both observation stays and ED visits which also characterize potentially preventable acute care. ED visits represent a significant proportion of post-discharge acute care utilization for all conditions, including patients with AMI. Two recent studies conducted in patients of all ages showed that 9.5 percent of patients return to the ED within 30 days of hospital discharge; additionally, about 12 percent of these patients are initially discharged from the ED and are not captured by the previously adopted HIQR Program readmission measures.[8,9] The rising use of observation stays among Medicare beneficiaries between 2001 and 2008 sparked concern among patients, providers, and policymakers that the AMI 30-day Readmission (NQF #0505) measure does not capture the full range of unplanned acute care events that occur in the post-discharge period. In order to address the rising use of observation stays amongst Medicare beneficiaries CMS is proposing the Excess Days in Acute Care after Hospitalization for AMI (AMI Excess Days) measure for use in the AMI model. The AMI Excess Days measure comprehensively captures all post-discharge, unplanned acute care events as a count of the excess days a hospital's patients spent as inpatients, in observation, or in the ED over a 3-year measurement period.

In 2014, we developed the proposed measure of excess days in acute care following AMI hospitalization, supported for use in the Hospital Quality Reporting Program by the MAP and submitted to the NQF for endorsement. We note that this measure was submitted for endorsement to the NQF All-Cause Admissions and Readmissions Committee in January 2016 with appropriate consideration for sociodemographic status. The measure was finalized for the HIQR Program FY 2018 payment determination (FY 2016 IPPS/LTCH final rule 80 FR 49690).

(b) Data Sources

We propose to use Medicare Part A and Part B FFS claims submitted by the AMI model participant as the data source for calculation of the AMI Excess Days measure as harmonized with the MORT–30–AMI(NQF #0230) and READM–30–AMI(NQF #0505) measures. Index admission diagnoses and in-hospital comorbidities are assessed using Medicare Part A claims. Additional comorbidities prior to the index admission are assessed as Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to the index (initial) admission. Enrollment and post-discharge mortality status are obtained from Medicare's enrollment database which contains beneficiary demographic, benefits/coverage, and vital status information.

(c) Cohort

The AMI Excess Days measure includes Medicare FFS beneficiaries, aged 65 years or older, discharged from non-federal acute care hospitals with a principal discharge diagnosis of AMI and with a complete claims history for the 12 months prior to index admission. Eligible hospitalizations are defined using the following ICD–10–CM codes: I2109, I2111, I2119, I2129, I214, and I213.

We propose that the measure will include index admissions to all non-federal acute care hospitals, which includes all participants in the AMI model. Hospital performance will only be publically reported for hospitals with 25 or more index admissions in the 3-year measurement period. The AMI model cohort would differ from the hospital cohort that is currently captured in the measure through the HIQR Program. Although performance on the measure will not be publically reported for hospitals with fewer than 25 cases, such hospitals will receive information about their performance on the measure. We refer readers to section III.B.5. of this proposed rule for a discussion of AMI model participant selection.

(d) Inclusion and Exclusion Criteria

We propose that an index admission is the hospitalization to which the excess days in acute care outcome is attributed. We note that for purposes of

[78] Krumholz HM, Merrill AR, Schone EM et al. Patterns of hospital performance in acute myocardial infarction and heart failure 30-day mortality and readmission. Circulation. Cardiovascular Quality & Outcomes. Sep 2009;2(5):407–413.

[79] Bernheim SM, Grady JN, Lin Z, et al. National patterns of risk-standardized mortality and readmission for acute myocardial infarction and heart failure. Update on publicly reported outcomes measures based on the 2010 release. Circulation. Cardiovascular Quality & Outcomes. Sep 2010;3(5):459–467.

[80] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook Performance Report on Outcome Measures September 2013. September 2013; Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/-Medicare-Hospital-Quality-Chartbook-2013.pdf.*

the EPMs where we need to identify episodes that are included in the EPMs, we use the terms anchor and chained anchor hospitalization to identify hospitalizations that initiate EPM episodes for beneficiaries whose care is included in the EPMs. In describing the quality measures themselves in detail in section III.E.4. of this proposed rule, we use the term index hospitalization to identify hospitalizations of beneficiaries whose outcomes are included in the measures. Thus, anchor hospitalizations and index hospitalizations would have varying degrees of overlap depending on the specific quality measure. The measure includes the following index admissions for patients:

- Having a principal discharge diagnosis of AMI.
- Enrolled in Medicare FFS.
- Aged 65 or over.
- Not transferred from another acute care facility.
- Enrolled in Medicare Part A and Part B for the 12 months prior to the date of index admission, and enrolled in Part A during the index admission.

The measure excludes the following index admissions for patients:

- Discharged alive on the day of index admission or the following day who were not transferred to another acute care facility.
- With inconsistent or unknown vital status or other unreliable demographic (age & gender) data.
- Enrolled in the Medicare hospice program any time in the 12 months prior to the index admission, including the first day of the index admission.
- Discharged AMA.
- Without at least 30 days of post-discharge enrollment in FFS Medicare as the 30-day excess days outcome cannot be assessed for these patients.

Finally, for the purpose of this measure, hospitalizations that occur within 30 days of discharge from an index admission are not eligible to also be index admission. Thus, only one index admission for AMI per beneficiary is randomly selected for inclusion in the cohort.

(e) Risk-Adjustment

We propose for the AMI model to align this measure with the risk-adjustment methodologies adopted for the AMI Excess Days measure under the HIQR Program in accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act, as finalized in the FY 2016 IPPS/LTCH final rule (80 FR 49682). We also note that the measure risk adjustment takes into account patient age, sex, and comorbidities to allow a fair assessment of hospital performance. The measure defines the patient risk factors for excess days using diagnosis codes collected from all patient claims 1 year prior to a patient's index hospitalization for AMI. Accordingly, only comorbidities that convey information about the patient at the time of index admission or in the 12 months prior, and not complications that arise during the course of the index hospitalization, are included in the risk-adjustment model. The measure does not adjust for patients' index admission source or their discharge disposition (for example, SNF) because these factors are associated with the structure of the healthcare system, not solely patients' clinical comorbidities. Regional differences in the availability of post-acute care providers and practice patterns might also exert undue influence on measure results. In addition, data fields that capture discharge disposition, for example to post-acute care settings, on inpatient claims are not audited and are not as reliable as diagnosis codes.

As previously noted in the AMI Excess Days measure, ICD–10–CM diagnosis codes present on Parts A and B administrative claims are used to inform the risk prediction for each patient. Diagnostic codes from post-acute care settings are utilized in the measure calculation, 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 note that the patient diagnosis codes are grouped using HCCs, which are clinically relevant diagnostic groups of codes. 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*.

In summary, age, sex, and comorbidities present at the time of index admission are adjusted for differences in hospital case mix (patient risk factors). The measure uses the HLM statistical methodology for risk adjustment.

(f) Calculating the Rate and Performance Period

We propose to calculate hospital 30-day excess days in acute care with the methodology used to risk standardize all excess days measures used in CMS hospital quality programs. The outcome of the measure is a count of the number of days the patient spends in acute care within 30 days of discharge. We define days in acute care as days spent in an ED, admitted to an observation unit, or admitted as an unplanned readmission for any cause within 30 days from the date of discharge from the index AMI hospitalization. Each ED treat-and-release visit is counted as 1 half-day (0.5 days). Observation stays are recorded in terms of hours and are rounded up to the nearest half-day. Each readmission day is counted as 1 full day (1 day). We count all eligible outcomes occurring in the 30-day period, even if they are repeat occurrences. The measure incorporates ''exposure time'' (the number of days each patient survives after discharge, up to 30). This exposure time is included to account for differential risk for excess days in acute care after discharge among those patients who do not survive the full post-discharge period. If a readmission or observation stay extends beyond the 30-day window, only those days within the 30-day window are counted.

Using a two-part random effects model, or ''hurdle'' model, we account for the structure of the data (patients clustered within hospitals) and the observed distribution of the outcome. Specifically, we model the number of acute care days for each patient as: (a) The probability that the patient will have a non-zero number of days in post-discharge acute care; and (b) the number of days the patient is predicted to spend given that this number is non-zero. The first part is specified as a legit model, and the second part is specified as a Poisson model, with both parts having the same risk-adjustment variables and each part having a random effect. This model is used to calculate the predicted (including random effects) and expected (assuming random effects are zero) number of days in post-discharge acute care for each patient. The average difference between patients' predicted and expected estimates for each hospital is used to construct the risk-standardized excess days outcome. The excess days outcome is reported at the hospital-level per 100 discharges.

We define the time period for the measure as within 30 days of the date of discharge of the index AMI hospitalization. The 30-day post-discharge window for assessing the outcome is consistent with the claims-based MORT–30–AMI (NQF #0230) and Hybrid AMI Mortality (NQF #2473) measures as noted in this proposed rule.

A 3-year rolling performance period would be consistent with that used for the HIQR Program (FY 2016 IPPS/LTCH final rule 80 FR 49681). Section III.E.5., Form, Manner, and Timing of Quality Measure Data Submission, of this proposed rule summarizes the proposed measure performance periods for AMI model performance years 1 through 5. We note that improvement on the AMI

Excess Days measure would be determined from the immediate 3-year rolling performance period available for the year preceding the AMI model performance year as explained in Table 30.

The proposal to include the Excess Days in Acute Care after Hospitalization for AMI measure in the AMI model is included in § 512.411(a)(2). We seek comment on this proposal to include the Excess Days in Acute Care after Hospitalization for AMI measure in the AMI model to assess quality performance.

(3) Hybrid Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF# 2473)(Hybrid AMI Mortality)

(a) Background

In keeping with our goal to move toward the use of EHRs, and in response to stakeholder feedback to include clinical data in outcome measures, we have developed the hospital 30-day risk-standardized acute myocardial infarction (AMI) mortality eMeasure (NQF #2473) (herein after referred to as Hybrid AMI Mortality measure). This measure will incorporate a combination of claims data and EHR data submitted by hospitals, and because of these combined data sources, it is referred to as a hybrid measure. The Hybrid AMI Mortality (NQF #2473) measure cohort and outcome are identical to those in the hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute myocardial infarction (AMI) (NQF #0230), measure which is also being proposed in the AMI model.

In contrast to the claims-only MORT–30–AMI (NQF #0230) measure, the proposed Hybrid AMI Mortality (NQF #2473) measure utilizes five core clinical data elements (age; heart rate; systolic blood pressure; troponin; creatinine) in the risk-adjustment methodology that are obtainable through EHR data. These five core clinical data elements are intended to reflect patients' clinical status when they first present to an acute care hospital for treatment of AMI. The clinical data elements include age at the time of admission, first-captured vital signs (heart rate, systolic blood pressure) collected within 2 hours of the patient first presenting to the hospital, and the first captured laboratory values (troponin, creatinine) collected within 24 hours of the patient first presenting to the hospital to which they are subsequently admitted. We note that these five data elements are routinely collected on hospitalized adults with AMI upon presentation to the hospital, consistently captured in medical records under current clinical practice, and can be feasibly electronically extracted from hospital EHRs.

In order to prepare for future reporting of the Hybrid AMI Mortality (NQF #2473) measure, we are proposing to seek and reward voluntary data submission of the five core clinical data elements included in the risk model for the Hybrid AMI mortality (NQF #2473) measure. We are also proposing to require submission of six additional linking variables (CCN, HIC Number, date of birth, sex, admission date, and discharge date) to ensure that the datasets containing administrative claims data are correctly linked with EHR datasets containing the core clinical data elements for proper risk adjustment. The voluntary data submission initiative will allow AMI model participants to build processes to extract and report the EHR data elements, as well as support CMS testing of systems required for Hybrid AMI Mortality measure (NQF #2473) production including data receiving and auditing, the merging EHR and claims data, calculation and production of measure results.

Finally, we are considering using the Hybrid AMI Mortality (NQF #2473) measure as a replacement for the current publicly reported MORT–30–AMI (NQF #0230) measure in CMS models or programs when appropriate. In future years CMS may implement the Hybrid AMI Mortality (NQF #2473) measure in models and/or programs, such as in the AMI model or HIQR Program. In that event, we would propose to adopt the measure through notice and comment rulemaking. We refer readers to more detailed information on the measure specifications in this proposed rule and to the CMS Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(b) Data Sources

We propose to use two sources of data submitted by AMI model participants to calculate the Hybrid AMI Mortality (NQF #2473) measure: Medicare Part A and Part B (FFS claims to identify index admission diagnoses; and EHR-captured clinical information collected at presentation for risk-adjustment of patients' severity of illness. Deaths are identified using the Medicare Enrollment Database which contains beneficiary demographic, benefits/coverage, and vital status information.

For the voluntary data submission initiative, EHR data submission will align with existing Electronic Clinical Quality Measure (eCQM) standards and data reporting procedures for hospitals. In alignment with these standards, we are posting the electronic specifications for the Hybrid AMI Mortality (NQF #2473) measure, which include the Measure Authoring Tool (MAT) output and value sets for all included data elements, on the CMS Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

The Office of the National Coordinator for Health Information Technology (ONC) adopted quality reporting document architecture (QRDA) as the standard to support both QRDA Category I (individual patient) and QRDA Category III (aggregate) data submission approaches for Meaningful Use Stage 2 in the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology rule (77 FR 54163 through 54292). We intend to provide AMI model participants with information about how many qualifying admissions are submitted successfully. We refer readers to the definition of ''successful data submission'' in section III. E.4.a.(3)(vii) of this proposed rule.

We seek comment on our proposal to use the following reporting mechanisms in performance year 1: QRDA, a simpler mechanism such as a spreadsheet, or both. We propose using QRDA in AMI model performance years 2 through 5. The purpose of the use of a simpler reporting format in the first performance year reporting format in the first performance year would be to allow hospitals to perfect data extraction with the 2017 data and postpone mastery of reporting in the QRDA format to the following year.

(c) Cohort

The Hybrid AMI Mortality (NQF #2473) measure includes Medicare FFS beneficiaries, aged 65 years or older, discharged from non-federal acute care hospitals with a principal discharge diagnosis of AMI. Eligible hospitalizations are defined using the following ICD–10–CM codes: I2109, I2111, I2119, I2129, I214, and I213.

Hospital performance for the Hybrid AMI Mortality (NQF #2473) measure will not be publicly reported. However, AMI model participants will receive hospital-specific reports for each performance year with information about the success of their voluntary submission of EHR data.

(d) Inclusion and Exclusion Criteria

We propose that an index admission is the hospitalization to which the mortality outcome is attributed. The Hybrid AMI mortality (NQF #2473) measure includes the following index admissions for patients:

- Having a principal discharge diagnosis of AMI.
- Enrolled in Medicare FFS.
- Aged 65 or over.
- Not transferred from another acute care facility.
- Enrolled in Medicare Part A and Part B for the 12 months prior to the date of index admission, and enrolled in Part A during the index admission.

This measure excludes the following index admissions for patients:

- Discharged alive on the day of admission or the following day who were not transferred to another acute care facility.
- With inconsistent or unknown vital status or other unreliable demographic (age & gender) data.
- Enrolled in the Medicare hospice program any time in the 12 months prior to the index admission, including the first day of the index admission.
- Discharged AMA.
- Without at least 30 days of post-discharge enrollment in FFS Medicare as the 30-day mortality outcome cannot be assessed for these patients.

Finally, for the purpose of this measure, only one index admission per patient for AMI is randomly selected for inclusion in the cohort.

(e) Risk-Adjustment

We note that this measure is aligned with the methodology approach adopted for the MORT–30–AMI (NQF #0230) measure under the HIQR Program in accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act, as finalized in FY 2008 IPPS/LTCH final rule (2008 IPPS/LTCH final rule 71 FR 67960). The Hybrid AMI Mortality (NQF #2473) measure uses EHR data and not administrative claims data to adjust for differences across hospitals in how at-risk their patients are for death, relative to patients cared for by other hospitals. The risk model was developed with input from the literature, clinical and EHR experts, and Health Information Technology vendors. In order to be included as risk variables, clinical data elements had to be—(1) consistently obtained in the target population (Medicare FFS AMI patients) based on current clinical practice; (2) captured with a standard definition and recorded in a standard format within the EHR; and (3) entered in structured fields that are feasibly retrieved from current EHR systems. The final measure includes five variables that meet these feasibility criteria, are present for most patients at the time of clinical presentation to the hospital, are clinically relevant to patients with AMI, and demonstrate a strong statistical association with 30-day mortality. Hospitals will submit the first-captured data values of each of the five core clinical data elements upon patient presentation to the hospital. They are: Age; the first-captured heart rate and systolic blood pressure measured within 2 hours of a patient presenting to the hospital; and the first captured troponin and creatinine values within 24 hours of a patient presenting to the hospital. Although EHRs likely will ultimately link across clinical episodes of care and contain historical patient data, given the EHR environment at the time of measure development and inability to reliably obtain data from the outpatient setting prior to admission, we only considered for inclusion those measure variables that would be available and consistently collected at first presentation to the hospital.

The overall performance of the model was comparable with or better than that of current publicly reported outcome measures.[81] We tested measure score validity by correlating the RSMR with that of the previously validated, publicly reported, administrative claims-based MORT–30–AMI (NQF #0230) measure. For more detailed information on the model performance, we refer readers to the CMS Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(f) Calculating the Risk-Standardized Mortality Ratio (RSMR) and Performance Period

We calculate hospital 30-day, all-cause, risk-standardized mortality rates consistent with the methodology used to risk standardize all readmission and mortality measures used in CMS hospital quality programs. Using an HLM statistical methodology for risk adjustment, we calculate the hospital-level risk-standardized mortality rate following AMI hospitalizations by producing a ratio of the number of ''predicted'' deaths (that is, the adjusted number of deaths at a specific hospital) to the number of ''expected'' deaths (that is, the number of deaths if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national observed mortality rate.

We propose defining AMI model performance years as outlined in section III.E.5. of this proposed rule. A performance period for the voluntary data submission are those timeframes in which a hospital discharge occurs for an eligible AMI index hospitalization. For performance year 1 of the AMI model, participants voluntarily submitting data will only be asked to submit data for a 2-month period. The 2-month period for AMI voluntary data reporting was identified due to data processing and coordination with other proposed timelines for this model. Data submitted for the first year would be for cases that fulfill the measure specifications described in section III.E.4.a.(3) of this proposed rule, and would be restricted to the data elements from eligible AMI index hospitalizations with discharges occurring between July 1, 2017 and August 31, 2017.

For performance year 2 of the AMI model, AMI voluntary data reporting would be 10 months of data for discharges from eligible AMI hospitalizations occurring between September 1, 2017 and June 30, 2018. For subsequent years of the model, the performance periods for submission of voluntary data will consist of discharges within calendar-year 12-month time periods from July 1 through June 30. The proposed performance periods would enable AMI model participants to receive points toward the AMI model composite quality score for data submission starting in performance year 1. We seek comment on our proposal for defining the data reporting period for performance year 1 episodes for an AMI model participant as eligible AMI index hospitalizations with discharges occurring between July 1, 2017 and August 31, 2017, and for performance year 2 as eligible AMI hospitalizations with discharges occurring between September 1, 2017 and June 30, 2018, with subsequent performance year data reporting periods each being calendar-year 12 month periods and starting every July 1st. Refer to Table 30 for summary of proposed performance periods.

(g) Requirements for Successful Submission of AMI Voluntary Data

In order for CMS to assess if AMI model participants that submit the AMI voluntary data are eligible for points toward the hospital's AMI model composite quality score, we propose to use the following criteria to determine if a participant has successfully submitted AMI voluntary data:

[81] AMI Mortality Hybrid Measure methodology report. *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Submission of the first-captured data values for the five core clinical data elements (age; first-captured heart rate and systolic blood pressure measured within 2 hours of a patient presenting to the hospital; and first-captured troponin and creatinine values measured within 24 hours of a patient presenting to the hospitals), and six linking variables required to merge with the CMS claims data CCN, HIC Number, date of birth, sex, admission date, and discharge date).

All of these data elements must be submitted for each qualifying AMI hospitalization as described in section III.E.5. of this proposed rule. If troponin was not measured in the patient within 24 hours of presentation to the hospital, the hospital will still receive credit for successful data submission if all other clinical data elements (age, heart rate, systolic blood pressure, and creatinine) as well as the six linking variables are all reported in the submission. We recognize that some patients may have clinical signs or symptoms that require emergent treatment; and that in such cases treatment might proceed without first obtaining a troponin level. However hospitals are required to report troponin values on all patients in whom a troponin test was performed within the first 24 hours of presenting to the hospital and to indicate in their data submission each instance in which a troponin value was not measured and therefore not available for a patient.

AMI voluntary data submission must occur within 60 days of the end of the most recent data collection period as described in the listing of reporting periods for all 5 model performance years in section III.E.5. of this proposed rule.

To fulfill AMI voluntary data collection criteria for model performance year 1, hospitals must submit valid data on 50 percent of qualifying AMI hospitalizations (identified by the denominator in the measure authorizing tool (MAT) output). To successfully submit AMI voluntary data for performance years 2 through 5, hospitals must submit valid data for all five core clinical data elements on over 90 percent of qualifying AMI patients (with the exception for troponin values described in this section). Further details on scoring of the voluntary data submission are discussed in section III.E.3.e.(1) of this proposed rule.

Each year, AMI model participants voluntarily submitting data for this measure will receive hospital-specific reports that detail submission results from the most recent performance period. The reports will include the match rate between the hospital's submitted EHR data and corresponding claims data, as well as the proportion of patient data submitted relative to all qualifying AMI admissions with all five core clinical data elements. As the initiative seeks to test and reward hospitals' ability to submit data, hospitals will not be penalized for missing troponin values for patients in whom these values were not measured at the time clinical treatment was provided. If hospitals successfully submit the remaining four clinical data elements and all of the linking variables, a missing troponin value which is due to troponin having not been measured in that patient will not result in an unsuccessful submission as long as hospitals indicate that the troponin value was not measured and therefore not available for that patient. Hospitals will still be rewarded for successfully submitting data in these cases.

We previously described a qualifying AMI patient in section III.E.4.a.(3)(iii) of this proposed rule. This description is important, as these patients are those for whom we seek submission of voluntary data from AMI model participants. We selected the requirement of submitting 90 percent of qualifying AMI patients' data for performance years 2 through 5 because this volume of cases will result in a high probability that we will have a national sample of AMI patient data representative of each hospital's patient case mix. Having 90 percent of the data for qualifying AMI patients in performance years 2 through 5 will enable an accurate and reliable assessment of the potential implementation of a Hybrid AMI mortality (NQF #2473) measure that utilizes EHR data. In addition, the testing we have performed in hospitals' EHR data indicate that these data elements are captured in over 90 percent of Medicare FFS patients who are 65 years or older and admitted to acute care hospitals for treatment of AMI.

We seek public comment on the proposed requirements to determine successful voluntary submission of AMI data, including the proposal to give hospitals credit for data submission if they submit all troponin values that were actually measured, each of the other four data elements, and all of the linking variables; to not penalize hospitals for failure to submit a troponin value if it was not measured during the admission; and the proposal on the specific minimum percentage requirements for data on the qualifying AMI patients.

b. CABG Model-Specific Measure

(1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558)(MORT–30–CABG)

(a) Background

CABG is a common procedure associated with considerable morbidity, mortality, and healthcare spending. In 2010, the National Hospital Discharge Survey (NHDS) estimated that 219,000 patients underwent a total of 397,000 CABG procedures. Among Medicare FFS beneficiaries, there were 139,133 hospitalizations for isolated CABG surgery between July 2012 and June 2015. CABG surgeries are costly procedures that account for the majority of major cardiac surgeries performed nationally. In FY 2009, isolated CABG surgeries accounted for almost half (47.6 percent) of all cardiac surgery hospital admissions in Massachusetts. This provides an example of the frequency in which a CABG is performed for a patient admitted for cardiac surgery. In 2008, the average Medicare IPPS payment was $30,546 for CABG without valve replacement and $47,669 for CABG with valve replacement surgeries.

The proposed Hospital-level 30-Day Risk-Standardized Mortality Rate (RSMR) following Coronary Artery Bypass Graft (CABG) Surgery (MORT–30–CABG) (NQF #2558) measure developed by CMS and currently implemented in the HIQR program, assesses hospitals' 30-day, all-cause risk-standardized rate of mortality, which is rate of death after admission for a CABG procedure for patients 65 and older during a 30-day period that begins with the date of the index admission for the specific hospital; an index admission is the hospitalization to which the mortality outcome is attributed. The data indicate that the median hospital-level risk-standardized mortality rate for 2016 public reporting on Hospital Compare was 3.2 percent, with a range of 1.4 percent to 8.3 percent among hospitals. The variation in these rates suggests that important differences in the quality of care delivered across hospitals exist, and that there is room for improvement.

More details about the measure can be found in the 2016 Annual Updates and Specifications Report for CABG Mortality posted on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

The proposed MORT–30–CABG (NQF #2558) measure was endorsed by the NQF in November 2014. This measure

has been publicly reported on Hospital Compare since FY 2015 and was incorporated into the HIQR Program for FY 2017 (FY 2015 IPPS/LTCH final rule 79 FR 50227).

(b) Data Source

Measure results for CABG model participants are calculated using Medicare Part A and Part B FFS claims submitted by all non-federal short-term acute care hospitals for the MORT–30–CABG (NQF #2558) measure. Index admission diagnoses and in-hospital comorbidities are assessed using Medicare Part A claims. Additional comorbidities prior to the index admission are assessed as Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to the index (initial) admission. Enrollment and post-discharge mortality status are obtained from Medicare's enrollment database which contains beneficiary demographic, benefits/coverage, and vital status information.

(c) Cohort

The MORT–30–CABG (NQF #2558) measure includes Medicare FFS beneficiaries, aged 65 years and older, discharged from a non-federal short-term acute care hospitals (including Indian Health Services hospitals) and critical access hospitals, who received a qualifying CABG procedure, and with a complete claims history for the 12 months prior to admission and through 30 days post-procedure.

We propose that the measure will include index admissions to all non-federal acute care hospitals, which includes all hospitals in the CABG model. Hospital performance will only be publically reported for hospitals with 25 or more index admissions in the 3-year measurement period. The CABG model cohort would differ from the hospital cohort that is currently captured in the measure through the HIQR Program. Although performance on the measure will not be publicly reported for hospitals with fewer than 25 cases, such hospitals will receive information about their performance. We refer readers to section III.B.5. of this proposed rule for a discussion of CABG model participant selection. For eligible hospitalizations defined using ICD–9–CM codes, we refer readers to the CMS Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

In order to include a clinically coherent set of patients in the measure, we sought input from clinical experts regarding the inclusion of other concomitant cardiac and non-cardiac procedures, such as valve replacement and carotid endarterectomy. Adverse clinical outcomes following such procedures are higher than those following ''isolated'' CABG procedures, that is, CABG procedures performed without concomitant high-risk cardiac and non-cardiac procedures. Limiting the measure cohort to ''isolated'' CABG patients is consistent with published reports of CABG outcomes; therefore, the measure cohort considers only patients undergoing isolated CABG as eligible for inclusion in the measure. We defined isolated CABG patients as those undergoing CABG procedures without concomitant valve or other major cardiac, vascular or thoracic procedures. In addition, our clinical experts, consultants, and Technical Expert Panel (TEP) members agreed that an isolated CABG cohort is a clinically coherent cohort for quality measurement. For detailed information on the cohort definition, we refer readers to the 2016 Annual Updates and Specifications Report for CABG Mortality on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(d) Inclusion and Exclusion Criteria

We propose that an index admission is the hospitalization to which the mortality outcome is attributed. The measure includes the following index admissions for patients:

- Having a qualifying isolated CABG surgery during the index admission;
- Enrolled in Medicare FFS Part A and Part B for the 12 months prior to the date of the index admission, and enrolled in Part A during the index admission; and,
- Aged 65 or over.

Isolated CABG surgeries are defined as those CABG procedures performed without the following concomitant valve or other major cardiac, vascular, or thoracic procedures:

- Valve procedures.
- Atrial and/or ventricular septal defects.
- Congenital anomalies.
- Other open cardiac procedures.
- Heart transplants.
- Aorta or other non-cardiac arterial bypass procedures.
- Head, neck, intracranial vascular procedures.
- Other chest and thoracic procedures.

This measure excludes the following index admissions for patients:

- With inconsistent or unknown vital status or other unreliable demographic (age and gender) data.
- Discharged AMA.
- For patients with more than one qualifying CABG surgery admission in the measurement period, the first CABG admission is selected for inclusion in the measure and the subsequent CABG admission(s) are excluded from the cohort.

(e) Risk-Adjustment

We note that this measure is aligned with the risk-adjustment methodologies adopted for the other mortality measures developed by CMS and implemented under the HIQR Program in accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act, as finalized in FY 2008 IPPS/LTCH final rule (2008 IPPS/LTCH final rule 71 FR 67960). We also note that the measure risk adjustment takes into account patient age, sex, and comorbidities to allow a fair assessment of hospital performance. The measure defines the patient risk factors for mortality using diagnosis codes collected from all patient claims 1 year prior to patient index hospitalization for CABG surgery. ICD–10–CM diagnosis codes on Parts A and B administrative claims are used to inform the risk prediction for each patient; diagnostic codes from post-acute care 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. Use of Parts A and B data does not mean the measure is applicable to post-acute care settings, only that it uses comprehensive data to predict the risk of the outcome and adjust for hospital patient case mix. We note that the patient diagnosis codes are grouped using HCCs. 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*.

In summary, age, sex, and comorbidities present at the time of admission are adjusted for differences in hospital case mix (patient risk factors). The measure uses the HLM statistical methodology for risk adjustment.

(f) Calculating the Risk-Standardized Mortality Ratio (RSMR) and Performance Period

We propose to calculate hospital 30-day, all-cause, risk-standardized mortality rates (RSMR) consistent with the methodology used to risk standardize all readmission and mortality measures used in CMS hospital quality programs. Using HLM, we calculate the hospital-level risk-

standardized mortality rate following AMI hospitalization by producing a ratio of the number of ''predicted'' deaths (that is, the adjusted number of deaths at a specific hospital) to the number of ''expected'' deaths (that is, the number of deaths if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw mortality rate. The RSMR is a point estimate—the best estimate of a hospital's mortality rate based on the hospital's case mix. For more detailed information on the calculation methodology we refer readers to the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

A 3-year rolling performance period would be consistent with that used for the HIQR Program (FY 2015 IPPS/LTCH final rule 79 FR 50227). Section III.E.5. of this proposed rule, Form, Manner, and Timing of Quality Measure Data Submission, summarizes the proposed measure performance periods for CABG model performance years 1 through 5. We note that improvement on the MORT–CABG–30 (NQF #2558) measure would be determined from the 3-year rolling performance period available for the year preceding the CABG model performance year as explained in Table 30.

We seek comment on this proposal to include Hospital-level 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following CABG Surgery (NQF #0230) measure in the CABG model to assess quality performance.

The EPM episodes are structured as 90-day periods with the hospital as the primary accountable entity, because we believe 90 days is a period over which hospitals have substantial ability to influence the quality and efficiency of the care that patients receive. We believe that there could be significant benefits for the quality of patient care from using quality measures that examine patient outcomes over a period that extends at least as long as the EPM episode (that is, 90 days after discharge). In particular, we believe that this approach could help ensure that hospitals are held fully accountable for the quality of the care they deliver during the period covered by the bundle.

However, as discussed in section III.E. of this proposed rule, several of the outcome measures we are proposing for these EPMs (MORT–30–AMI (NQF #0230), AMI excess days, and MORT–30–CABG (NQF #2558)) assess outcomes over a 30-day period following discharge. We are proposing to use these existing 30-day measures, at least initially, because they are in wide use and have gained acceptance among hospitals and because the mortality measures have been reviewed and endorsed by the National Quality Forum.

Nevertheless, we believe that it is appropriate to seek to adapt these measures or to develop new related measures to assess outcomes over a longer timeframe, including timeframes at least as long as the EPM episodes. In developing measures that use a longer timeframe, CMS would perform empirical analyses to ensure that such measures are scientifically robust and to identify appropriate risk-adjustment approaches. Once such measures were available, CMS would consider when and how to incorporate these measures into the EPM quality payment methodology. We invite public comment on refining the existing 30-day measures to extend the period of outcome assessment following admission for AMI or CABG surgery, including the length of the period that should be examined by an extended measure, any important considerations in developing the refined measures, and any factors CMS should consider in incorporating these measures into the EPM quality payment methodologies.

c. SHFFT Model-Specific Measures

(1) Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) (Hip/Knee Complications)

(a) Background

THA and TKA are commonly performed procedures for the Medicare population that improve quality of life. 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.[82] The post-operation complications of these procedures are high considering these are elective procedures, and usually, the complications are devastating to patients. For example, rates for periprosthetic joint infection, a rare but devastating complication, have been reported at 2.3 percent for THA/TKA patients with rheumatoid arthritis after 1 year of follow-up[83] and 1.6 percent in Medicare patients undergoing TKA after 2 years of follow up.[84] Two studies reported 90-day death rates following THA at 0.7 percent[85] and 2.7 percent, respectively.[86] Reported rates for pulmonary embolism following TKA range from 0.5 percent to 0.9 percent.[87] [88] [89] Reported rates for septicemia range from 0.1 percent, during the index admission[90] to 0.3 percent, 90-days following discharge for primary TKA.[91] Rates for bleeding and hematoma following TKA have been reported at 0.94 percent[92] to 1.7 percent.[93] Combined, THA and TKA procedures account for the largest payments for procedures under

[82] 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*.

[83] 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.

[84] 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.

[85] 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.

[86] 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. 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.

[87] 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.

[88] 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.

[89] 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.

[90] 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.

[91] 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.

[92] 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.

[93] 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.

Medicare.[94] Both hip and knee arthroplasty procedures improve the function and quality of life of patients with disabling arthritis, and the volume and cost associated with these procedures are very high. We believe it is important to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures.

The proposed measure developed by CMS, and currently implemented the HIQR and HVBP Programs and the CJR model, assesses a hospital's risk standardized complication rate, which is the rate of complications occurring after elective primary THA and TKA surgery. The measure outcome is the rate of complications occurring after THA and TKA during a 90-day period that begins with the date of the index admission for a specific hospital; an index admission is the hospitalization to which the complications outcome is attributed. The following outcomes (either one or more) 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. The data indicated that the median hospital-level risk-standardized complication rate for 2008 was 4.2 percent, with a range from 2.2 percent to 8.9 percent in hospitals. The variation in complication rates suggests that there are important differences in the quality of care delivered across hospitals, and that there is room for quality improvement.

In 2010, we developed the proposed measure of hospital-level risk-standardized complication rate (RSCR) following elective primary THA and TKA surgery, which was later endorsed by the NQF (NQF #1550). In its Pre-Rulemaking Report for 2012,[95] the Measure Application Partnership (MAP) also recommended the inclusion of this measure in the HIQR Program; we have not submitted this measure for use in post-acute care settings as the measure was developed for the acute care hospital setting. This measure has been publicly reported on Hospital Compare since FY 2014 and in the HIQR Program since FY 2015 (FY 2015 IPPS/LTCH final rule 79 FR 50062). Finally, we note a comparison of the median hospital-level risk-standardized complication rates for hospitals between April 1, 2011 and March 31, 2014 illustrates 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.[96]

(b) Data Sources

Measure results are calculated using Medicare Part A and Part B FFS claims submitted by all non-federal acute care hospitals. Index admission diagnoses and in-hospital comorbidities are assessed using Medicare Part A claims. 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. Enrollment and post-discharge mortality status are obtained from Medicare's enrollment database which contains beneficiary demographic, benefits/coverage, and vital status information.

(c) Cohort

The Hip/Knee Complications (NQF #1550) measure includes Medicare FFS beneficiaries, aged 65 years or older, admitted to non-federal acute care hospitals for elective primary THA or TKA. THA and TKA procedures eligible for inclusion are defined using ICD–9–CM codes 81.51 and 81.54, respectively. The following 24 codes in ICD–10 correspond to these two ICD–9–CM codes.

- ICD–9 code 81.51 (Total Hip Replacement) = ICD–10 codes 0SR90J9, 0SR90JA, 0SR90JZ, 0SRB0J9, 0SRB0JA, 0SRB0JZ.
- ICD–9 code 81.54 (Total Knee Replacement) = ICD–10 codes 0SRC07Z, 0SRC0JZ, 0SRC0KZ, 0SRD07Z, 0SRD0JZ, 0SRD0KZ, 0SRT07Z, 0SRT0JZ, 0SRT0KZ, 0SRU07Z, 0SRU0JZ, 0SRU0KZ, 0SRV07Z, 0SRV0JZ, 0SRV0KZ, 0SRW07Z, 0SRW0JZ, 0SRW0KZ.

We propose that the measure will include index admissions to all non-federal acute care hospitals, which includes all hospitals included in the SHFFT model. Hospital performance will only be publicly reported for hospitals with 25 or more index admissions in the 3-year measurement period. The SHFFT model participant hospital cohort would differ from the hospital cohort that is currently captured in the measure through the HIQR Program. Although performance on the measure will not be publicly reported for hospitals with fewer than 25 cases, such hospital will receive information about their performance. We refer readers to section III.B.5. of this proposed rule for discussion of the selection of participants for the SHFFT model.

(d) Inclusion and Exclusion Criteria

An index admission is the hospitalization to which the complication outcome is attributed. We note that for purposes of the EPMs where we need to identify episodes that are included in the EPMs, we use the terms anchor and chained anchor hospitalization to identify hospitalizations that initiate EPM episodes for beneficiaries whose care is included in the EPMs. In describing the quality measures themselves in detail in section III.E.4. of this proposed rule, we use the term index hospitalization to identify hospitalizations of beneficiaries whose outcomes are included in the measures. Thus, anchor hospitalizations and index hospitalizations would have varying degrees of overlap depending on the specific quality measure. The MS–DRGs for the anchor or chained hospitalizations included in the SHFFT model will identify beneficiaries that do not overlap with the index hospitalizations used in the SHFFT model measures, since the SHFFT model measures use the elective THA/TKA cases as proxies for hip or femur fracture cases. The measure includes 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.
- Have 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.

++Partial hip arthroplasty (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.

[94] 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.

[95] 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.

[96] 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.

++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.

The following admissions would be excluded from the measure:

- Admissions for patients discharged 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.

After applying these exclusion criteria, 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 admission from being mutually independent. Therefore only one index admission is selected to maintain measure integrity.

We note that the Hip/Knee Complications (NQF #1550) measure does not capture patients undergoing partial hip arthroplasty procedures. We excluded partial hip arthroplasty procedures primarily because partial hip arthroplasty procedures are done for hip fractures. Therefore, they are not elective procedures. Also, partial hip arthroplasty procedures are typically performed on patients who are older, frailer, and have more comorbid conditions. Although this exclusion is not fully harmonized with MS–DRGs 469 and 470, which includes partial hip arthroplasty procedures, use of this measure will still provide strong incentives for improving and maintaining care quality across joint replacement patients as hospitals typically develop protocols for lower extremity joint arthroplasty that will address peri-operative and post-operative care for both total and partial hip arthroplasty procedures. Fiscal year 2014 claims data indicate that among inpatient claims with MS–DRG 469 or 470, partial hip arthroplasty (ICD–9–CM procedure code: 81.52) accounted for 12 percent, while Total Hip Replacement (ICD–9 code: 81.51) and total knee replacement (ICD–9 code: 81.54) accounted for 87 percent (80 FR 73300 and 73474). We also note that the same surgeons and care teams frequently perform both procedures. Therefore, quality improvement efforts initiated in response to the Hip/Knee Complications (NQF #1550) measure are likely to benefit patients undergoing similar elective procedures, such as partial hip arthroplasty and revision THA/TKA procedures, and possibly even non-elective lower extremity hip fracture surgery as described in section III.E.2.d. of this proposed rule.

(e) Risk-Adjustment

We note that this measure is aligned with the risk-adjustment methodologies adopted for the HIQR Program and 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 note that the risk-adjustment takes into account the patient case-mix to assess hospital performance. The patient risk factors are defined using the HCCs.[97] The HCCs 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=1228772782693*). We note that the measure uses ICD–9–CM diagnosis codes on Parts A and B administrative claims for the year prior to and including the index admission. The ICD–9–CM codes are used to inform the risk prediction for each patient. Diagnostic codes from post-acute care settings are utilized for the measure calculation, 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. Use of the administrative claims data does not mean the measures are applicable to post-acute care settings, only that they use comprehensive data to predict the risk of the outcome and adjust for hospital patient case mix. 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. The decision on the 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 post the date of index admission. We 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.

(f) Calculating the Risk-Standardized Complication Rate and Performance Period

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 calculate the hospital risk-standardized complication rate 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. The 3-year rolling performance period would be consistent with that used for HIQR Program (FY 2015 IPPS/LTCH final rule 79 FR 50208 and 50209). Section III.E.5. of this proposed rule summarizes measure performance periods for SHFFT model years 1 through 5. We note that improvement on the Hip/Knee Complications (NQF #1550) measure would be determined from the immediate 3-year rolling performance period available for the year preceding the SHFFT model performance year as explained in Table 33.

We seek comment on this proposal to assess quality performance for SHFFT model participants 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.

[97] 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.

(2) Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty

(a) Background

As part of our goal to move towards outcome measures that assess patient-reported outcomes, we have begun development on a measure to assess improvement in patient-reported outcomes following THA/TKA procedures. 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. 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.[98 thnsp;99 thnsp;100] We also note 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. Patient-reported outcomes would be assessed separately for THA and TKA procedures, though these results may be combined into a single composite measure for reporting. Therefore, we will refer to a single measure, but acknowledge the possibility of two measures, one for THA patients and one for TKA patients.

During measure development, we discovered 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. The rationale for requesting access to a national THA and TKA inpatient surgical procedures patient-reported data source are 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 believe access to such data would allow for completion and testing of the current measure under development that can be appropriately used for nationwide hospital performance evaluation. We implemented the initial data collection for this measure initially in the CJR model in order to test and resolve these measurement development issues through the collection of THA and TKA patient-reported outcome data. We propose to test SHFFT model episodes in mainly the same hospitals as the CJR model as discussed in section III.B.4. of this proposed rule. We note that approximately 50 hospitals currently excluded from CJR model participation because they are testing BPCI LEJR episodes would be included in the SHFFT model. Access to this data through the SHFFT and CJR models 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.

In summary, the voluntary data collection that is already underway in most SHFFT model participants who are also participants in the CJR model would provide data from the patient's perspective that is necessary to finalize and test the measure specifications, including the risk model. Access to this nationally 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.

In order to encourage participation with voluntary data submission of patient-reported outcome data, we are proposing to seek and reward voluntary participation in submission of THA/TKA patient-reported outcome-based measure data as outlined in section III.E.4.c.(2)(viii) of this proposed rule. We note that we would not publicly report the THA/TKA voluntary data.

Finally, we intend to use a fully tested and completed THA/TKA patient-reported outcome-based measure in CMS models or programs when appropriate. If there is a decision to implement the fully developed THA/TKA patient-reported outcome-based measure, we would propose to adopt the measure through notice and comment rulemaking. We refer reviewers to 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*.

(b) Data Sources

As previously discussed, this measure is under development, and we propose to reward SHFFT model participants that volunteer to submit provider- and patient-level data elements. We note that there is currently 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

[98] 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.

[99] 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.

[100] 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.

procedures. In the voluntary data submission for the THA/TKA patient-reported outcome-based measure, we are trying 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). Furthermore, in order to minimize provider and hospital burden associated with data collection and submission of provider- and hospital-level data elements, we propose using a variety of data sources for measure development. We anticipate using the following data sources are:

- Patient-reported data.
- Administrative claims-based data.
- One or both physician-reported and electronic health record data.

Through this voluntary data submission proposal, we hope to identify a uniform set of provider- and patient-level data elements while also identifying data sources that are the least burdensome for the patients, providers, and hospitals. We propose to request that SHFFT model participants provide administrative claims-based data whenever possible, in order to minimize burden on patients, providers, and hospitals. Additionally, we propose to request that SHFFT model participants submit either hospital documentation, chart abstraction, or abstraction from the electronic health records. We propose to request submission of the following data elements as finalized in the CJR model final rule (80 FR 73494 through 73495):

- Pre-operative Assessments (to be collected between 90 and 0 days prior to THA/TKA procedure):

++ Date of Birth.

++ Race and Ethnicity.

++ Date of admission to anchor hospitalization.

++ Date of eligible THA/TKA procedure.

++ Unique Identifier (Medicare Health Insurance Claim Number).

++ Hip-specific PROM Instrument for THA Procedures.

Either VR–12 or PROMIS-Global [collected pre-operatively (90 to 0 days prior to 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 pre-operatively (90 to 0 days prior to 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 pre-operatively (90 to 0 days prior to the THA procedure).

++ Knee-specific PROM instrument for TKA procedures.

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].

++ Body Mass Index (or height in cm and weight in kg).

++ Pre-operative use of narcotics.

++ Patient-Reported Pain in Non-operative Lower Extremity Joint.

++ Patient-Reported Back Pain (Oswestry Index question).

++ Patient-Reported Health Literacy

- Post-operative Assessments (To be collected between 270 and 365 days following THA/TKA procedure):

++ Date of admission to anchor hospitalization.

++ Date of eligible THA/TKA procedure.

++ Medicare Health Insurance Claim Number (Unique Identifier).

++ Generic PROM Instrument for THA and TKA Procedures.

++ Knee-Specific PROM Instrument for TKA Procedures.

Either VR–12 or PROMIS-Global [collected post-operatively (270 to 365 days after the TKA procedure)], AND either (A) the KOOS Jr. (7 items total) [collected 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 post-operatively (270 to 365 days after the TKA procedure)].

++ Hip-Specific PROM Instrument for THA Procedures.

Either VR–12 or PROMIS-Global [collected 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 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 post-operatively (270 to 365 days after the THA procedure)].

Finally, we note that as the measure continues to undergo development that the list of data elements may be simplified. As stated earlier in this section, 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).

In accordance with, and to the extent permitted by, the HIPAA Privacy Rule and other applicable law, we propose to request that participants 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 propose 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 successful submission determination for use in assigning the SHFFT composite quality score as described in section III.E.3.e.(3). of this proposed rule (or validated subscales or abbreviated versions of these instruments). We believe that voluntary participation in the submission of THA/TKA patient-reported outcome-based measure data will provide the minimum information we would need that would inform us on how to continuously improve the currently specified measure in development.

We note that some of these data elements are closely aligned with data elements in e-clinical 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 believe 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 SHFFT model participants to voluntarily submit.

(c) Cohort

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 would exclude from the cohort patients with fractures and mechanical complications or those undergoing revision procedures. The THA/TKA patient-reported outcome-based measure cohort is harmonized with the Hip/Knee Complications (NQF #1550) measure and with the cohort definition in the CJR model final rule (80 FR 73477). THA and TKA patient-reported outcomes will be assessed separately but may be combined into a single composite measure for reporting.

(d) Inclusion and Exclusion Criteria

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 infeasible 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.

(e) Outcome

The measure will assess change between pre- and post-operative patient-reported outcomes for THA and TKA separately or as a composite measure for both procedures. 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 TEP 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. 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.

(f) Risk-Adjustment (if Applicable)

We note that the measure's risk model has yet to be developed. 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. To the extent feasible, the risk model methodology will adhere to established statistical recommendations.[101]

[101] 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/Hospital Quality Inits/Downloads/Statistical-Issues-in-Assessing-Hospital-Performance.pdf* . Accessed on April 15, 2015.

(g) Calculating the Risk-Standardized Rate

We note that the approach to reporting this measure(s) has yet to be developed. 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 (270–365 days following the elective primary THA/TKA procedure) periods.

(h) Performance Period for Successful Submission of THA/TKA Patient-Reported-Outcome-Based Voluntary Data

We propose defining data reporting performance periods for each performance year of the SHFFT model as outlined in Table 29. Performance periods for voluntary reporting of THA/TKA patient-reported outcome-based measure data are those timeframes in which a hospital admission occurs for an eligible THA/TKA voluntary data submission procedure. Data submitted for the first SHFFT model performance year would be for cases that fulfill the measure specifications described in section III.E.4.c.(2)(i) of this proposed rule, and would be restricted to the pre-operative data elements on cases performed between September 1, 2016 and June 30, 2017. We note that SHFFT model participants generally would have the opportunity for voluntary data submission on cases performed in this timeframe through the hospitals' participation in the CJR model, which uses the same timeframe for voluntary submission of pre-operative data elements on cases. 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. For SHFFT model performance year 2, THA/TKA voluntary data reporting would be 10 months of post-operative data for cases performed between September 1, 2016 and June 30, 2017, and 12 months of pre-operative data for cases performed between July 1, 2017 and June 30, 2018. For SHFFT model performance year 3 and subsequent years of the model, the performance periods for submission of voluntary data will consist of 12- month time periods.

TABLE 29—DURATION OF PERFORMANCE PERIODS FOR PRE- AND POST-OPERATIVE THA/TKA VOLUNTARY DATA SUBMISSION

SHFFT model performance year	Duration of performance period	Patient population eligible for THA/TKA voluntary data submission	Requirements for successful THA/TKA voluntary data submission *
2017 Performance Year 1.	10 months	All patients undergoing elective primary THA/TKA procedures performed between September 1, 2016 and June 30, 2017.	• Submit PRE-operative data on primary elective THA/TKA procedures for ≥60% or ≥75 procedures performed between September 1, 2016 and June 30, 2017.
2018 Performance Year 2.	10 months	All patients undergoing elective primary THA/TKA procedures performed between September 1, 2016 and June 30, 2018.	• Submit POST-operative data on primary elective THA/TKA procedures for ≥60% or ≥75 procedures performed between September 1, 2016 and June 30, 2017. • 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 Performance Year 3.	24 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2017 and June 30, 2019.	• Submit POST-operative data on primary elective THA/TKA procedures for ≥70% or ≥100 procedures performed between July 1, 2017 and June 30, 2018. • 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 Performance Year 4.	24 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2018 and June 30, 2020.	• Submit POST-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 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, 2019 and June 30, 2020.
2021 Performance Year 5.	24 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2019 and June 30, 2021.	• Submit POST-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 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, 2020 and June 30, 2021.

The proposed performance periods would enable SHFFT model participants to receive points toward the SHFFT model composite quality score starting in performance year 1, 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 1 year after surgery. We emphasize that SHFFT model participants that are also participating in the CJR model do not need to submit data twice to satisfy the successful submission requirements of both models. If those hospitals successfully submit voluntary data for the CJR model they will be credited with successful submission under the SHFFT model.

We seek comment on our proposed measure reporting periods for the performance years of the SHFFT model.

(i) Requirements for Successful Submission of THA/TKA Patient-Reported-Outcome-Based Voluntary Data

In order for CMS to assign points in the SHFFT model composite quality score for successful participant submission of THA/TKA voluntary data, requirements to determine if the submitted data will inform measure development have been identified.

We believe that the following criteria should be used to determine if a participant has successfully submitted THA/TKA voluntary data. We note that successful THA/TKA voluntary data submission requires completion of all of the following:

- Submission of the data elements listed in section III.E.4.c.(2)(ii) of this proposed rule.
- Data elements listed in section III.E.4.c.(2)(ii) of this proposed rule must be submitted on at least 80 percent of their eligible elective primary THA/TKA patients.
- THA/TKA voluntary data submission must occur within 60 days of the end of the most recent data collection period.

To successfully submit THA/TKA voluntary data for performance years 1 through 5, SHFFT model hospitals must submit both pre-operative and post-operative patient reported outcome data on an increasing proportion of eligible elective primary THA/TKA patients over the performance years as described in Table 29 of this proposed rule. Performance periods for which we propose to have THA/TKA voluntary data submitted are displayed in Table 29 of this proposed rule. Table 29 also summarizes the performance periods for pre-operative and post-operative THA/TKA voluntary data. Finally, SHFFT model 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 are not 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 previously described a THA/TKA eligible patient in section III.E.4.c.(2)(iii) of this proposed rule. This description is important as these patients are those in which we seek submission of voluntary data. We also selected the requirement of submitting an increasing percent of eligible elective primary THA/TKA patients' data starting at 60

percent in performance year 1 and reaching 80 percent by performance years 4 and 5 because this volume of cases would result in a high probability that we will have a have a national sample of THA/TKA patient data representative of each hospital's patient case mix. Having at least 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 note 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. 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 set the requirement in SHFFT model performance year 4 and beyond at 80 percent of the eligible elective primary THA/TKA patients. We believe acquisition of 80 percent of the eligible elective primary THA/TKA patients will provide representative data for measure development while decreasing patient, provider and hospital burden.

The proposal for voluntary submission of THA/TKA data is included in § 512.413(b). We seek public comment of these requirements to determine successful voluntary submission of THA/TKA data. We also seek comment specifically on the requirement for data collection on an increasing percentage of eligible patients starting with at least 60 percent in SHFFT model performance year 1 and increasing to 80 percent of the eligible elective primary THA/TKA patients by SHFFT model performance year 4.

d. Measure Used for All EPMs

(1) Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey (NQF #0166)

(a) Background

The HCAHPS Survey (NQF #0166) is a CMS survey and a national, standardized, publicly reported survey of patients' experience of hospital care. The HCAHPS Survey is endorsed by the NQF (#0166); CMS is the measure steward. The HCAHPS Survey, also known as CAHPS® Hospital Survey, is a survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience. The HCAHPS Survey asks recently discharged patients 32 questions about aspects of their hospital experience that they are uniquely suited to address. The core of the survey contains 21 items that ask ''how often'' or whether patients experienced a critical aspect of hospital care. 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 (77 FR 53513 through 53515). Eleven HCAHPS measures (seven composite measures, two individual items, and two global items) are currently publicly reported on the Hospital Compare Web site for each hospital participating in the HIQR Program (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 propose to adopt a measure in the EPMs that uses HCAHPS survey data to assess quality performance and capture patient experience of care.

(b) Data Sources

The HCAHPS Survey is administered to a random sample of adult inpatients between 48 hours and 6 weeks after discharge. The HCAHPS survey data is collected on inpatient experience, is not limited to Medicare beneficiaries, and does not distinguish between types of Medicare beneficiaries. Patients admitted in the medical, surgical, and maternity care service lines are eligible for the survey; the survey is not restricted to Medicare beneficiaries. 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). 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).

Regardless of the mode used, hospitals are required to make multiple attempts to contact patients. Hospitals may use the HCAHPS Survey alone, or include additional questions after the 21 core items discussed previously. Hospitals must survey patients throughout each month of the year, and 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 as set for publicly reported HCAHPS scores (see 79 FR 50259). 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*.)

(c) Cohort

Hospitals, or their survey vendors, submit HCAHPS data in calendar quarters (3 months). Consistent with other quality reporting programs, we propose that HCAHPS scores would be publicly reported on Hospital Compare 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).

(d) Inclusion and Exclusion Criteria

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 1 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 skilled nursing facilities.

The HCAHPS Survey is intended for short-term, acute care hospitals. Both IPPS and Critical Access Hospitals participate in the survey; specialty hospitals, psychiatric hospitals and children's hospitals do not.

(e) Case-Mix Adjustment

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, 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.
• Age by service line interaction.
• Language other than English spoken at home.

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). Information on patient-mix adjustment (risk adjustment) and survey mode adjustment of HCAHPS scores can be found at *http://www.hcahpsonline.org/modeadjustment.aspx*.

(f) HCAHPS Scoring

Regarding the HCAHPS Survey (NQF #0166) measure, we identified the methodology used to assess hospitals in the HIQR Program as reasonable for use in the EPMs since this is a survey that many hospitals and patients are familiar with. In determining HCAHPS performance, we propose to utilize the HCAHPS Linear Mean Roll-up (HLMR) score. The HLMR summarizes performance across 10 of the 11 publicly reported HCAHPS measures for IPPS hospitals with 100 or more completed HCAHPS surveys in a 4-quarter period. All of the publicly reported measures are included except for how well hospital staff helps patients manage pain since revisions are under consideration for that measure. The HLMR is calculated by taking the average of the linear mean scores (LMS) for each of the 10 publicly reported HCAHPS measures. We note that the HLMR is not current publicly reported but may be calculated using the LMS, which are publicly reported in the Patient Survey Results in the Hospital Compare downloadable database found on Data.Medicare.gov at *https://data.medicare.gov/data/hospital-compare?sort=relevance&tag=patient%20survey%20results*. 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 propose that EPM participants must have at least 100 completed HCAHPS surveys over a given 4-quarter period to be evaluated on HCAHPS for the EPMs. The responses to the survey items used in each of the 10 HCAHPS measures described previously are combined and converted to a 0 to 100 linear-scaled score as follows:

• ''Never'' = 0; ''Sometimes'' = 331/3; ''Usually'' = 662/3; and ''Always'' = 100 (For HCAHPS Survey items 1–9, 11, 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 item 21).
• ''Definitely No'' = 0; ''Probably No'' = 331/3; ''Probably Yes'' = 662/3; and ''Definitely Yes'' = 100 (For item 22).
• ''Strongly Disagree'' = 0; ''Disagree'' = 331/3; ''Agree'' = 662/3; and ''Strongly Agree'' = 100 (For items 23, 24, and 25).

The linear-scaled scores are then adjusted for patient mix, survey mode, and quarterly weighting to create the LMS, see *http://www.hcahpsonline.org/files/HCAHPS_Stars_Tech_Notes_Apr 2015.pdf*.

The HLMR summarizes performance across the 10 HCAHPS measures by taking an average of each of the LMS of the 10 HCAHPS measures, using a weight of 1.0 for each of the 6 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 an EPM participant, the hospital's percentile of performance can be determined by applying the aforementioned methods to the linear mean scores for all IPPS hospitals with 100 or more completed surveys in a 4-quarter period. As previously noted, linear mean scores are publicly reported, but HLMRs are not. An EPM model participant can estimate the national distribution of HLMRs and the performance percentiles by using the Patient Survey Results in the Hospital Compare downloadable database found on *Data.Medicare.gov, https://data.medicare.gov/data/hospital-compare?sort=relevance&tag=patient%20survey%20results*, to calculate the HLMRs for all IPPS hospitals with 100 or more completed surveys in a 4-quarter period.

(g) Calculating the Rate and Performance Period

We propose to be consistent with the HIQR Program, which uses 4 quarters of data for HCAHPS (79 FR 50259). For the EPMs, we propose to use the most recently available HCAHPS 4-quarter roll-up to calculate the HLMR score for the initial year of the EPMs. The proposed measure performance period is discussed in section III.E.5. of this proposed rule, and summarizes measure performance periods for performance years 1 through 5 of the EPM performance years. We note that improvement on the HCAHPS Survey (#0166) measure would be determined from the measure performance period available for the year immediately preceding the EPM model performance year. We seek comment on this proposal to include the HCAHPS Survey (NQF #0166) measure in the EPMs to assess quality performance and capture patient experience of care.

e. Potential Future Measures

CMS recognizes that there remain gaps in quality measures targeting AMI, CABG, and hip fracture care.

Specifically with regard to hip fracture care, examples of potential measures suitable for consideration for inclusion in the SHFFT model in future performance years include: (1) Claims-based or hybrid risk-standardized hospital-level mortality, complication, and/or readmission measures intended for assessing hospital or provider performance for patients with hip fracture; and (2) patient-reported outcome data-based measures of functional status, symptom burden, number of days at home and/or return to home and/or independent living suitable for patients with hip fractures and/or patients undergoing total hip or knee arthroplasty as referred to in 79 FR 50259. Additionally we would consider including measures of all–cause harm across the models in future years and appropriateness of procedures. CMS also recognizes that care for patients with AMI, CABG, and hip fractures extends across care settings and providers, and includes care provided by a multitude of clinicians and possible post-acute care facilities (for example, inpatient rehabilitation facilities, intermediate care facilities, and/or home health services). CMS welcomes comments on measure concepts for future measures that potentially could be included in the AMI, CABG, and SHFFT models, including measures that are attributable to acute care and post-acute care facilities and clinicians. CMS also welcomes information about existing patient-centered outcomes measures that address quality gaps relevant to the AMI, CABG, and SHFFT models. Any changes to the measures included in the AMI, CABG, and SHFFT models would be subject to future rulemaking.

5. Form, Manner, and Timing of Quality Measure Data Submission

We believe 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 propose that data submission for Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230)(MORT–30–AMI); Excess Days in Acute Care after Hospitalization for an Acute Myocardial Infarction (AMI Excess Days); Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558) (MORT–30–CABG); and Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) (Hip/Knee Complications) be accomplished through the existing HIQR Program processes. Since these measures are claims-based measures, hospitals will not need to submit data.

We propose that the same mechanisms used in the HIQR Program to collect HCAHPS Survey (NQF #0166) measure data also be used in the AMI, CABG, and SHFFT models (79 FR 50259). For the hospitals that voluntarily submit data for the Hybrid AMI mortality measure, we anticipate, if it is technically feasible, for data submission processes to be broadly similar to those summarized for the HIQR Program for electronic clinical quality measures. We propose to allow hospitals to submit the data elements using either QRDA–1 or to submit to data elements using a simpler spreadsheet in performance year 1. We propose to require hospitals to submit data elements using only QRDA–1 in performance years 2 through 5. We would create a template for data reporting, 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 hybrid AMI voluntary data. We describe processes for voluntary data collection in section III.E.4.c.(2)(ii) of this proposed rule. The use of QRDA for reporting of EHR data is aligned with requirements used by the HIQR Program for electronic clinical quality measures. We seek comment on the proposal to collect EHR data through either QRDA–1 or through a simple spreadsheet in performance year 1 and to collect EHR data through only QRDA–1 in performance years 2 through 5.

The proposed quality measure performance periods for required and voluntary reporting measures by the performance year of the AMI, CABG, and SHFFT models are displayed in Tables 30, 31, 32, 33, and 34.

TABLE 30—SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE AMI MODEL

Measure title	Model performance year				
	1st	2nd	3rd	4th	5th
MORT-30-AMI*	July 1, 2014–June 30, 2017.	July 1, 2015–June 30, 2018.	July 1, 2016–June 30, 2019.	July 1, 2017–June 30, 2020.	July 1, 2018–June 30, 2021.
AMI Excess Days	July 1, 2014–June 30, 2017.	July 1, 2015–June 30, 2018.	July 1, 2016–June 30, 2019.	July 1, 2017–June 30, 2020.	July 1, 2018–June 30, 2021.

*Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230) (MORT–30–AMI).

**Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (AMI Excess Days).

TABLE 31—SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE CABG MODEL

Measure title	Model year				
	1st	2nd	3rd	4th	5th
MORT-30-CABG*	July 1, 2014–June 30, 2017.	July 1, 2015–June 30, 2018.	July 1, 2016–June 30, 2019.	July 1, 2017–June 30, 2020.	July 1, 2018–June 30, 2021.

*Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558) (MORT–30–CABG).

TABLE 32—SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE VOLUNTARY DATA SUBMISSION

	Model performance year				
	1st	2nd	3rd	4th	5th
Submission of EHR data elements for the Hybrid AMI Mortality Measure.	July 1, 2017–August 31, 2017.	September 1 2017–June 30, 2018.	July 1, 2018–June 30, 2019.	July 1, 2019–June 30, 2020.	July 1, 2020 –June 30, 2021.
Submission of functional status data for elective primary THA/TKA procedures.	September 1, 2016–June 30, 2017.	July 1, 2017–June 30, 2018.	July 1, 2018–June 30, 2019.	July 1, 2019–June 30, 2020.	July 1, 2020–June 30, 2021.

TABLE 33—SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE SHFFT MODEL

Measure title	Model performance year				
	1st	2nd	3rd	4th	5th
Hip/Knee Complications* ..	April 1, 2014–March 31, 2017.	April 1, 2015–March 31, 2018.	April 1, 2016–March 31, 2019.	April 1, 2017– March 31, 2020.	April 1, 2018–March 31, 2021.

*Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) (Hip/Knee Complications).

TABLE 34—SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR FOR REQUIRED MEASURES FOR ALL EPMS

Measure title	Model performance year				
	1st	2nd	3rd	4th	5th
HCAHPS*	July 1, 2016–June 30, 2017.	July 1, 2017–June 30, 2018.	July 1, 2018–June 30, 2019.	July 1, 2019–June 30, 2020.	July 1, 2020–June 30, 2021.

*Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey (NQF #0166).

6. Display of Quality Measures and Availability of Information for the Public From the AMI, CABG, and SHFFT Models

We believe that the display of measure results is an important way to educate the public on hospital performance and increase the transparency of the model. We propose to display quality measure results on the Hospital Compare Web site (*http://www.hospitalcompare.hhs.gov*). We believe that the public and hospitals are familiar with this Web site and how the information is displayed. The proposed measures have been displayed on Hospital Compare over the past few years. Finally, we believe that the public and hospitals' familiarity with the Hospital Compare Web site will make it simpler to access data. We seek comment on this proposal.

III. Provisions of the Proposed Regulations

F. Compliance Enforcement and Termination of an Episode Payment Model

1. Overview and Background

We must have certain mechanisms to enforce compliance with the requirements of the EPMs. The following discussion details the enforcement mechanisms we propose to make available to CMS for the EPMs when an EPM participant or certain other individuals and entities fails to comply with the requirements of these models.

Section 510.410 established that CMS will enforce the CJR model requirements against CJR participant hospitals, and will hold such hospital responsible for its own and its CJR collaborators' compliance with CJR model requirements. Given that CJR participant hospitals may receive reconciliation payments, and choose to distribute or share those payments with its CJR collaborators, CMS believed that enhanced scrutiny and monitoring of CJR participant hospitals was necessary and appropriate. We also noted in the CJR final rule that by making the CJR participant hospitals responsible for compliance with the model, CMS indirectly will be accounting for CJR collaborators' compliance, in addition to any direct monitoring of such CJR collaborators that HHS (including CMS and OIG) conducts. Further, § 510.410 established that upon discovering an instance of CJR collaborator noncompliance with the CJR model, CMS, HHS, or a respective designee may take remedial action against the CJR participant hospital, including requiring such hospital to terminate a sharing arrangement with a CJR collaborator and to prohibit further engagement in the CJR model by such collaborator, and CMS may also increase a participant hospital's repayment. Section 510.410 as well as the Section 1115A of the Social Security Act authorizes CMS to reduce or eliminate a participant hospital's reconciliation payment as well as increase a participant hospital's repayment amount. We propose an enforcement structure that would be consistent with the CJR model, as we believe the CJR model and the EPMs share many of the same policy characteristics.

2. Proposed Compliance Enforcement for EPMs

We propose that CMS would have the remedial actions detailed in section § 512.460(b)(2) available for use against any EPM participant where such EPM participant or its EPM collaborator, collaboration agent or downstream collaboration agent is not compliant with applicable requirements in any of the ways listed in § 512.460(b)(1). These mechanisms will support CMS's goal for EPMs to maintain or improve quality of

care, reduce program expenditures, safeguard program integrity, protect against fraud and abuse and deter noncompliance of EPM requirements. Further, preventing EPM participants from avoiding the high cost and high severity patients or from targeting low cost and low severity patients will further CMS's goal under the CR incentive payment to reduce cardiovascular mortality, improve health-related quality of life, and reduce the risk of hospital admission. Additionally, these mechanisms will support CMS's goal for EPMs to provide beneficiaries with complete and accurate information, including notices which promote increasing consumer engagement and freedom of choice. Given that EPM participants may choose to gainshare with their EPM collaborators, and those EPM collaborators may have distribution arrangements with any collaboration agent, and those collaboration agents may have downstream distribution arrangements with any downstream collaboration agent, we believe that enhanced scrutiny and monitoring of EPM participants and their EPM collaborators, collaboration agents, and downstream collaboration agents is necessary and appropriate. Similar to the CJR model, we propose to hold the EPM participant responsible for its own and its EPM collaborators' compliance with the EPM requirements. In this proposed rule, we are adding EPM participant responsibility for the other individuals and entities with financial arrangements under the EPM requirements as well. This is based in part on the addition of ACOs and hospitals, including CAHs, as EPM collaborators. Specifically, we believe that because we are allowing additional entities and individuals to be EPM collaborators, collaboration agents, or downstream collaboration agents, we must ensure that such entities and individuals comply with all requirements of the EPMs, such as notifying beneficiaries of the model and maintaining access to care. Overall, we have concluded that EPM participants should ensure that any entity or individual participating in the model should only be permitted to enter into certain financial arrangements that comply with model requirements and safeguard program integrity. Upon discovering an instance of noncompliance by an EPM collaborator, collaboration agent, or any downstream collaboration agent with the requirements of the EPM, CMS, HHS, or a designee of such Agencies may take remedial action against the EPM participant, including requiring such EPM participant to terminate a sharing arrangement with an EPM collaborator and prohibit further engagement by the EPM participant in sharing arrangements with the EPM collaborator. Where a participant is terminated from an EPM, we propose that the EPM participant would remain liable for all negative NPRA generated from episodes of care that occurred prior to termination. Any information collected by CMS in relation to termination of a participant from the model would be shared with our program-integrity colleagues at HHS, the Department of Justice, and their respective designees. Should such participant, or one of its EPM collaborators, collaboration agents, or downstream collaboration agents, be noncompliant with the requirements of the EPMs or engage in unlawful behavior related to participation in the EPMs, we note that such information could be used in proceedings unrelated to the enforcement mechanisms in this section.

These remedial actions are necessary to safeguard program integrity and protect against abuse or fraud. Further, we believe the proposed remedial actions would deter noncompliance of EPM requirements.

In summary, we propose in § 512.460 that EPM participants must comply with all requirements outlined in part 512. Except as specifically noted in this part, the regulations under this part must not be construed to affect the applicable payment, coverage, program integrity, or other requirements under this chapter (such as those in parts 412 and 482).

Further, we propose in § 512.460 that CMS may take the remedial actions later discussed in this section, if an EPM participant or its related EPM collaborators, collaboration agents or downstream collaboration agents—

- 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 applicable model, including but not limited to—

++ Avoiding potentially high cost or high severity patients;

++ Targeting potentially low cost or low severity patients;

++ Failing to provide medically appropriate services or systematically engaging in the over or under delivery of appropriate care;

++ Failing to provide beneficiaries with complete and accurate information, including required notices;

++ Failing to allow beneficiary choice of medically-necessary options, including non-surgical options; or

++ Failing to follow the requirements related to sharing arrangements.

- Has signed a sharing arrangement, distribution arrangement, or downstream distribution arrangement that is noncompliant with the requirements of this part;
- Takes any action that threatens the health or safety of patients;
- Avoids at risk Medicare beneficiaries, as this term is defined in § 425.20;
- 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 of this part;
- Takes any action that CMS determines for program integrity reasons is not in the best interests of the applicable episode payment model, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of EPM;
- 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
- 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 EPM.

We propose the remedial actions to include the following:

- Issuing a warning letter to the EPM participant.
- Requiring the EPM participant to develop a corrective action plan, commonly referred to as a CAP.
- Reducing or eliminating the EPM participant's reconciliation payment.
- Reducing or eliminating the EPM participant's CR incentive payment.
- Requiring the EPM participant to terminate a sharing arrangement with an EPM collaborator and prohibit further engagement by the EPM participant in sharing arrangements with the EPM collaborator.
- Terminating the EPM participant's in the EPM. Where a participant is terminated from an EPM, the EPM participant will remain liable for all negative NPRA generated from episodes of care that occurred prior to termination.

Further we propose that CMS may add 25 percent to a repayment amount

on an EPM participant's reconciliation report if all of the following conditions are true:

- CMS has required a corrective action plan from the EPM participant.
- The EPM participant owes a repayment amount to CMS.
- The EPM participant fails to timely comply with the corrective action plan or is noncompliant with the EPM's requirements.

The proposals for compliance enforcement are included in § 512.460. We seek comment on our proposals.

3. Proposed Termination of an Episode Payment Model

We further propose under § 512.900, CMS may terminate any episode payment model for reasons including but not limited to the following::

- CMS no longer has the funds to support the applicable model.
- CMS terminates the applicable 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.

G. Monitoring and Beneficiary Protection

1. Introduction and Summary

With the AMI, CABG, and SHFFT models, we are proposing to expand upon the CJR model implemented in 2016, as we believe the proposed EPMs represent additional opportunities to improve beneficiary access, patient outcomes, and overall quality of care across a broader spectrum of clinical conditions. EPM policies are intended to support making care more easily-accessible to consumers when and where they need it, increasing consumer engagement and thereby informing consumer choices. Given the similarity between the CJR model and the proposed EPMs, we are proposing to extend some waivers to these EPMs that initially were offered under the CJR model and that we believe are clinically-appropriate for the proposed episodes. These waivers would offer AMI model, CABG model, and SHFFT model participants additional flexibilities with respect to furnishing telehealth services and post-discharge home visits and waiving the 3-day stay requirement for covered SNF services when clinically-appropriate and are discussed further in section III.J. of this proposed rule.

We believe that the proposed EPMs will improve beneficiary access and outcomes, but 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. Therefore, we direct readers to section III.D of this proposed rule for discussion of the methodology for incorporating quality into the payment structure and the measures utilized for these models, which we believe can help identify and mitigate these possibilities.

2. Beneficiary Choice

As with the CJR model, we propose that participation in the proposed EPMs by hospitals would be mandatory in the selected geographic areas covered under each EPM. An individual beneficiary would not be able to opt out of an EPM episode of care provided by an EPM participant in the applicable model. We do not believe that it is appropriate or consistent with other Medicare programs to allow a patient 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. Moreover, we do not believe that an ability to opt out of a payment system is a factor in upholding beneficiary choice or is otherwise advantageous to beneficiaries or even germane to beneficiary decisions, given that the proposed EPMs would not increase beneficiary cost-sharing. However, we also believe that full notification and disclosure of the EPMs and their possible implications is critical for beneficiary understanding and protection. Further, it is important to create safeguards for beneficiaries to ensure that care recommendations are based on clinical needs and not inappropriate cost savings. This is particularly important when one entity is held accountable for payments across multiple provider settings as will be done in the proposed EPMs. It also is important for beneficiaries to know that they can raise any concerns with their physicians, with 1–800–Medicare, or with their local Quality Improvement Organizations.

As with the CJR model and other episode-based payment models, the proposed EPMs would not limit a beneficiary's ability to choose among Medicare providers or the range of services that would be available to them. Beneficiaries would continue to choose any Medicare participating provider, or any provider that has opted out of Medicare, with the same costs, copayments and responsibilities as they have with other Medicare services. Although the proposed EPMs would allow EPM participants to enter into sharing arrangements with certain providers and may recommend to beneficiaries such preferred providers within the constraints of current law, hospitals may not restrict beneficiaries to a list of preferred or recommended providers that surpass any restrictions that already exist under current statutes and regulations. Moreover, an EPM participant may not charge any EPM collaborator a fee to be included on a list of preferred providers or suppliers, nor may such EPM participant accept such payments, which would be considered to be outside the realm of risk-sharing arrangements. Although the emergent nature of some of the services covered under the proposed EPMs' episodes may limit beneficiaries' abilities to plan where they will be treated for these services, such constraint should be no different than it would be in the absence of the EPMs. Thus, these proposed EPMs would not create any new restriction of beneficiary freedom to choose providers, including surgeons, hospitals, post-acute care, or any other providers or suppliers.

3. Beneficiary Notification

We believe that beneficiary notification and engagement is essential because under the proposed EPMs, there would be a change in the way EPM participants are paid, which could affect the care beneficiaries receive. While we believe that existing Medicare provisions can be effective in protecting beneficiary freedom of choice and access to appropriate care, we also believe that the additional safeguards implemented with the CJR model would also be appropriate under the proposed EPMs. We believe that appropriate beneficiary notification should—(1) explain the model; (2) advise beneficiaries and their families or caregivers of the beneficiaries' clinical needs and care-delivery choices; and (3) clearly specify that any non-hospital provider holding a risk-sharing arrangement with the EPM participant should be identified to the beneficiary as a financial partner of such EPM participant for the purposes of services covered under the proposed EPMs' episodes. Through these policies, we seek to enhance beneficiaries' understanding of their care, improve their abilities to share in the decision-making, and give them the opportunity to consider competing benefits even as they are presented with cost-saving recommendations. We believe that appropriate beneficiary notification should do all of the following:

- Explain the model and how it may or may 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 care-givers to their Blue Button® electronic health information.
- Advise patients that all standard Medicare beneficiary protections remain in place, including the ability to report concerns of substandard care to Quality Improvement Organizations (QIO) and 1–800–MEDICARE.

However, we acknowledge that because of the emergent nature of admissions related to services covered under the proposed EPMs, in particular the AMI and SHFFT models, many patients initially admitted for such episodes may not, at the time of admission, be capable of receiving appropriate notification. In addition, there may be situations in which it is not determined until after an admission that the patient would be covered under an EPM's episode of care. In such situations, because the decision to admit may not be made in advance, it would be appropriate that the notifying entity be the EPM participant. Nonetheless, consistent with CJR policy, we are proposing that EPM participants must: (1) Require all providers and suppliers that execute EPM sharing arrangements with such EPM participants to share with beneficiaries or beneficiary representatives certain notification materials, to be developed or approved by CMS, that detail the applicable EPM; and (2) where feasible, provide such information in advance of admissions for services covered under EPM episodes. When, due to the emergent nature of the admission, it is not feasible to provide such notification in advance of admissions, we propose that the EPM participant would be responsible for providing such notifications as soon as reasonably practicable but no later than discharge from the hospital accountable for the episode. Under our proposal, EPM participants would be required to provide such notifications as a condition of any EPM sharing arrangements. Where an EPM participant does not have such sharing arrangements with providers or suppliers that furnish services to beneficiaries during EPM episodes of care, or where admissions for covered episodes of care are ordered by physicians who do not have such EPM sharing arrangements, we propose that the EPM participant must provide such beneficiary-notification materials at the earliest time that is reasonably practicable but no later than discharge from the hospital accountable for the episode. Further, we propose that participants of an ACO that has entered into a sharing arrangement with the EPM participant provide written notice to any EPM beneficiary of the applicable EPM's structure and the existence of the ACO's sharing arrangement with the EPM participant. Under this proposal, the ACO must require any ACO participants with which such ACO has relevant distribution arrangements, to provide the written notification. We propose the ACO must provide such beneficiary notification no later than the time at which the beneficiary first receives services from such ACO's participant and/or an ACO PGP member collaboration agent during the EPM episode. We understand that various providers and suppliers, including hospitals, may be ACO participants; therefore, if, due to the emergent nature of a particular admission, it is not feasible to provide such notification in advance of such admission, the ACO participant would be responsible for providing such notification as soon as reasonably practicable but no later than discharge from the hospital accountable for the episode. The purpose of this proposed policy is to ensure that all beneficiaries who initiate EPM episodes and/or their designated representatives receive the beneficiary notification materials as early as possible. We believe that this proposal targets beneficiaries for whom information is relevant, and increases the likelihood that patients will become engaged and seek to understand the applicable EPMs and their potential impact on their care.

We propose that all providers and suppliers that are required to provide notice to beneficiaries of the EPM model (participant and collaborator hospitals, PGPs, physicians, non-physician practitioners, post-acute care providers and suppliers, and ACOs) must be able to, upon request by CMS, indicate compliance with the beneficiary notification requirements outlined in this section and in the final rule. The participant hospital or collaborator should be able to generate a list of beneficiaries that received such notification and when the notification was received and provide it to CMS or its designee upon request. We note that the method employed to document beneficiary notification may vary; for example, some hospitals and collaborators may retain a list of all beneficiaries that received the notification, document in the medical record that the beneficiary received the beneficiary notification, add a barcode to the notification form to be scanned into the medical record, or employ another method of recordkeeping. Regardless of the method used for recordkeeping, the entity must be able to provide CMS or its designee with a list of all beneficiaries that received the notification materials in a specified time period. This requirement will aid CMS in monitoring participant hospital and collaborator compliance with the final rule.

We note that Medicare beneficiaries are accustomed to receiving similar notices of rights and obligations from healthcare providers prior to the start of inpatient care, or, as appropriate, under emergency conditions. In following the same guidelines established for the CJR model, we aim to limit confusion and to provide consistent direction to hospitals which may be participating in both the CJR model and EPMs. We invite comment on ways in which the timing and source of beneficiary notification might be modified to best serve the needs of beneficiaries without creating unnecessary administrative work for providers.

4. Monitoring for Access to Care

Given that an EPM participant would receive a reconciliation payment when such participant reduces average costs per case and meets quality thresholds, such EPM participant could have an incentive to avoid complex, high-cost cases by not admitting patients at all or by transferring patients to nearby facilities or specialty referral centers that would be outside of the model. We intend to monitor the EPM participants' claims data—for example, to compare each EPM participant's case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded. We propose to publish these data as part of the EPMs' evaluations to promote transparency and an understanding of the EPMs' effects. We also propose to continue to review and audit EPM participants if we have reason to believe that they are compromising beneficiary access to care. For example, we would review claims data to determine whether there is an unusual pattern of referral to regional hospitals located outside of the applicable EPM's catchment area or a clinically-unexplained increase or decrease in CABGs or rates of other related surgical procedures not covered under the EPMs.

5. Monitoring for 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 higher-cost services at the expense

of better outcomes and higher quality. However, we believe that professionalism, the quality measures proposed for the applicable EPM, and clinical standards can be effective in preventing denials of medically-necessary care in both the inpatient and post-acute care settings during the 90 days post-discharge. Accordingly, we believe that the potential for the denial of medically-necessary care within EPMs will not be greater than that which currently exists under the IPPS. However, we also believe that we have the authority and responsibility to audit EPM participants' and their EPM collaborators' medical records and claims to verify that beneficiaries receive medically-necessary services, and we propose to perform such auditing activities as we deem appropriate. We also propose to monitor arrangements between EPM participants and their EPM collaborators to ensure that such arrangements do not result in the denial of medically-necessary care or other programmatic or patient abuses. This is consistent with the policy that has been established for the CJR model.

With respect to post-acute care, we believe that requiring EPM participants to engage patients in shared decision-making is the most important safeguard to prevent inappropriate recommendations for lower-cost care, and that such a requirement can be best effected by requiring EPM participants to make shared decision making a condition of any EPM sharing arrangements with practitioners who provide these services. We also believe the 90-day episode is sufficiently long so as to create financial accountability and to encourage the provision of high-quality care that minimizes the risk of complications and readmissions that typically could occur within such time period. Clinical standards of care also constrain physician patterns of practice, 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. Therefore, we are proposing to require that, similar to CJR participant hospitals, EPM participants must, as part of discharge planning, account for potential financial bias by providing each patient with a complete list of all available post-acute care options in the applicable service area consistent with medical need, including beneficiary cost-sharing and quality information (where available and as applicable). We expect that the treating physician as well as all other treating practitioners continue to identify and discuss all medically-appropriate options with the beneficiary, and that the EPM participant will discuss the various facilities and providers available to meet the clinically-identified needs. These proposed requirements for EPM participants would supplement the discharge-planning requirements under existing conditions of participation (CoPs). We also specifically note that neither the CoPs nor this proposed transparency requirement preclude EPM participants 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 EPMs. We invite comment on this proposal, including additional opportunities to ensure high-quality care.

6. Monitoring for Delayed Care

We are proposing the EPMs in part to incent EPM participants to create efficiencies in the delivery of care within a 90-day episode following an acute clinical event. Theoretically, such EPMs also could create incentives for EPM participants or their EPM collaborators to delay services until after such 90-day window has closed. Consistent with the CJR model, we believe that existing Medicare safeguards are sufficient to protect beneficiaries in the EPMs.

First, our experience with other episode-based payment models such as the BPCI initiative has shown that providers focus first on appropriate care and then on efficiencies only as obtainable in the setting of appropriate care. We believe that a 90-day post-discharge episode is sufficient to minimize the risk that EPM participants and their EPM collaborators would compromise services furnished in relation to a beneficiary's care. While we recognize that ongoing care for underlying conditions may be required after the 90-day episode of care, we believe that EPM participants would be unlikely to postpone key services beyond a 90-day period because the consequences of delaying care beyond such episode duration would be contrary to usual standards of care.

However, we also note that additional monitoring would occur as a function of the proposed EPMs. As with the CJR model, we propose as part of the payment definition (see section III.D.7. of this 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 including such a payment adjustment would create an additional deterrent to delaying care beyond the episode duration. In addition, we believe the data collection and calculations used to determine such adjustment would provide a mechanism to check whether providers are inappropriately delaying care. Finally, we note that the proposed quality measures create additional safeguards as such measures are used to monitor and influence clinical care at the institutional level.

In accordance with section 1115A of the Act, we are proposing to codify these proposals in regulation in the proposed 42 CFR part 512. We invite public comment on our proposed requirements for notification of beneficiaries and our proposed methods for monitoring participants' actions and compliance as well as on other methods to safeguard delivery of high-quality, clinically-appropriate care.

H. Access to EPM Records and Record Retention

Consistent with the Shared Savings Program, the BPCI initiative, CJR model, and other Innovation Center models, we propose specific access to EPM records and record retention requirements for individuals and entities involved with the EPM. For the CJR model, the record access and retention requirements were originally located in Subpart F (Financial Arrangements and Beneficiary Incentives). However, we propose to include them in Subpart B (Episode Payment Model Participants) for the EPM and move them to Subpart B for the CJR model as discussed in section V.L. of this proposed rule, so that these requirements can be applied to categories of information that are broader than those solely related to financial arrangements and beneficiary incentives, as discussed later in this section.

We propose that EPM participants, EPM collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities performing EPM activities must allow both scheduled and unscheduled access to all books, contracts, records, documents, and other evidence (including data related to utilization and payments, quality of care criteria, billings, lists of EPM collaborators, sharing arrangements, distribution arrangements, downstream distribution arrangements, and the documentation required under § 512.500(d) and § 512.525(d)) sufficient to enable the audit, evaluation, inspection, or investigation of six categories of information. We further propose that all such books, contracts, records, documents, and other evidence be

maintained for a period of 10 years from the last day of the EPM participant's participation in the EPM or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless CMS determines a particular record or group of records should be retained for a longer period and notifies the EPM participant at least 30 calendar days before the disposition date; or there has been a dispute or allegation of fraud or similar fault against the EPM participant, EPM collaborator, collaboration agent, downstream collaboration agents, or any other individual or entity performing EPM activities in which case the records must be maintained for 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

In the CJR model, we applied these record access and retention obligations only to participant hospitals and CJR collaborators (80 FR 73432 through 73433). However, because we propose additional types of EPM collaborators and types of financial arrangements in section III.I. of this proposed rule for the EPM, as well as define EPM activities as those related to promoting accountability for the quality, cost, and overall care for EPM beneficiaries, we propose to apply the record access and retention obligations to EPM participants and all individuals and entities with EPM financial arrangements where payments are substantially based on quality of care and the provision of EPM activities, as well as to other individuals and entities providing EPM activities. While this proposal is an expansion of the current record access and retention obligations under the CJR model to additional categories of individuals and entities, we believe the expansion is necessary and appropriate for the six categories of information to which we propose that the access and retention requirements would apply. Access to this information from those individuals and entities providing EPM activities that are the basis of care redesign in the EPM provides an important program safeguard by allowing monitoring for compliance with EPM requirements. The alternative of limiting the requirements solely to EPM participants and EPM collaborators as we finalized for the CJR model would result in no record access and retention obligation for certain individuals and entities that have financial arrangements under the EPM and engage in EPM activities, thereby limiting the Government's ability to audit, evaluate, inspect, or investigate compliance with EPM requirements. We similarly propose changes to the individuals and entities subject to record access and retention obligations under the CJR model as discussed in section V.L. of this proposed rule.

We have identified six categories of information related to key EPM parameters for which we propose that the record access and retention requirements would apply. Like the CJR model, we propose that one category of information consists of those documents related to the individual's or entity's compliance with EPM requirements. Given the individuals and entities who must comply with the requirements of the EPM either directly or through their arrangements, including EPM participants, EPM collaborators, collaboration agents, and downstream collaboration agents, an important program safeguard is record access and retention that allow compliance with the EPM requirements to be monitored and assessed.

Additionally, similar to the CJR model, we propose that a second category of information consists of documents related to the calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments. This list includes all types of payments proposed under EPM financial arrangements as discussed in section III.I. of this proposed rule and is different from the current CJR model requirement to the extent that we propose additional types of EPM financial arrangements in view of our proposal that ACOs can be EPM collaborators. Because of the proposed EPM requirements for these types of payments that are designed to ensure that all financial arrangements are for the sole purpose of aligning the financial incentives of individuals and entities with the goals of the EPM participant to improve the quality and efficiency of EPM episode care, we believe that these records of all the individuals and entities who enter such arrangements should be accessible and retained to allow compliance with the EPM requirements for the payments to be monitored and assessed. We propose similar changes to this category of information under the CJR model as discussed in section V.L. of this proposed rule.

The third category of information for which we propose to require record access and retention is related to an EPM participant's obligation to repay to CMS any reconciliation payment or CR incentive payments owed. The CR incentive payment has been added to this provision which otherwise applied to the CJR model because we propose a CR incentive payment in section VI. of this proposed rule for AMI and CABG model participants in selected MSAs, while the CJR model does not include this payment. Requiring record access and retention about repayment obligations under the EPM provides an important program integrity safeguard for repayments to CMS.

We propose to require record access and retention on the quality of the services furnished to an EPM beneficiary during an EPM episode as the fourth category of information. While the CJR model specified the quality of services furnished without further limitation in the record access and retention requirements, given our EPM proposals that require gainsharing, distribution, and downstream distribution payments to be substantially based on quality of care and EPM activities, we believe that it is appropriate to specify that the record access and retention requirements apply specifically to the services furnished to an EPM beneficiary during an EPM episode. The quality of services furnished without further limitation could result in an overly broad record access and retention requirement for services that are delivered outside of EPM episodes, where these services are not subject to EPM requirements. Services furnished to EPM beneficiaries during EPM episodes are the services for which we will also be monitoring for access to care, delayed care, and quality of care, important activities to safeguard the program and Medicare beneficiaries, so access to documents to support this monitoring is necessary. We propose similar changes to this category of information under the CJR model as discussed in section V.L. of this proposed rule.

Given the beneficiary notification requirements that we propose for the EPM in section III.G. of this proposed rule, we propose to require access to records and record retention about the sufficiency of EPM beneficiary notifications. The beneficiary notification requirement is an important beneficiary protection under the EPM, and the access to records and record retention requirements provide a program integrity safeguard to monitor for compliance with this requirement. We propose to add this same category of information for the CJR model as discussed in section V.L. of this proposed rule.

Finally, we propose to establish CEHRT use attestation for EPM participants so that an EPM participant

could be in a Track 1 EPM that meets the proposed requirements in the Quality Payment Program proposed rule to be an Advanced APM as discussed in section III.A.2 of this proposed rule. Thus, we propose to require access to records and record retention about the accuracy of each Track 1 EPM participant's submissions under CEHRT use requirements. Specifically, attestation to CEHRT use and submission of clinician financial arrangements lists are key requirements for Track 1 EPMs that are Advanced APMs, and the access to records and record retention requirements provide a program integrity safeguard by allowing us to assess the completeness and accuracy of the EPM participant's compliance with the requirements for those submissions. We propose to add this same category of information for the CJR model as discussed in section V.L. of this proposed rule.

We believe the proposed requirements regarding access to EPM records and record retention are necessary to safeguard program integrity and protect against abuse, in view of the EPM design and requirements as discussed throughout this proposed rule that would lead to achieving the EPM goals of improved EPM episode quality and efficiency. We also believe that by providing access to EPM records, we promote transparency of activities under the EPM. Furthermore, we believe the proposed access to records and record retention requirements would promote the compliance of EPM participants, EPM collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities providing EPM activities with EPM requirements by ensuring that compliance with these requirements can be monitored and assessed. Finally, these records may be necessary in the event that an EPM participant appeals any matter that is subject to dispute resolution through CMS. As such, CMS would have the resources necessary to prepare and respond to any such appeal.

The proposals for access to records and record retention are included in § 512.110. We seek comment on our proposals, including whether it is necessary, reasonable and appropriate to impose these access and retention obligations on all of the proposed categories of individuals and entities for all the proposed categories of information to be retained and made accessible. In addition, we seek comment on whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the EPM are met.

I. Financial Arrangements Under the EPM

1. Background

In November, 2015 we finalized regulations for financial arrangements for the CJR model (80 FR 73550 through 73553), an episode payment model that is similar to the three new proposed EPMs. In this rulemaking, we propose three new episode payments models that fall under the overarching term EPM, specifically the AMI model, CABG model, and SHFFT model. Both the CJR model and the three proposed EPMs place financial responsibility for the episode on the hospital where the episode begins with a hospitalization and require participation of hospitals in the selected MSAs for the models. Like LEJR episodes under the CJR model, the AMI, CABG, and SHFFT episodes in the proposed EPMs would be broadly defined to include most Part A and Part B services and extend 90 days following discharge from the hospitalization that initiates the EPM episode. During the design of the EPMs, we considered proposing the same CJR financial arrangements that were finalized through notice and comment rulemaking because the EPMs have a similar design to the CJR model with the same goals of improving the quality and efficiency of model episodes. We expect that the types of financial arrangements needed to align the financial incentives of CJR participants and EPM participants with other providers and suppliers caring for CJR beneficiaries or EPM beneficiaries during episodes to improve episode quality and efficiency would be similar. We also believe that program integrity safeguards that would provide protections against abuse under the financial relationships permitted for the EPMs should be comparable to those for the CJR model. However, we believe that it is possible to improve on the current regulatory structure for financial relationships that we established for the CJR model in our proposals for the EPMs. Our EPM proposals reflect changes from the current CJR model regulations that generally fall into the following four categories:

- Removing duplication of requirements in similar provisions.
- Streamlining and reorganizing the provisions for clarity and consistency.
- Providing additional flexibility in response to feedback from CJR participant hospitals and other stakeholders.
- Expanding the scope of financial arrangements under the EPM.

We note that in section V.J. of this proposed rule, we propose changes to the CJR model financial arrangements regulations in Part 510 to parallel those we propose for the EPMs. These proposals would result in the same provisions and requirements for CJR model and EPM financial arrangements when the first performance year of the EPMs begins on July 1, 2017.

2. Overview of EPM Financial Arrangements

For purposes of this section, the term ''EPM'' refers to one model specifically among the AMI model, CABG model, or SHFFT model and should be read throughout Subpart F—Financial Arrangements and Beneficiary Incentives (§§ 512.500 through 512.525) of the proposed regulations as a single one of these three proposed EPMs. For example, when reading the proposed regulations for the CABG model, § 512.500(b)(6), the provision would read as, ''The board or other governing body of the [CABG model] participant must have responsibility for overseeing the [CABG model] participant's participation in the [CABG model], its arrangements with [CABG model] collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the [CABG model].'' We use this approach because we mean for the proposed requirements to apply to every participant in the EPM regardless of whether the EPM is the AMI, CABG, or SHFFT model.

As discussed in section III.D.2.b. of this proposed rule, we propose that each EPM would be a retrospective episode payment model, under which Medicare payments for items and services included in an EPM episode would continue to be made to all providers and suppliers under the existing FFS payment systems, and episode payment would be based on later reconciliation of actual spending for an EPM episode under the FFS payment systems to the EPM episode's quality-adjusted target price. If the actual episode spending is less than the quality-adjusted target price, the EPM participant financially responsible for the EPM episode would receive a reconciliation payment, assuming the EPM composite quality score for the EPM participant is in the ''acceptable,'' ''good,'' or ''excellent'' quality category. If an EPM episode's actual spending exceeds the quality-adjusted target price, then, beginning in performance year 2, the EPM participant would begin to repay the difference to Medicare up to the stop-loss threshold.

Similar to the CJR model (80 FR 73412), we believe that EPM participants may wish to enter into financial arrangements with providers and suppliers caring for EPM

beneficiaries to share financial risks and rewards under the EPM, in order to align the financial incentives of those providers and suppliers with the EPM goals of improving the quality and efficiency of EPM episodes. We further believe that EPM participants may wish to enter into financial arrangements with ACOs that participate in EPM care redesign and EPM beneficiary care management and whose ACO participants and ACO providers/suppliers care for EPM beneficiaries. We expect that EPM participants would identify key providers and suppliers caring for EPM beneficiaries, as well as ACOs to which EPM beneficiaries are aligned, in their communities and referral regions. The EPM participants then could establish close partnerships with these individuals and entities to promote accountability for the quality, cost, and overall care for EPM beneficiaries, including managing and coordinating care; encouraging investment in infrastructure, enabling technologies, and redesigned care processes for high quality and efficient service delivery; the provision of items and services during an EPM episode in a manner that reduces costs and improves quality; and carrying out other obligations or duties under the EPM. These providers, suppliers, and ACOs may invest substantial time and other resources in these activities, yet they would neither be the direct recipients of any reconciliation payments from Medicare, nor directly responsible for repaying Medicare for excess episode spending. Therefore, we believe it is possible that an EPM participant that may receive a reconciliation payment from Medicare or may need to repay Medicare may want to enter into financial arrangements with other providers, suppliers, or ACOs to share risks and rewards under the EPM. We expect that all financial relationships established between EPM participants and providers, suppliers, or ACOs for purposes of the EPM would be those permitted only under applicable law and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

In addition to providers, suppliers, and ACOs with which the EPM participant may want to enter into financial arrangements to share risks and rewards under the proposed EPMs, we expect that EPM participants 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; beneficiary care coordination and management; monitoring EPM participants' compliance with the EPM's terms and conditions; or other EPM-related activities. Such organizations may play important roles in an EPM participant's plans to implement an EPM based on the experience these organizations may bring, such as prior experience with bundled payment initiatives, care coordination expertise, familiarity with a particular local community, or knowledge of Medicare claims data. We expect that all relationships established between EPM participants and these organizations for purposes of the EPM would be those permitted only under existing law and regulation, including any relationships that would include the EPM participant's sharing of EPM risks and rewards with such organizations. We also expect that all of these relationships solely would be based on the level of engagement of the organization's resources to directly support the participants' EPM implementation.

Finally, because the proposed broadly defined EPM episodes would extend 90 days post-discharge from their respective anchor or chained anchor hospitalizations, similar to the CJR model (80 FR 73433), we believe that EPM participants caring for EPM beneficiaries may want to offer beneficiary engagement incentives to encourage adherence to recommended treatment and active patient engagement in recovery. Such incentives should be closely related to the provision of high quality EPM care and advance a clinical goal for an EPM beneficiary, and should not serve as inducements for beneficiaries to seek care from the EPM participants or other specific suppliers and providers. The incentives may help an EPM participant reach their quality and efficiency goals for EPM episodes, while also benefitting beneficiaries' health and the Medicare Trust Fund if the EPM participant improves the quality and efficiency of episodes through care redesign that results in EPM beneficiary reductions in hospital readmissions, complications, days in acute care, and mortality, while recovery continues uninterrupted or accelerates.

3. EPM Collaborators

Given the financial incentives of episode payment under the EPM, an EPM participant may want to engage in financial arrangements with individuals and entities making contributions to the EPM participant's episode performance on spending or quality. Such arrangements would allow the EPM participant to share all or some of the reconciliation payments they may be eligible to receive from CMS, or the EPM participant's internal cost savings that result from care for beneficiaries during EPM episodes. Likewise, such arrangements could allow the EPM participant to share the responsibility for the funds needed to repay Medicare with individuals and entities engaged in providing care to EPM beneficiaries, if those individuals and entities have a role in the EPM participant's episode spending or quality performance. We propose to use the term ''EPM collaborator'' to refer to these individuals and entities.

Since each proposed EPM's episode duration is 90 days following discharge from the anchor or chained anchor hospitalization and such episodes are broadly defined as discussed in section III.C.3.b. of this proposed rule, many providers and suppliers other than the EPM participant will furnish related services to beneficiaries during EPM episodes. Those providers and suppliers may include SNFs, HHAs, LTCHs, IRFs, physicians, nonphysician practitioners, providers or suppliers of outpatient therapy services, PGPs, hospitals, and critical access hospitals (CAHs). In addition, ACOs may be actively involved in coordinating the care of beneficiaries during EPM episodes. The proposed definition of EPM collaborator includes each of these categories of individuals and entities as eligible to be an EPM collaborator. The proposed list of types of EPM collaborators is the same list as CJR collaborators, but with the addition of hospitals, CAHs, and ACOs.

We expect that hospitals and CAHs that are not EPM participants may frequently play roles in care delivered to EPM beneficiaries during a chained anchor hospitalization as discussed in section III.C.4.a.(5) of this proposed rule or following discharge from an anchor or chained anchor hospitalization that initiates an EPM episode. For example, an AMI model participant without cardiac surgery or interventional cardiology capacity may need to transfer certain AMI model beneficiaries after initial admission to transfer hospitals or transfer CAHs for revascularization through PCI or through CABG. A transfer hospital may, itself, be participating in the AMI and CABG models (a CAH cannot be an AMI or CABG model participant), but the AMI model episode would be the responsibility of the AMI model participant that first admitted the beneficiary. In addition, hospital or CAH readmission during the proposed

EPM episodes would be common for beneficiaries post-anchor or post-chained anchor hospitalization discharge for AMI, CABG, and SHFFT model beneficiaries, and, because care for these clinical conditions may sometimes be provided at transfer hospitals that initiate EPM episodes as EPM participants, we expect that readmissions during such episodes may sometimes be to other hospitals or CAHs that are not EPM participants near beneficiaries' home communities. Thus, we believe it is important to allow EPM participants to enter into financial arrangements with other hospitals and CAHs that care for EPM beneficiaries, in order to align the financial incentives of such other hospitals and CAHs with the EPM goals of improving the quality and efficiency of EPM episodes.

Many accountable care organizations and other stakeholders have expressed strong interest in being collaborators in episode payment models generally, including sharing potential financial risks and rewards with model participants. Multiple commenters on the CJR proposed rule stated that robust accountable care organizations have proven track records of providing Medicare providers and suppliers with care redesign and care management assistance for Medicare beneficiaries, as well as managing the overall care of accountable care organization-aligned beneficiaries to improve the quality and efficiency of care (80 FR 73417). They reasoned that accountable care organizations might be able to provide CJR participant hospitals with care coordination assistance at reduced cost due to economies of scale and existing accountable care organization resources, as well as potentially assume a percentage of downside risk, in order to mitigate that risk to CJR participant hospitals. In the CJR Final Rule (80 FR 73417), we did not adopt accountable care organizations as CJR collaborators, responding that we decided to limit the testing of gainsharing relationships to solely those between hospitals and providers and suppliers enrolled in Medicare because we expected enrolled providers and suppliers to be most directly and specifically engaged with the CJR participant hospitals in care redesign and episode care for CJR beneficiaries who had surgeries at those hospitals. We also noted that a number of scenarios discussed by commenters to support their request to allow accountable care organizations to be CJR collaborators could be achieved outside of the context of gainsharing relationships between the CJR participant hospitals and those organizations.

With the steady growth in the number of accountable care organizations and accountable care organization-aligned beneficiaries, we have further considered the potential for accountable care organizations to be EPM collaborators. Our current proposed EPMs include beneficiaries with cardiovascular disease as well as beneficiaries with hip fracture who commonly are older with multiple comorbidities, and accountable care organizations have expertise in care coordination and accountability for the quality and expenditures for health care for accountable care organization-aligned beneficiaries over an annual period.

While we propose to exclude certain accountable care organization-aligned beneficiaries from EPM episodes, we note that the challenges of attributing savings and changes in the quality of care for beneficiaries simultaneously in EPMs and total cost-of-care models or programs, such as accountable care organizations, remain under consideration without full resolution, as discussed further in section III.D.6. of this proposed rule. Local relationships between providers, suppliers, and accountable care organizations vary in the care of beneficiaries, and it would be difficult for CMS at this time to provide standard program or model rules that would fairly distribute savings among different models and programs for overlapping periods of beneficiary care, when variable local arrangements determine which entity provides the resources for coordinating and managing a particular beneficiary's care over time. Finally, we note that accountable care organizations are groups of physicians, hospitals, and other health care providers and suppliers that come together to furnish coordinated, high quality care to their aligned Medicare beneficiaries to ensure that these beneficiaries, especially the chronically ill, get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors. Accountable care organizations' goals of delivering high quality care and spending health care dollars more wisely are the same as those of hospitals that would participate in the EPMs. Therefore, we believe it is especially important to further encourage collaborative partnerships between accountable care organizations and EPM participants that maximize their organizational efficiency and effectiveness, given their shared goals.

In considering the accountable care organizations that could be EPM collaborators engaged in collaborative relationships with EPM participants, we limited our consideration to accountable care organizations under Medicare because the EPM is an episode payment model for Medicare FFS beneficiaries. We note that in section III.D.6. of this proposed rule, we propose to exclude from the proposed EPM episodes beneficiaries who are aligned to the Next Generation ACO model or tracks of the Comprehensive ESRD Care Model incorporating downside risk for financial losses. Downside risk for financial losses and prospective alignment of beneficiaries are important criteria in selection of these models and tracks of models for this proposed exclusion. We also seek comment in that section on extending this exclusion proposal to Track 3 of the Shared Savings Program. Because we propose to allow financial arrangements under the EPM only with those entities that are involved in the delivery of care to EPM beneficiaries with goals of improving the quality and efficiency of EPM episodes, we do not believe it would be appropriate to permit Next Generation ACOs to be EPM collaborators because their aligned beneficiaries would be excluded from the EPM. Similarly, because we propose that beneficiaries eligible for Medicare on the basis of ESRD be excluded from the EPM as discussed in section III.C.4.a. of this proposed rule, we do not believe that participants in the Comprehensive ESRD Care initiative which predominantly include beneficiaries eligible for Medicare on the basis of ESRD should be permitted to be EPM collaborators. Finally, we note that the Pioneer ACO model ends in CY 2016, so that model will not overlap with the EPM which is proposed to begin on July 1, 2017.

Thus, we propose that ''ACOs,'' meaning those ACOs as defined at § 425.20 of regulations that are participating in the Shared Savings Program, be permitted to be EPM collaborators. This proposal would allow locally variable financial arrangements that could account for the way care in EPM episodes is coordinated and managed in communities, and ensure that entities with appropriate skills and experience are permitted to share the proposed EPM's risks and rewards with EPM participants. Medicare has a close relationship with such ACOs, which are regulated by CMS, so we can verify that these ACOs meet current Shared Savings Program requirements that could make them suitable for a role as EPM collaborators. Finally, in this way,

ACO participants and ACO providers/suppliers may be engaged in EPM care redesign directly through their ACO, instead of bypassing the ACO to become involved directly in the EPM through the EPM participant. We are limiting our proposal of entities that are not providers or suppliers but that are permitted to be EPM collaborators to ACOs alone. We propose to allow financial arrangements under the EPM only with those entities that are involved in the delivery of care to EPM beneficiaries.

We propose in § 512.2 that ACOs and the following types of providers and suppliers may be EPM collaborators:

- SNF.
- HHA.
- LTCH.
- IRF.
- Physician.
- Nonphysician practitioner.
- Provider or supplier of outpatient therapy services.
- PGP.
- Hospital.
- CAH.
- ACO.

We seek comment on the proposed definition of EPM collaborators. In addition to general comment, we are specifically interested in comment on the proposal to include hospitals, CAHs, and ACOs in the definition of EPM collaborators. Furthermore, we seek comment specifically on the accountable care organizations that we propose to include in the definition of ACO and which accountable care organizations should be included and excluded from the definition of ACO that may be EPM collaborators to best advance the goals of the EPM and program generally. Finally, we also seek comment on the regulatory and practical implications of establishing that ACOs may be EPM collaborators under the EPM, including without limitation how the requirements under the EPM would relate to how financial arrangements within ACOs are currently regulated under the Medicare Shared Savings Program.

4. Sharing Arrangements Under the EPM

a. General

Similar to the CJR model (80 FR 73430), we propose that certain financial arrangements between an EPM participant and an EPM collaborator be termed ''sharing arrangements.'' A sharing arrangement would be a financial arrangement to share only—(1) EPM reconciliation payments; (2) the EPM participant's internal cost savings; and (3) the EPM participant's repayment amount. Where a payment from an EPM participant to an EPM collaborator is made pursuant to a sharing arrangement, we define that payment as a ''gainsharing payment.'' A gainsharing payment may be composed only of—(1) EPM reconciliation payments; (2) the EPM participant's internal cost savings; or (3) both. A ''reconciliation payment'' is defined as a payment made by CMS to an EPM participant as determined in accordance with § 512.305(d) and as discussed in section III.D.5. of this proposed rule. ''Internal cost savings'' are the measurable, actual, and verifiable cost savings realized by the EPM participant resulting from care redesign undertaken by such participant in connection with providing items and services to beneficiaries within specific EPM episodes. Internal cost savings does not include savings realized by any individual or entity that is not the EPM participant. Where a payment from an EPM collaborator to an EPM participant is made pursuant to an EPM sharing arrangement, we define that payment as an ''alignment payment.'' An alignment payment may consist only of a portion of the ''repayment amount,'' which is the amount owed by an EPM participant to CMS, as reflected on a reconciliation report. An EPM participant must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement. We propose that a sharing arrangement must comply with the provisions of § 512.500 and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

We propose that the EPM participant must develop, maintain, and use a set of written policies for selecting individuals and entities to be EPM collaborators, and that the selection criteria must include the quality of care delivered by the potential EPM collaborator. The selection criteria cannot be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent. With the exception of adding ''past or anticipated'' to the selection criteria for EPM collaborators, these proposed criteria are similar to the existing requirements of the CJR model (80 FR 73430). By adding this language, all previous and future referrals between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent are encompassed. We do not believe it would be appropriate for sharing arrangements to be based on criteria that include the volume or value of past or anticipated referrals because the sole purpose of sharing arrangements is to create financial alignment between EPM participants and EPM collaborators toward the EPM goals of improving the quality and efficiency of episode care. Thus, we proposed to require EPM participants to select EPM collaborators based on criteria that include the quality of care furnished by the potential EPM collaborator to ensure that the selection of EPM collaborators takes into consideration the likelihood of their future performance in improving the quality of episode care. In addition, requiring that selection criteria include quality of care furnished by the potential EPM collaborator provides a safeguard against abuse.

Finally, we propose that if an EPM participant enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the EPM. Requiring oversight of sharing arrangements to be include in the compliance program provides a program integrity safeguard.

The proposals for the general provisions for sharing arrangements under the EPM are included in § 512.500(a). We seek comment about all of the provisions 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 EPM are met.

b. Requirements

We propose a number of specific requirements for sharing arrangements to help ensure that their sole purpose is to create financial alignment between EPM participants and EPM collaborators toward the goals of the EPM through program integrity safeguards. We propose that the sharing arrangement must be in writing, signed by the parties, and entered into before care is furnished to EPM beneficiaries under the sharing arrangement. In addition, participation in a sharing arrangement must be voluntary and without penalty for nonparticipation. It is important that providers, suppliers, and ACOs with

ACO participants and ACO providers/suppliers rendering items and services to EPM beneficiaries during EPM episodes have the freedom to provide medically necessary items and services to EPM beneficiaries without any requirement that they participate in a sharing arrangement, in order to safeguard beneficiary freedom of choice, access to care, and quality of care. Similarly, we believe that if a provider, supplier, or ACO enters into a sharing arrangement with an EPM participant, that sharing arrangement must precede the provision of care to the EPM beneficiary under the sharing arrangement. We expect the sharing arrangement to set out the mutually agreeable terms for the financial arrangement between the parties to guide and reward EPM care redesign for future EPM episodes, rather than reflect the quality and financial results of EPM episodes that have already occurred and where the financial outcome of the sharing arrangement terms would be known before signing.

We propose that the sharing arrangement must require the EPM collaborator and its employees, contractors, and subcontractors to comply with certain requirements that are important for program integrity under the arrangement. We note that the terms contractors and subcontractors, respectively, include collaboration agents and downstream collaboration agents as defined later in this section. The sharing arrangement must require all of the individuals and entities in this group to comply with the applicable provisions of Part 512, 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, because these individuals and entities all would play a role in EPM care redesign and be part of financial arrangements under the EPM. The sharing arrangement must also require all individuals and entities in the group to comply with the applicable Medicare provider enrollment requirement at § 424.500, including having a valid and active TIN or NPI, during the term of the sharing arrangement. This is to ensure that the individuals and entities have the required enrollment relationship with CMS under the Medicare program, although we note that they are not responsible for complying with requirements that do not apply to them. Finally, the sharing arrangement must require individuals and entities to comply with all other applicable laws and regulations.

We propose that the sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care so that financial relationships between EPM participants and EPM collaborators do not negatively impact beneficiary protections under the EPM. The sharing arrangement must require the EPM collaborator to have a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the EPM, just as we require EPM participants to have a compliance program for this purpose as a program integrity safeguard. We understand that some stakeholders may have interpreted the substantially similar requirement in the CJR model as obligating CJR collaborators to adopt specific compliance programs components (for example, an externally staffed hotline to receive complaints) and the perceived cost of adopting those components may be a disincentive for certain individuals and entities to be CJR collaborators in the CJR model. However, we note that the CJR compliance program requirement does not mandate that a CJR collaborator's compliance program take a particular form or include particular components. OIG has repeatedly and consistently emphasized that there is no ''one size fits all'' compliance program (for example, refer to OIG compliance program guidance for Individual and Small Group Physician Practices, 65 FR 59434, 59434–52 (October 5, 2000)). Like OIG, we understand the variances and complexities within the industry and appreciate differences in the size and resources of different providers and suppliers, particularly the financial constraints on individual physicians and nonphysician practitioners and small PGPs. Accordingly, we do not believe that the compliance program requirement for CJR collaborators as properly understood should be a disincentive for individuals or small PGPs to become CJR collaborators. Thus, we propose to adopt a substantially similar requirement for the EPM. We seek comment on the anticipated effect of the proposed compliance program requirement for EPM collaborators, particularly with regard to individual physicians and nonphysician practitioners and small PGPs, and whether alternative compliance program requirements for all or a subset of EPM collaborators should be adopted to mitigate any effect of the proposal that could make participation as an EPM collaborator infeasible for any provider, supplier, or other entity on the proposed list of types of EPM collaborators.

It is necessary that EPM participants have adequate oversight over sharing arrangements to ensure that all arrangements meet the requirements of this section and provide program integrity protections. Therefore, we propose that the board or other governing body of the EPM participant have responsibility for overseeing the EPM participant's participation in the EPM, its arrangements with EPM collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the EPM.

For purposes of financial arrangements under the EPM, we propose to define activities related to promoting accountability for the quality, cost, and overall care for EPM beneficiaries, including managing and coordinating care; encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery; the provision of items and services during an EPM episode in a manner that reduces costs and improves quality; or carrying out any other obligation or duty under the EPM as ''EPM activities.'' In addition to the quality of care provided during episodes, we believe the activities that would fall under this proposed definition encompass the totality of activities upon which it would be appropriate for certain financial arrangements under the EPM to be based in order to value the contributions of providers, suppliers, and other entities toward meeting the EPM goals of improving the quality and efficiency of episodes. We seek comment on the proposed definition of EPM activities as an inclusive and comprehensive framework for capturing direct care and care redesign for EPM episodes that contribute to improving the quality and efficiency of these episodes. We propose to use the term EPM activities in identifying certain obligations of parties in a sharing arrangement that are described as ''changes in care coordination or delivery'' in the CJR regulations governing the contents of the written agreement memorializing the sharing arrangement. We note that as discussed in section V.J. of this proposed rule, we propose to define and use the term CJR activities in the CJR regulations just as we propose to define and use the term EPM activities in the EPM regulations.

We propose that the written agreement memorializing a sharing arrangement must specify a number of parameters of the arrangement, including the following:

- The purpose and scope of the sharing arrangement.
- The identities and obligations of the parties, including specified EPM activities and other services to be performed by the parties under the sharing arrangement.
- The date of the sharing arrangement.
- Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out EPM activities.
- The financial or economic terms for payment, including the following:

++ Eligibility criteria for a gainsharing payment.

++ Eligibility criteria for an alignment payment.

++ Frequency of gainsharing or alignment payment.

++ Methodology and accounting formula for determining the amount of a gainsharing payment that is substantially based on quality of care and the provision of EPM activities.

++ Methodology and accounting formula for determining the amount of an alignment payment.

Finally, we propose to require that the terms of the sharing arrangement must not induce the EPM participant, EPM collaborator, or any employees, contractors, or subcontractors of the EPM participant or EPM collaborator to reduce or limit medically necessary services to any Medicare beneficiary or restrict the ability of an EPM collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments. These requirements are to ensure that the quality of care for EPM beneficiaries is not negatively affected by sharing arrangements under the EPM.

The proposals for the requirements for sharing arrangements under the EPM are included in § 512.500(b). We seek comment 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 EPM are met.

c. Gainsharing Payment, Alignment Payment, and Internal Cost Savings Conditions and Restrictions

We propose a number of conditions and limitations for gainsharing payments, alignment payments, and internal cost savings as program integrity protections for the payments to and from EPM collaborators. We propose to require that gainsharing payments be derived solely from reconciliation payments, internal costs savings, or both; that they be distributed on an annual basis, not more than once per calendar year; that they not be a loan, advance payment, or payment for referrals or other business; and that they be clearly identified as a gainsharing payment at the time they are paid.

We believe that gainsharing payment eligibility for EPM collaborators should be conditioned on two requirements—(1) meeting quality of care criteria; and (2) rendering items and services to EPM beneficiaries during EPM episodes—as safeguards to ensure that eligibility for gainsharing payments is solely based on aligning financial incentives for EPM collaborators with the EPM goals of improving EPM episode quality and efficiency. The second requirement, which is discussed later in this section, would also apply to eligibility of an EPM collaborator to make an alignment payment. With respect to the first requirement, we propose that to be eligible to receive a gainsharing payment, an EPM collaborator must meet quality of care criteria for the performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment. The quality of care criteria that are established by the EPM participant must be directly related to EPM episodes. With regard to the second requirement, to be eligible to receive a gainsharing payment, or to be required to make an alignment payment, an EPM collaborator other than a PGP or an ACO must have directly furnished a billable item or service to an EPM beneficiary during an EPM episode that occurred in the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. For purposes of this requirement, we consider a hospital, CAH or post-acute care provider to have ''directly furnished'' a billable service if one of these entities billed for an item or service for an EPM beneficiary during an EPM episode that occurred in the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. The phrase ''performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount'' does not mean the year in which the gainsharing payment was made. These requirements ensure that there is a required relationship between eligibility for a gainsharing payment and the quality of direct care for EPM beneficiaries during EPM episodes for these EPM collaborators. We believe the provision of direct care is essential to the implementation of effective care redesign, and the requirement provides a safeguard against payments to EPM collaborators other than a PGP or an ACO that are unrelated to direct care for EPM beneficiaries during EPM episodes.

We propose to establish similar requirements for PGPs and ACOs that vary because these entities do not themselves directly furnish billable services. To be eligible to receive a gainsharing payment or required to make an alignment payment, a PGP must have billed for an item or service that was rendered by one or more members of the PGP to an EPM beneficiary during an EPM episode that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. To be eligible to receive a gainsharing payment or required to make an alignment payment, an ACO must have had an ACO provider/supplier that directly furnished, or an ACO participant that billed for, an item or service that was rendered to an EPM beneficiary during an EPM episode that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. With respect to ACOs, an ''ACO participant'' and ''ACO provider/supplier'' have the meaning set forth in § 425.20 of regulations. Like the proposal for EPM collaborators that are not PGPs or ACOs, these proposals also require a linkage between the EPM collaborator that is the PGP or ACO and the provision of items and services to EPM beneficiaries during EPM episodes by PGP members or ACO participants or ACO providers/suppliers, respectively.

Moreover, we further propose that because PGPs and ACOs do not directly furnish items and services to beneficiaries, in order to be eligible to receive a gainsharing payment or be required to make an alignment payment, the PGP or ACO must have contributed to EPM activities and been clinically involved in the care of EPM beneficiaries during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation

payment that comprises the gainsharing payment or was assessed a repayment amount. For example, a PGP or ACO might have been clinically involved in the care of EPM beneficiaries by providing care coordination services to EPM beneficiaries during and/or after inpatient admission; engaging with an EPM participant in care redesign strategies, and actually performing a role in implementing such strategies that are designed to improve the quality of care for EPM episodes and reduce EPM episode spending; or in coordination with providers and suppliers (such as members of the PGP, ACO participants, ACO providers/suppliers, the EPM participant, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of EPM beneficiaries.

Because internal cost savings may be shared through gainsharing payments with EPM collaborators, we propose certain requirements for their calculation as a safeguard against fraud and abuse. First, the methodology for accruing, calculating and verifying internal cost savings must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book). Second, because we believe it is necessary that the internal cost savings reflect care redesign under the EPM in order to be eligible to be shared through gainsharing payments, the methodology used to calculate internal cost savings must reflect the actual, internal cost savings achieved by the EPM participant through the documented implementation of EPM activities identified by the EPM participant and must exclude any savings realized by any individual or entity that is not the EPM participant and ''paper'' savings from accounting conventions or past investment in fixed costs. We note that unlike the current CJR model policy where we require that sharing arrangements document the 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 collaborator (80 FR 73431), we do not propose to require in the EPM that the calculation of internal cost savings be tied to the activities of any specific EPM collaborator. Rather, we believe it is appropriate for EPM participants to calculate internal cost savings based on the implementation of EPM activities and then provide gainsharing payments to EPM collaborators that may include internal cost savings, reconciliation payments, or both based on a methodology that meets the requirements described later in this section. We propose this same change to the internal cost savings calculation requirements for the CJR model in section V.J. of this proposed rule.

We propose to limit the total amount of gainsharing payments for a performance year to EPM collaborators that are physicians, nonphysician practitioners, or PGPs. For EPM collaborators that are physicians or nonphysician practitioners, that limit is 50 percent of the Medicare-approved amounts under the PFS for items and services furnished by that physician or nonphysician practitioner to the EPM participant's EPM beneficiaries during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made. For EPM collaborators that are PGPs, that limit is 50 percent of the Medicare-approved amounts under the PFS for items and services billed by the PGP and furnished to the EPM participant's EPM beneficiaries by members of the PGP during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made. These limits are consistent with those in the CJR model (80 FR 73430).

We propose that the amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of EPM activities. The methodology may take into account the amount of such EPM activities provided by an EPM collaborator relative to other EPM collaborators. While we emphasize that financial arrangements may not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent so that their sole purpose is to align the financial incentives of the EPM participant and EPM collaborators toward the EPM goals of improved EPM episode care quality and efficiency, we believe that accounting for the relative amount of EPM activities by EPM collaborators in the determination of gainsharing payments does not undermine this objective. Rather, the proposed requirement allows flexibility in the determination of gainsharing payments where the amount of an EPM collaborator's provision of EPM activities (including direct care) to EPM beneficiaries during EPM episodes may contribute to both the internal cost savings and EPM participant's reconciliation payment that may be available for making a gainsharing payment. Greater contributions of EPM activities by one EPM collaborator versus another EPM collaborator that result in greater differences in the funds available for gainsharing payments may be appropriately valued in the methodology used to make gainsharing payments to those EPM collaborators in order to reflect these differences in EPM activities among EPM collaborators. For example, a physician who is an EPM collaborator who treats 100 EPM beneficiaries during EPM episodes that result in high quality, less costly care could receive a larger gainsharing payment than a physician who is an EPM collaborator who treats 10 EPM beneficiaries during episodes that similarly result in high quality, less costly care.

However, we do not believe it would be appropriate to allow the selection of EPM collaborators or the opportunity to make or receive a gainsharing payment or an alignment payment to take into the account the amount of EPM activities provided by a potential or actual EPM collaborator relative to other potential or actual EPM collaborators because these financial relationships are not to be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent. Specifically, with respect to the selection of EPM collaborators or the opportunity to make or receive a gainsharing payment or an alignment payment, we do not believe that the amount of EPM activities provided by a potential or actual EPM collaborator relative to other potential or actual EPM collaborators could be taken into consideration by the EPM participant without a significant risk that the financial arrangement in those instances could be based directly or indirectly on the volume or value of past or anticipated referrals or business

generated by, between or among the parties. Similarly, if the methodology for determining alignment payments was allowed to take into the account the amount of EPM activities provided by an EPM collaborator relative to other EPM collaborators there would be a significant risk that the financial arrangement could directly account for the volume or value of past or anticipated referrals or business generated by, between or among the parties and, therefore, we propose that the methodology for determining alignment payments may not directly take into account the volume or value of past or anticipated referrals or business generated by, between or among the parties.

We propose a change to this same standard for gainsharing payments under the CJR model as discussed in section V.J. of this proposed rule. We seek comment on this proposal for gainsharing payments, where the methodology could take into account the amount of EPM activities provided by an EPM collaborator relative to other EPM collaborators. We are particularly interested in comments about whether this standard would provide sufficient additional flexibility in the gainsharing payment methodology to allow the financial reward of EPM collaborators commensurate with their level of effort that achieves improvements in EPM episode quality and efficiency. In addition we are interested in comment on whether additional safeguards or a different standard is needed to allow for greater flexibility to provide certain performance-based payments consistent with the goals of program integrity, protecting against abuse and ensuring the goals of the EPM are met.

We propose that for a performance year, the aggregate amount of all gainsharing payments that are derived from a reconciliation payment must not exceed the amount of the reconciliation payment the EPM participant receives from CMS. In accordance with the prior discussion, no entity or individual, whether a party to a sharing arrangement 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 past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent. We propose that an EPM participant must not make a gainsharing payment to an EPM 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 EPM episodes or other integrity problems. Finally, the sharing arrangement must require the EPM participant to recoup any gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation report or was based on the submission of false or fraudulent data. These requirements provide program integrity safeguards for gainsharing under sharing arrangements.

With respect to alignment payments, we propose that alignment payments from an EPM collaborator to an EPM participant may be made at any interval that is agreed upon by both parties. They must not be issued, distributed, or paid prior to the calculation by CMS of a repayment amount reflected in a reconciliation report; loans, advance payments, or payments for referrals or other business; or assessed by an EPM participant if it does not owe a repayment amount. The EPM participant must not receive any amounts under a sharing arrangement from an EPM collaborator that are not alignment payments.

We also propose certain limitations on alignment payments that are consistent with the CJR model (80 FR 73430). For a performance year, the aggregate amount of all alignment payments received by the EPM participant must not exceed 50 percent of the EPM participant's repayment amount. Given that the EPM participant would be responsible for developing and coordinating care redesign strategies in response to its EPM participation, we believe it is important that the participant retain a significant portion of its responsibility for repayment to CMS. For example, upon receipt of a reconciliation report indicating that the EPM participant owes $100 to CMS, the EPM participant would be permitted to receive no more than $50 in alignment payments, in the aggregate, from its EPM collaborators. In addition, the aggregate amount of all alignment payments from an EPM collaborator to the EPM participant may not be greater than 25 percent of the EPM participant's repayment amount for an EPM collaborator that is not an ACO and 50 percent of the EPM participant's repayment amount for an EPM collaborator that is an ACO. We propose to allow a higher percentage of the EPM participant's repayment amount to be paid by an ACO than by EPM collaborators that are not ACOs in recognition that some ACOs are sizable organizations with significant financial and other resources. In addition, their expertise in managing the cost and quality of care for Medicare beneficiaries over a period of time may make some ACOs uniquely capable of sharing a higher percentage of downside risk under the EPM with the EPM participant under a sharing arrangement between the ACO and EPM participant that meets all requirements for such arrangements, including that participation in the sharing arrangement must be voluntary and without penalty for nonparticipation as discussed previously. We seek comment on our proposed aggregate and individual EPM collaborator limitations on alignment payments, and particularly on the proposed limitation that would apply to ACOs that are EPM collaborators.

The following examples illustrate the effects of the proposed limitations on alignment payments. In one scenario, upon receipt of a reconciliation report indicating that the EPM participant owes $100 to CMS, the EPM participant would be permitted to receive no more than $25 in an alignment payment from a single entity or individual that is one of the EPM participant's EPM collaborators that is not an ACO. In the second scenario where an ACO is an EPM collaborator, upon receipt of that same reconciliation report, the EPM participant would be permitted to receive no more than $50 in an alignment payment from the ACO. Finally, in accordance with the prior discussion, the methodology for determining alignment payments must not directly account for the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent.

We propose that all gainsharing payments and any alignment payments must be administered by the EPM participant in accordance with GAAP and Government Auditing Standards (The Yellow Book). Additionally, we propose that all gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction. While the CJR model required gainsharing payments and alignment payments to be made by electronic funds transfer (EFT) (80 FR 73431), we propose a different requirement for the EPM to provide additional flexibility for entities making gainsharing payments and alignment payments. We make this

proposal to mitigate the administrative burden that the EFT requirement would place on the financial arrangements between certain EPM participants and EPM collaborators, especially individual physicians and nonphysician practitioners and small PGPs, which could discourage participation of those suppliers as EPM collaborators. We propose a change to this same standard under the CJR model as discussed in section V.J. of this proposed rule. We seek comment on the effect of this proposal on reducing the administrative barriers to individual physician and nonphysician practitioner and small PGP participation in the EPM as EPM collaborators.

The proposals for the conditions and restrictions on gainsharing payments, alignment payments, and internal cost savings under the EPM are included in § 512.500(c). We seek comment about all of the conditions and restrictions set out in the preceding discussion, including the feasibility of implementing the proposed safeguards in the context of the current regulatory framework applicable to ACOs and whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the EPM are met.

d. Documentation Requirements

To ensure the integrity of the sharing arrangements, we propose that EPM participants must meet a variety of documentation requirements for these arrangements. Specifically, the EPM participant must—

- Document the sharing arrangement contemporaneously with the establishment of the arrangement;
- Maintain accurate current and historical lists of all EPM collaborators, including EPM collaborator names and addresses; update such lists on at least a quarterly basis; and publicly report the current and historical lists of EPM collaborators on a Web page on the EPM participant's Web site; and
- Maintain and require each EPM collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum the—

++ Nature of the payment (gainsharing payment or alignment payment);

++ Identity of the parties making and receiving the payment;

++ Date of the payment;

++ Amount of the payment;

++ Date and amount of any recoupment of all or a portion of an EPM collaborator's gainsharing payment; and

++ Explanation for each recoupment, such as whether the EPM collaborator received a gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation report, or was based on the submission of false or fraudulent data.

In addition, we propose that the EPM participant must keep records for all of the following:

- Its process for determining and verifying its potential and current EPM collaborators' eligibility to participate in Medicare.
- Its 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; and
- Its plan to track gainsharing payments and alignment payments.

Finally, we propose that the EPM participant must retain and provide access to, and must require each EPM collaborator to retain and provide access to, the required documentation in accordance with § 512.110.

The proposals for the requirements for documentation of sharing arrangements under the EPM are included in § 512.500(c). We seek comment 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 EPM are met.

5. Distribution Arrangements Under the EPM

a. General

Similar to the CJR model, we propose that certain financial arrangements between EPM collaborators and other individuals or entities called ''collaboration agents'' be termed ''distribution arrangements.'' A distribution arrangement is a financial arrangement between an EPM collaborator that is an ACO or PGP and a collaboration agent for the sole purpose of sharing a gainsharing payment received by the ACO or PGP. A collaboration agent is an individual or entity that is not an EPM collaborator and that is either a PGP member that has entered into a distribution arrangement with the same PGP in which he or she is an owner or employee or an ACO participant or ACO provider/supplier that has entered into a distribution arrangement with the same ACO in which it is participating. Where a payment from an EPM collaborator to a collaboration agent is made pursuant to an EPM distribution arrangement, we define that payment as a ''distribution payment.'' A collaboration agent may only make a distribution payment in accordance with a distribution arrangement which complies with the provisions of § 512.505 and all other applicable laws and regulations, including the fraud and abuse laws.

The proposals for the general provisions for distribution arrangements under the EPM are included in § 512.505(a). We seek comment about all of the provisions 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 EPM are met.

b. Requirements

We propose a number of specific requirements for distribution arrangements as a program integrity safeguard to help ensure that their sole purpose is to create financial alignment between EPM collaborators and collaboration agents toward the goals of the EPM to improve the quality and efficiency of EPM episodes. These requirements largely parallel those proposed in § 512.500(b) and (c) for sharing arrangements and gainsharing payments based on similar reasoning for these two types of arrangements and payments. We propose that all distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to EPM beneficiaries under the distribution arrangement. Furthermore, we propose that participation must be voluntary and without penalty for nonparticipation, and the distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

Like our proposal for gainsharing payments, we propose that the opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent. We propose more flexible standards for the determination

of the amount of distribution payments from ACOs and PGPs for the same reasons we propose this standard for the determination of gainsharing payments. Specifically, for ACOs we propose that the amount of any distribution payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of EPM activities and that may take into account the amount of such EPM activities provided by a collaboration agent relative to other collaboration agents. We believe that the amount of a collaboration agent's provision of EPM activities (including direct care) to EPM beneficiaries during EPM episodes may contribute to the EPM participant's internal cost savings and reconciliation payment that may be available for making a gainsharing payment to the EPM collaborator with which the collaboration agent has a distribution arrangement. Greater contributions of EPM activities by one collaboration agent versus another collaboration agent that result in different contributions to the gainsharing payment made to the EPM collaborator with which those collaboration agents both have a distribution arrangement may be appropriately valued in the methodology used to make distribution payments to those collaboration agents. Accordingly, we believe this is the appropriate standard for determining the amount of distribution payments from an ACO to its collaboration agents.

We note that for distribution payments made by a PGP to PGP members, the requirement that the amount of any distribution payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of EPM activities may be more limiting in how a PGP pays its members than is allowed under existing law. Therefore, to retain existing flexibility for distribution payments by a PGP to PGP members, we propose that the amount of the distribution payment from a PGP to PGP members must be determined either using the methodology previously described for distribution payments from an ACO or in a manner that complies with § 411.352(g). We note that the proposed option to allow the amount of the distribution payment from a PGP to a PGP member to be determined in a manner that complies with § 411.352(g) is not currently permitted under the CJR model, although we propose this change for the CJR model in section V.J. of this proposed rule. This proposal would allow a PGP the choice either to comply with the general standard that the amount of a distribution payment must be substantially based on quality of care and the provision of EPM activities or to provide its members a financial benefit through the EPM without consideration of the PGP member's individual quality of care. In the latter case, PGP members who are not collaboration agents (including those who furnished no services to EPM beneficiaries) would be able receive a share of the profits from their PGP that includes the monies contained in a gainsharing payment. We believe this is an appropriate exception to the general standard for determining the amount of distribution payment under the EPM from a PGP to a PGP member because CMS has determined under the physician self-referral law that payments from a group practice as defined under § 411.352 to its members that comply with § 411.352(g) are appropriate.

We seek comment on this proposal and specifically whether there are additional safeguards or a different standard is needed to allow for greater flexibility in calculating the amount of distribution payments that would avoid program integrity risks and whether additional or different safeguards are reasonable, necessary, or appropriate for the amount of distribution payments from a PGP to its members.

Similar to our proposed requirements for sharing arrangements for those EPM collaborators that furnish or bill for items and services, except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g), we propose that a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to an EPM beneficiary during an EPM episode that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed. We note that all individuals and entities that fall within our proposed definition of collaboration agent may either directly furnish or bill for items and services rendered to EPM beneficiaries. This proposal ensures that, absent the alternative safeguards afforded by a PGP's distribution payments in compliance with § 411.352(g), there is the same required relationship between direct care for EPM beneficiaries during EPM episodes and distribution payment eligibility that we require for gainsharing payment eligibility. We believe this requirement provides a safeguard against payments to collaboration agents that are unrelated to direct care for EPM beneficiaries during EPM episodes when the amount of the distribution payment is not determined in a manner that complies with § 411.352(g).

Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g), we propose the same limitations on the total amount of distribution payments to physicians, nonphysician practitioners, and PGPs as we propose for gainsharing payments. In the case of a collaboration agent that is physician or nonphysician practitioner, we propose to limit the total amount of distribution payments paid for a performance year to the collaboration agent to 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the collaboration agent to the EPM participant's EPM beneficiaries during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed. In the case of a collaboration agent that is a PGP, we propose that the limit would be 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by the PGP for items and services furnished by members of the PGP to the EPM participant's EPM beneficiaries during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed. We believe that, absent the alternative safeguards afforded by a PGP's distribution payments in compliance with § 411.352(g), these proposed limitations on distribution payments, which are the same as those for gainsharing payments to physicians, nonphysician practitioners, and PGPs, are necessary to eliminate any financial incentives for these individuals or entities to engage in a financial arrangement as an EPM collaborator versus as a collaboration agent. Furthermore, we believe that PGPs should be able to choose whether to engage in financial arrangements directly with EPM participants as EPM collaborators or in distribution arrangements with the ACO in which they are an ACO participant if that ACO plays a role in EPM care redesign as an EPM collaborator, without having a different limit on their maximum financial gain from one arrangement versus another.

We further propose that with respect to the distribution of any gainsharing payment received by a PGP or ACO, the total amount of all distribution payments must not exceed the amount of the gainsharing payment received by the EPM collaborator from the EPM participant. Like gainsharing and alignment payments, we propose that all distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction. The collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments. Finally, the distribution arrangement must not induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary or reward the provision of items and services that are medically unnecessary.

We propose that the EPM collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.110, including:

- The relevant written agreements;
- The date and amount of any distribution payment(s);
- The identity of each collaboration agent that received a distribution payment; and
- A description of the methodology and accounting formula for determining the amount of any distribution payment.

We propose that the EPM collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same EPM participant. This proposal ensures that the proposed separate limitations on the total amount of gainsharing payment and distribution payment to PGPs, physicians, and nonphysician practitioners that are substantially based on quality of care and the provision of EPM activities are not exceeded in absolute dollars by a PGP, physician, or nonphysician practitioner's participation in both a sharing arrangement and distribution arrangement for the care of the same EPM beneficiaries during EPM episodes. Allowing both types of arrangements for the same individual or entity for care of the same EPM beneficiaries during EPM episodes could also allow for duplicate counting of the individual or entity's same quality of care and provision of EPM activities in the methodologies for both gainsharing and distribution payments, leading to financial gain that is disproportionate to the quality of care and provision of EPM activities by that individual or entity. Finally, we propose that the EPM collaborator must retain and provide access to, and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 512.110.

The proposals for requirements for distribution arrangements under the EPM are included in § 512.505(b). We seek comment 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 EPM are met. In addition, we seek comment on how the regulation of the financial arrangements under this proposal may interact with how these or similar financial arrangements are regulated under the Medicare Shared Savings Program.

6. Downstream Distribution Arrangements Under the EPM

a. General

We propose that the EPM allow for certain financial arrangements within an ACO between a PGP and its members. Specifically, we propose that certain financial arrangements between a collaboration agent that is both a PGP and an ACO participant and other individuals termed ''downstream collaboration agents'' be termed a ''downstream distribution arrangement.'' A downstream distribution arrangement is a financial arrangement between a collaboration agent that is both a PGP and an ACO participant and a downstream collaboration agent for the sole purpose of sharing a distribution payment received by the PGP. A downstream collaboration agent is an individual who is not an EPM collaborator or a collaboration agent and who is a PGP member that has entered into a downstream distribution arrangement with the same PGP in which he or she is an owner or employee, and where the PGP is a collaboration agent. Where a payment from a collaboration agent to a downstream collaboration agent is made pursuant to a downstream distribution arrangement, we define that payment as a ''downstream distribution payment.'' A collaboration agent may only make a downstream distribution payment in accordance with a downstream distribution arrangement which complies with the requirements of this section and all other applicable laws and regulations, including the fraud and abuse laws.

The proposals for the general provisions for downstream distribution arrangements under the EPM are included in § 512.510(a). We seek comment about all of the provisions 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 EPM are met.

b. Requirements

We propose a number of specific requirements for downstream distribution arrangements as a program integrity safeguard to help ensure that their sole purpose is to create financial alignment between collaboration agents that are PGPs which are also ACO participants and downstream collaboration agents toward the goals of the EPM to improve the quality and efficiency of EPM episodes. These requirements largely parallel those proposed in § 512.500(b) and (c) and § 512.505(b) for sharing and distribution arrangements and gainsharing and distribution payments based on similar reasoning for these three types of arrangements and payments. We propose that all downstream distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and entered into before care is furnished to EPM beneficiaries under the downstream distribution arrangement. Furthermore, we propose that participation must be voluntary and without penalty for nonparticipation, and the downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

Like our proposals for gainsharing and distribution payments, we propose that the opportunity to make or receive a downstream distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent. We propose the more flexible standard for the determination of the amount of downstream distribution payments for the same reasons we propose this standard for the determination of distribution payments by a PGP to PGP members. Specifically, the amount of any downstream distribution payments must be determined either in a manner that complies with § 411.352(g) or in accordance with a methodology that is substantially based on quality of care and the provision of EPM activities and

that may take into account the amount of such EPM activities provided by a downstream collaboration agent relative to other downstream collaboration agents. We believe that the amount of a downstream collaboration agent's provision of EPM activities (including direct care) to EPM beneficiaries during EPM episodes may contribute to the EPM participant's internal cost savings and reconciliation payment that may be available for making a gainsharing payment to the EPM collaborator that is then shared through a distribution payment to the collaboration agent with which the downstream collaboration agent has a downstream distribution arrangement. Greater contributions of EPM activities by one downstream collaboration agent versus another downstream collaboration agent that result in different contributions to the distribution payment made to the collaboration agent with which the downstream collaboration agents both have a downstream distribution arrangement may be appropriately valued in the methodology used to make downstream distribution payments to those downstream collaboration agents. Just as we propose an alternative to a methodology that is substantially based on quality of care and the provision of EPM activities for determining the amount of a distribution payment from a PGP to a PGP member, we similarly propose an alternative that the amount of a downstream distribution payment from a PGP to a PGP member may be determined in a manner that complies with § 411.352(g)

Similar to our proposed requirements for distribution arrangements for those EPM collaborators that are PGPs, we propose that, except for a downstream distribution arrangement that complies with § 411.352(g), a downstream collaboration agent is eligible to receive a downstream distribution payment only if the PGP billed for an item or service furnished by the downstream collaboration agent to an EPM beneficiary during an EPM episode that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprise the gainsharing payment from which the ACO made the distribution payment to the PGP that is an ACO participant. This proposal ensures that, absent the alternative safeguards afforded by a PGP's downstream distribution payments in compliance with § 411.352(g), there is the same required relationship between direct care for EPM beneficiaries during EPM episodes and downstream distribution payment eligibility that we require for gainsharing and distribution payment eligibility. We believe this requirement provides a safeguard against payments to downstream collaboration agents that are unrelated to direct care for EPM beneficiaries during EPM episodes when the amount of the downstream distribution payment is not determined in a manner that complies with § 411.352(g).

We propose the same limitations on downstream distribution payments to downstream collaboration agents as we propose for distribution payments by EPM collaborators that are PGPs. We propose that, absent the alternative safeguards afforded by compliance with § 411.352(g), the total amount of downstream distribution payments paid for a performance year to the downstream collaboration agent would be limited to 50 percent of the total Medicare-approved amounts under the PFS for services billed by the PGP and furnished by the downstream collaboration agent to the EPM participant's EPM beneficiaries during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment from which the ACO made the distribution payment to the PGP. We believe that, absent the alternative safeguards afforded by a PGP's downstream distribution payments in compliance with § 411.352(g), this proposed limitation on downstream distribution payments that is the same as those for distribution payments to physicians and nonphysician practitioners is necessary to eliminate any financial incentives for a PGP member to engage in a specific financial arrangement as a collaboration agent versus a downstream collaboration payment.

We further propose that the total amount of all downstream distribution payments made to downstream collaboration agents must not exceed the amount of the distribution payment received by the collaboration agent (that is, the PGP that is an ACO participant) from the ACO that is an EPM collaborator. Like gainsharing, alignment, and distribution payments, we propose that all downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction. The downstream collaboration agent must retain the 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 downstream collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary or reward the provision of items and services that are medically unnecessary.

We propose that the PGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 512.110, including all of the following:

- The relevant written agreements.
- The date and amount of any downstream distribution payment(s).
- The identity of each downstream collaboration agent that received a downstream distribution payment.
- A description of the methodology and accounting formula for determining the amount of any downstream distribution payment.

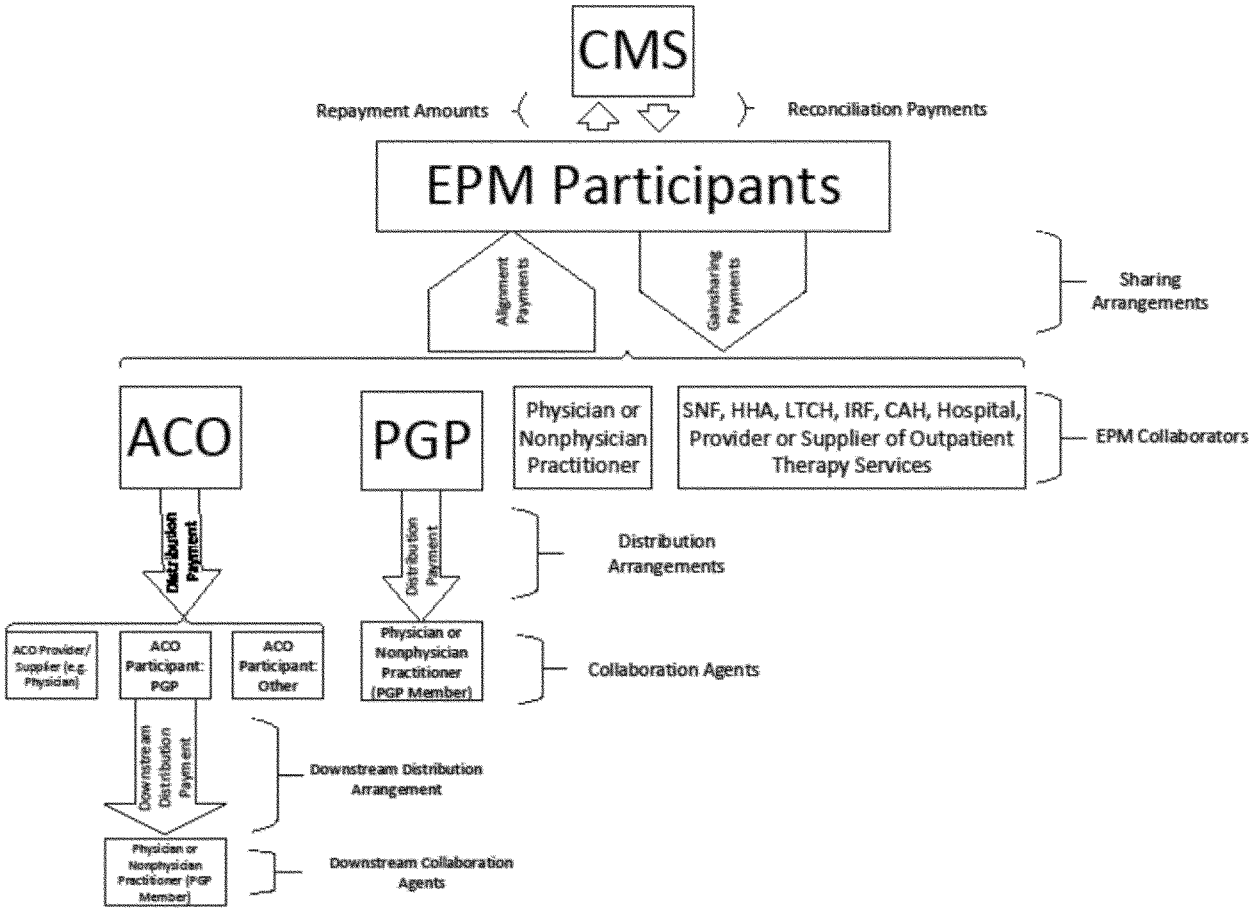
We propose that the PGP may not enter into a downstream distribution arrangement with any PGP member who has a sharing arrangement with an EPM participant or distribution arrangement with the ACO the PGP is a participant in. This proposal ensures that the proposed separate limitations on the total amount of gainsharing payment, distribution payment, and downstream distribution payment to PGP members that are substantially based on quality of care and the provision of EPM activities are not exceeded in absolute dollars by a PGP member's participation in more than one type of arrangement for the care of the same EPM beneficiaries during EPM episodes. Allowing more than one arrangement for the same PGP member for the care of the same EPM beneficiaries during EPM episodes could also allow for duplicate counting of the PGP member's same quality of care and provision of EPM activities in the methodologies for the different payments. Finally, we propose that the PGP must retain and provide access to, and must require downstream collaboration agents to retain and provide access to, the required documentation in accordance with § 512.110.

The proposals for requirements for downstream distribution arrangements under the EPM are included in § 512.510(b). We seek comment 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 EPM are met.

7. Summary of Proposals for Sharing, Distribution, and Downstream Distribution Arrangements Under the EPM

Figure 2 summarizes the proposals for the defined terms and financial arrangements discussed in sections III.I.4. through 6. of this proposed rule.

Figure 2: PROPOSED EPM FINANCIAL ARRANGEMENTS



8. Enforcement Authority

OIG authority is not limited or restricted by the provisions of the EPM, including the authority to audit, evaluate, investigate, or inspect the EPM participant, EPM collaborators, collaboration agents, or any other person or entity or their records, data, or information, without limitations. Additionally, no EPM provisions limit or restrict the authority of any other Government Agency to do the same.

The proposals for enforcement authority under the EPM are included in § 512.520. We seek comment 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 EPM are met.

9. Beneficiary Engagement Incentives Under the EPM

a. General

Similar to our reasoning for the CJR model (80 FR 73433 through 73437), we believe that the EPM would incentivize EPM participants to furnish directly and otherwise coordinate items and services throughout the EPM episodes that lead to higher quality care for EPM beneficiaries and lower EPM episode spending. We believe that one mechanism that may be useful to EPM participants in achieving these goals is the provision of certain items and services as in-kind patient engagement incentives to the EPM beneficiary during the EPM episode. Under such an approach, the costs of the patient engagement incentives would be borne by the EPM participant. However, we believe that certain conditions on these incentives are necessary to ensure that their provision is solely for the purpose of achieving the EPM goals of improving episode quality and efficiency.

We propose that the incentive must be provided directly by the EPM

participant or by an agent of the EPM participant under the EPM participant's direction and control to the EPM beneficiary during an EPM episode. We considered whether this policy on beneficiary incentives should extend to providers and suppliers other than the EPM participant that furnish services during the EPM episode, or to other entities altogether, such as ACOs that are EPM collaborators. However, as discussed in section III.B.3. of this proposed rule, given our belief that the EPM participant is best positioned to coordinate the care of beneficiaries in the EPM, we believe that EPM participants are also better suited than other individuals and entities to provide beneficiary incentives.

We propose that the item or service provided as an incentive must be reasonably connected to medical care provided to an EPM beneficiary during an EPM episode. For example, EPM participants could provide incentives such as post-surgical or cardiac monitoring equipment to track patient weight and vital signs for post-surgical or post-AMI patients discharged directly to home, but could not provide theater tickets, which would bear no reasonable connection to the patient's medical care. Similarly, EPM participants might provide cardiac or 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-hospital discharge care, such as a smartphone. 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 inappropriately induce beneficiaries to receive other medical care that is not included in the episode. We also propose that the incentive must be a preventive care item or service or an item or service that advances a clinical goal, as described later in this section, for a beneficiary in an EPM episode by engaging the beneficiary in better managing his or her own health.

We further propose that the item or service provided as an incentive must not be tied to the receipt of items or services outside the EPM episode and that the item or service must not be tied to the receipt of items or services from a particular provider or supplier. These provisions provide safeguards against the provision of in-kind patient engagement incentives to steer beneficiaries toward certain providers or suppliers for care.

We propose that the availability of the items or services provided as incentives 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. This condition provides a safeguard against the advertisement of in-kind patient engagement incentives to certain beneficiaries that could increase an EPM participant's number of EPM episodes and shift the patient severity for an EPM participant compared to historical EPM episodes by encouraging more beneficiaries with less severe clinical conditions in the EPM to seek care at the EPM participant. Such changes could produce financial gain for the EPM participant that is not related to improvements in EPM quality and efficiency by resulting in the EPM participant's quality-adjusted target prices for EPM episodes being higher than would be appropriate based on the lower average patient severity during the EPM performance years. We do not intend for any of the financial arrangements proposed for the EPM, including beneficiary incentives, to alter an EPM participant's market share of care for a clinical condition in the EPM, nor do we intend for these arrangements to shift the patient severity for an EPM participant or cause access problems for Medicare beneficiaries. Finally, we propose that 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.

Our proposals for the general provisions for beneficiary incentives are included in § 512.525(a). We seek comment on our proposed general provisions for beneficiary incentives and welcome comment on additional or alternative program integrity safeguards.

b. Technology Provided to an EPM Beneficiary

In some cases, items or services involving technology may be useful as beneficiary engagement incentives that can advance a clinical goal of the EPM by engaging a beneficiary in managing his or health during the 90 days following discharge from the anchor or chained anchor hospitalization. However, we believe specific enhanced safeguards are necessary for these items and services to prevent abuse, and our proposals are consistent with the CJR model policies (80 FR 73437). Specifically, we propose that items or services involving technology provided to a beneficiary may not exceed $1,000 in retail value for any one beneficiary in any one EPM episode, and that items or services involving technology provided to a beneficiary must be the minimum necessary to advance a clinical goal as discussed in this section for a beneficiary in an EPM episode.

We propose additional enhanced requirements for items of technology exceeding $100 in retail value as an additional safeguard against misuse of these items as beneficiary engagement incentives. Specifically, we propose that these items of technology remain the property of the EPM participant and be retrieved from the beneficiary at the end of the EPM episode. The EPM participant must document all retrieval attempts, including the ultimate date of retrieval. However, because we understand that EPM participants may not always be able to retrieve these items after the EPM episode ends, such as when a beneficiary dies or moves to another geographic area, documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

Our proposals for enhanced requirements for technology provided to EPM beneficiaries as beneficiary engagement incentives under the EPM are included in § 512.525(b). We seek comment on our proposed requirements for beneficiary engagement incentives that involve technology and welcome comment on additional or alternative program integrity safeguards for this type of beneficiary engagement incentive, including whether the financial thresholds proposed in this section are reasonable, necessary, and appropriate.

c. Clinical Goals of the EPM

As discussed in section III.C.3. of this proposed rule, the proposed EPMs are broadly defined to include most Part A and Part B items and services furnished during EPM episodes that extend 90 days following discharge from the anchor or chained anchor hospitalization that begins the episode, excluding only those Part A and Part B services that are unrelated to the EPM episode based on hospital readmissions or diagnoses for which care is unrelated to the EPM episode diagnosis and procedures based on clinical rationale. Therefore, we believe that in-kind patient engagement incentives may appropriately be provided for managing acute conditions arising from EPM episodes, as well as chronic conditions if the condition is likely to have been affected by care during the EPM episode or when substantial services are likely to be provided for the chronic condition during the EPM episode.

We propose that the following are the clinical goals of the EPM, which may be advanced through beneficiary incentives:

- Beneficiary adherence to drug regimens.
- Beneficiary adherence to a care plan.
- Reduction of readmissions and complications resulting from treatment for the EPM clinical condition.
- Management of chronic diseases and conditions that may be affected by treatment for the EPM clinical condition.

Our proposals for the clinical goals of the EPM that a beneficiary engagement incentive that is not a preventive care item or service must be intended to advance are included in § 512.525(c). We seek comment on our proposed clinical goals of the EPM, as well as whether the advancement of additional or different clinical goals through beneficiary engagement incentives may better advance the overarching goals of the EPM while maintaining appropriate program integrity safeguards.

d. Documentation of Beneficiary Engagement Incentives

As a program safeguard against misuse of beneficiary engagement incentives under the EPM, we propose that EPM participants must maintain documentation of items and services furnished as beneficiary engagement incentives that exceed $25 in retail value. In addition, we propose to require that the documentation established contemporaneously with the provision of the items and services must include at least the following:

- The date the incentive is provided.
- The identity of the beneficiary to whom the item or service was provided.

We further propose that the documentation regarding items of technology exceeding $100 in retail that are required to be retrieved from the beneficiary at the end of an EPM episode must also include contemporaneous documentation of any attempt to retrieve technology. We reiterate that documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement. Finally, we propose that the EPM participant must retain and provide access to the required documentation in accordance with § 512.110.

Our proposals for the documentation requirements for beneficiary engagement incentives under the EPM are included in § 512.525(c). We seek comment on our proposed documentation requirements, including whether additional or different documentation requirements may provide better program integrity safeguards.

10. Compliance With Fraud and Abuse Laws

Certain arrangements between and among EPM participants and third parties or beneficiaries may implicate civil monetary penalty (CMP) law (subsections 1128A(a)(5), (b)(1), and (b)(2) of the Act), the Federal Anti-kickback statute (subsections 1128B(b)(1) and (2) of the Act), or the physician self-referral law (section 1877 of the Act). In many cases, arrangements that implicate these laws can be structured to comply with them by using existing safe harbors and exceptions. Section 1115A(d)(1) of the Act authorizes the Secretary to waive certain specified fraud and abuse laws as may be necessary solely for purposes of testing of payment models under section 1115A(b) of the Act. A waiver is not needed for an arrangement that does not implicate the fraud and abuse laws or that implicates the fraud and abuse laws but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law. Accordingly, pursuant to section 1115A(d)(1) of the Act, the Secretary will consider whether waivers of certain fraud and abuse laws are necessary to test the EPM as such models develop. Such waivers, if any, would be promulgated separately from this proposed regulation by OIG (as to sections 1128A and 1128B of the Act) and CMS (as to section 1877 of the Act), to which the respective authorities have been delegated.

Requirements for the EPM will bear on the need for and scope of any fraud and abuse waivers that might be granted for the EPM. Because of the close nexus between the regulations governing the structure and operations of the EPM and the development of any fraud and abuse waivers necessary to carry out the provisions of the EPM, CMS and OIG may, when considering the need for or scope of any waivers, consider comments submitted in response to this proposed rule and provisions of the EPM's final rule.

J. Proposed Waivers of Medicare Program Requirements

1. Overview

Under the CJR model, we stated that it may be necessary and appropriate to provide additional flexibilities to hospitals participating in the CJR model, as well as other providers that furnish services to beneficiaries in CJR episodes. The purpose of such flexibilities is to increase CJR-episode quality and decrease episode spending or internal costs or both of providers and suppliers that results in better, more coordinated care for beneficiaries and improved financial efficiencies for Medicare, providers, and beneficiaries. These additional flexibilities were implemented through our waiver authority under section 1115A of the Act, which affords broad authority for the Secretary to waive statutory Medicare program requirements as necessary to carry out the provisions of section 1115A.

In proposing to test the EPMs described in this proposed rule, we continue to believe that certain program waivers, similar to those adopted under the CJR model, will offer providers and suppliers more flexibility so that they may increase coordination of care and management of beneficiaries in EPM episodes. However, before adopting the same waivers as we adopted in the CJR model for the proposed EPMs, we believe further examination is necessary to determine if doing so increases financial vulnerability for the Medicare program or creates inappropriate clinical incentives that may reduce the quality of beneficiary care.

Based on our analysis of data available from current models being tested and other available clinical data, specific program requirements for which we propose waivers under the AMI, CABG, and SHFFT models and for which we invite comments are included in the sections that follow. In addition, for providers or suppliers of cardiac rehabilitation and intensive cardiac rehabilitation services furnished to EPM beneficiaries during an AMI and CABG episode, we are proposing to waive the physician definition to allow a qualified nonphysician practitioner to perform specific physician functions.

We propose that these waivers of program requirements would apply to the care of beneficiaries who are in the proposed AMI, CABG, or SHFFT episodes at the time when such waivers would be used to bill for services furnished to the beneficiary, even if the episode is later cancelled as described in section III.C.4.b. of this proposed rule. Thus, it may have been appropriate for the hospital to have used a waiver if there was a reasonable expectation that the beneficiary was in the model at the time the waiver was used. However, if a service is found to have been billed and paid by Medicare under circumstances allowed only by a program requirement waiver for a beneficiary not in the proposed AMI, CABG, or SHFFT models at the time the service 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.

We also generally seek comment on any additional Medicare program requirements that may be necessary to waive using our authority under section 1115A of the Act in order to effectively test the proposed EPMs that we could consider in the context of our early model implementation experience to inform any future proposals we may make. While we cannot finalize program requirement waivers that we have not specifically proposed, we will continually monitor the use of program waivers in each EPM to ensure that the appropriate outcomes in provider/supplier financial incentives and patient care are achieved.

2. Summary of Waivers Adopted Under the CJR Model

As part of the CJR model implemented in 2016, we issued regulatory waivers of the following Medicare program requirements:

- Section 510.600 of the regulations waives the direct supervision requirement to allow clinical staff to furnish certain post-discharge home visits under the general, rather than direct, supervision of a physician or nonphysician practitioners. This waiver allows a CJR beneficiary who does not qualify for home health benefits to receive up to 9 post-discharge visits in his or her home or place of residence any time during the episode. All other Medicare rules for coverage and payment of services incident to a physician's service continue to apply.
- Section 510.615 waives current Medicare billing rules to allow the separate billing of these post-discharge home visits for CJR beneficiaries during a 90-day post-operative global surgical period. All other Medicare rules for global-surgery billing during the 90-day post-operative period continue to apply.
- Section 510.605 of the regulations allows a Medicare-approved telehealth service to be furnished to a CJR beneficiary regardless of the beneficiary's geographic location, and in his or her home or place of residence. CMS also waives certain telehealth payment provisions. Specifically, Medicare will not pay the originating site facility fee if the service originates in the beneficiary's home or place or residence, and the telehealth home visits will be paid using unique HCPCS codes with payment based on comparable office visits, less the practice expense portion of the payment paid for these comparable visits when furnished in-person. All other requirements for Medicare coverage and payment of telehealth services continue to apply.
- Section 510.610 of the regulations waives the 3-day hospital stay requirement before a beneficiary may be discharged from a hospital to a qualified SNF, which CMS define as SNFs that are rated an overall of 3 stars or better on the Nursing Home Compare Web site. This waiver applies to episodes being tested under the CJR model for specific performance years. For example, under CJR, the waiver applies beginning in performance year 2 (as hospitals are not bearing risk in their first year). All other Medicare rules for coverage and payment of Part A-covered SNF services continue to apply.
- Section 510.620 of the regulations waives the deductible and coinsurance statutory requirements to the extent necessary to make reconciliation payments or receive repayments based on the episodic payment methodology under the final payment model for CJR participant hospitals. The reconciliation or repayments do not affect the beneficiary's cost sharing amounts for services furnished under the CJR model.

3. Analysis of Current Model Data

We believe that before we adopt the same regulatory waivers offered under the CJR model, we must determine if doing so would: (1) Be clinically-appropriate; (2) not introduce financial vulnerabilities to the Medicare program; and, more importantly, (3) not decrease desired outcomes of patient care. To make this determination, we analyzed waiver usage data and post-acute care usage from Medicare claims data current being tested in other EPMs. In addition, we analyzed the latest arithmetic and geometric means for the MS–DRGs associated with the proposed AMI, CABG, and SHFFT models published as Table 5 in the IPPS FY 2016 Correction Notice to the Final Rule (CMS–1632–CN; 80 FR 60055). The following summarizes the available data.

a. Analysis of Waiver Usage

Waiver usage data is currently not available from the CJR model, thus we reviewed waiver usage data from the BPCI model. Waivers were offered for all 48 episodes under the BPCI model. However, we note that such waivers were significantly different from those adopted under the CJR model. For example, many BPCI model awardees were concerned about the difficulties in accurately identifying beneficiaries in BPCI episodes, which we believe might have been a disincentive to using the waiver of the SNF 3-day hospital stay. For the CJR model, we attempted to address this by codifying that the SNF stay would be covered if the beneficiary was in the episode at the time that the SNF waiver was utilized. With respect to the home visit, the BPCI model only allows 3 visits in a 90-day period (less if the episode is shorter), and awardees might not consider it worth the effort to incorporate this limited number of visits into their care design for episode beneficiaries. For the CJR model, we increased this allowance to 9 post-discharge visits in a 90-day period to allow for one visit a week for the two thirds of the 90-days post-discharge when the beneficiary was not receiving post-acute care. Finally, in the BPCI model we waived the geographic restrictions for telehealth visits, whereas for the CJR model we allow telehealth visits originating in the home, regardless of geographic location.

Given that the waivers offered under the BPCI model differ from the waivers in the CJR model, and presumably for the waivers that we propose in this proposed rule, the BPCI model data shows—

- The use of the home visit and telehealth waiver is minimal; and
- The waiver of the SNF 3-day rule may be getting the most use.

b. Analysis of Discharge Destination—Post-Acute Care Usage

The following Table 35 shows the discharge destination and post-acute care usage for the cardiac related episodes (CABG, PCI, and AMI) in the BPCI model.

TABLE 35—DISCHARGE DESTINATION FOR BPCI CARDIAC DIAGNOSES *

[Source: Medicare Claims Data]

MS–DRG	MS–DRG Title	Discharge destination (in rounded percentages)			
		Home w/o home health	Home with home health	SNF	Other
CABG					
231	W PTCA W MCC	14	30	43	13
232	W PTCA W/O MCC	28	49	15	8
233	W CARDIAC CATH W MCC	12	34	40	14
234	W CARDIAC CATH W/O MCC	20	46	27	7
235	W/O CARDIAC CATH W MCC	13	34	36	17
236	W/O CARDIAC CATH W/O MCC	23	50	19	8
PCI					
246	W DES W MCC OR 4+ VES/STENTS.	66	18	13	3
247	W DES STENT W/O MCC	89	8	3	0
248	W NON DES W MCC OR 4+ VES/STENTS.	68	17	12	3
249	W NON-DES W/O MCC	85	10	5	0
250	W/O CAS W MCC	63	25	8	4
251	W/O CAS W/O MCC	86	10	4	0
AMI					
280	DISCHARGED ALIVE W MCC	42	22	34	2
281	DISCHARGED ALIVE W CC	57	20	22	1
282	DISCHARGED ALIVE W/O CC/MCC.	71	17	10	2

* ABBREVIATIONS:
PTCA—Percutaneous Transluminal Coronary Angioplasty.
CC—Complications.
MCC—Major Complications.
DES—Drug-Eluting Stent.
CAS—Coronary Artery Stent.
VES—Vessels.

Analysis of the data in Table 35 shows—

- Patients with CABG have high post-acute care usage;
- Patients with PCI have very little post-acute care usage; and
- Patients with AMI have average post-acute care usage compared to patients with PCI and CABG.

Analysis of the CJR model data shows post-acute care usage of about 30 days for MS–DRGs associated with the CJR model.

c. Analysis of Hospital Mean Length of Stay Data

Table 36 shows the geometric and arithmetic mean length of stay (LOS) for MS–DRGs associated with the proposed CABG, AMI (including PCI) and SHFFT models.

TABLE 36—GEOMETRIC AND ARITHMETIC MEAN LENGTH OF STAY FOR BPCI CARDIAC DIAGNOSES AND SHFFT *

[Source: FY 2016 IPPS Correction Notice; Table 5] *

MS–DRG	MS–DRG Title	Geometric mean LOS	Arithmetic mean LOS
CABG			
231	W PTCA W MCC	9.9	11.7
232	W PTCA W/O MCC	7.9	8.6
233	W CARDIAC CATH W MCC	11.6	13.0
234	W CARDIAC CATH W/O MCC	8.0	8.6
235	W/O CARDIAC CATH W MCC	8.9	10.3
236	W/O CARDIAC CATH W/O MCC	6.0	6.5
PCI			
246	W DES W MCC OR 4+ VES/STENTS	4.1	5.5
247	W DES STENT W/O MCC	2.2	2.7
248	W NON DES W MCC OR 4+ VES/STENTS	4.8	6.3
249	W NON-DES W/O MCC	2.5	3.1
250	W/O CAS W MCC	4.2	5.7

TABLE 36—GEOMETRIC AND ARITHMETIC MEAN LENGTH OF STAY FOR BPCI CARDIAC DIAGNOSES AND SHFFT *—Continued

[Source: FY 2016 IPPS Correction Notice; Table 5] *

MS–DRG	MS–DRG Title	Geometric mean LOS	Arithmetic mean LOS
251	W/O CAS W/O MCC	2.4	2.9
	AMI		
280	DISCHARGED ALIVE W MCC	4.5	5.8
281	DISCHARGED ALIVE W CC	2.9	3.6
282	DISCHARGED ALIVE W/O CC/MCC	2.0	2.4
	SHFFT		
480	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT W MCC.	6.7	7.9
481	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT W CC.	4.6	5.0
482	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT W/O CC/MCC.	3.7	4.0

* ABBREVIATIONS:
PTCA—Percutaneous Transluminal Coronary Angioplasty.
CC—Complications.
MCC—Major Complications.
DES—Drug-Eluting Stent.
CAS—Coronary Artery Stent.
VES—Vessels.

Analysis of data in Table 36 shows—

- Patients under all CABG MS–DRGs have a mean LOS of 6 days up to 11–13 days;
- Patients under all PCI MS–DRGs have a mean LOS of about 2 days up to about 6 days;
- Patients under all AMI MS–DRGs have a mean LOS of about 2 days up to about 6 days; and
- Patients under all SHFFT MS–DRGs have a mean LOS of about 4 days up to about 8 days.

Analysis of the CJR model data shows the mean LOS for MS–DRGs associated with the CJR model of about 3 days up to about 7 days.

Based on our analysis of the available data, we believe that minimal program and patient outcome vulnerabilities exist with proposing to adopt the same CJR regulatory waivers to the following program requirements for EPMs:

- The direct supervision requirement for certain post-discharge home visits and the Medicare billing requirement that will allow the separate billing of these post-discharge home visits for EPM beneficiaries during a 90-day post-operative global surgical period.
- The telehealth geographic site requirement and the requirement that will allow in-home telehealth visits.
- The deductible and coinsurance statutory requirements to the extent necessary to make reconciliation payments or receive repayments based on the episodic payment methodology under the final payment model for EPM participants.

Therefore, as discussed in the sections that follow, we will be proposing to adopt waivers for these program requirements for EPMs.

In addition, based on our analysis of the available data, we believe some program and patient outcome vulnerabilities may exist with proposing to adopt the same CJR regulatory waivers for the following program requirements for some EPMs:

- The SNF 3-day rule, for episodes beginning on or after April 1, 2018.
- The number of post-discharge home visits allowed during the model episode.

Therefore, as discussed in the sections that follow, we are proposing to adopt model-specific limits to the number of post-discharge home visits and to offer the waiver of the SNF 3-day rule on a model-specific basis.

4. Post-Discharge Home Visits

As with the LEJR episodes, we expect that the broadly-defined EPM episodes with a duration of 90 days following hospital discharge as we propose in section III.A.1. of this proposed rule will result in EPM participants redesigning care by increasing care coordination and management of beneficiaries following surgeries. We believe that beneficiaries might have substantial mobility limitations during EPM episodes following discharge to their homes or places 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 post-acute care setting will also be important to high-quality episode care. Scientific evidence exists to support the use of home nursing visits among Medicare beneficiaries in improving care coordination following hospital discharge.[102] In addition, we believe the financial incentives in the EPMs will encourage hospitals to closely examine the most appropriate post-acute care settings for beneficiaries so that the clinically-appropriate setting of the lowest acuity is recommended following discharge from the anchor hospitalization. We expect that all these considerations will lead to greater interest on the part of hospitals and other providers and suppliers caring for EPM beneficiaries in furnishing services to beneficiaries in their homes or places of residence. Such services could include visits by licensed clinical staff other than physicians and nonphysician practitioners.

In order for Medicare to pay for home health services, a beneficiary must be determined to be ''homebound.'' 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

[102] Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, Schwartz JS. JAMA. 1999:281(7):613–620. doi:10/1001/jama.281.7.613.

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 typically could 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 less-costly outpatient settings. 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 AMI, CABG and SHFFT models, 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 are not proposing to waive the homebound requirement under the proposed EPMs for several reasons. Based on the typical clinical course of beneficiaries after procedures in the proposed EPMs, we believe that many beneficiaries would meet the homebound requirement for home health services immediately following discharge from the anchor hospitalizations or following discharge to their home or place of residence from a SNF that furnished post-acute care 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 episode or who are discharged during the episode. For those EPM beneficiaries who could benefit from home visits by licensed clinical staff for purposes of assessment and monitoring of their clinical conditions, care coordination, and improving adherence with treatment but who are not homebound, we do 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 the BPCI initiative and the CJR model, we have not waived the homebound requirement for home health services.

For EPMs, we propose to adopt program requirement waivers similar to the post-discharge home visit waivers implemented for the CJR model. We propose to waive the ''incident to'' rule set forth in § 410.26(b)(5), to allow an EPM 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 to beneficiaries who would qualify for home health services under the Medicare program, as set forth under § 409.42. Therefore, these visits would not be billed for such beneficiaries. Under the proposed waiver, we would allow licensed clinical staff, 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 would allow services furnished under the waiver to be billed under the PFS by the physician or nonphysician practitioner or by the hospital to which the supervising physician has reassigned his or her benefits. In the latter scenario, we note that the post-discharge home visit services will not be ''hospital services,'' even when furnished by clinical staff of the hospital.

Under the CJR model, we allow up to 9 post-discharge home visits to be billed and paid during each 90-day post-anchor hospitalization CJR episode. This limit on the number of visits is based on the average post-acute care LOS of approximately 30 to 45 days for CJR episodes and the incentives under CJR to improve efficiency, which may shorten post-acute care stays. Thus, 9 visits 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 post-acute care in an efficient episode.

Since current model data shows that the average post-acute care LOS may vary or in some case post-acute care may not be used at all, for EPMs, we are proposing to use model-specific limits on post-discharge home visits as follows:

a. AMI Model

Current model data show that most beneficiaries with AMI diagnoses, regardless of AMI medical treatment or PCI treatment for AMI, are not discharged to post-acute care. Based on no post-acute care usage, we are proposing that a beneficiary in the AMI model could receive up to 13 home visits, which represents a home visit on average of once per week for the entire 90-day AMI episode.

b. CABG Model

Current model data show that most beneficiaries with CABG diagnoses are discharged to SNFs or to home health. Assuming an average post-acute care LOS of 30 days, we are proposing that a beneficiary in the CABG model could receive up to 9 home visits, which represents a home visit on average of once per week for 60 days, or two-thirds of a 90-day CABG episode.

c. SHFFT Model

Current model data show that most beneficiaries with SHFFT diagnoses are discharged to SNFs with average post-acute care LOSs of 30 days. Thus, we are proposing that a beneficiary in the SHFFT model could receive up to 9 home visits, which represents a home visit on average of once per week for 60 days, or two-thirds of a 90-day SHFFT episode.

We believe that a home visit of once a week to a non-homebound beneficiary who has concluded or has not used post-acute care 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 nonphysician practitioner as proposed in the next section, should be sufficient to allow comprehensive assessment and management of the beneficiary throughout the AMI, CABG, or SHFFT episode.

Similar to the CJR model, we propose that the service be billed with HCPCS code GXXXX (EPM–AMI, CABG, or SHFFT 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 EPM–AMI, CABG, or SHFFT model; may not be billed for a 30-day period covered by a transitional care management code) and paid at approximately $50 under the PFS. The standard PFS rate setting methodologies establish relative value units (RVUs) based on the resources required to furnish the typical service. Final RVUs under the CY 2017 PFS for the proposed new HCPCS code for AMI, CABG, and SHFFT home visits will be included in the EPM Final Rule. In addition, we propose to update the values each year to correspond to final values established under the PFS.

The waiver would not apply with respect to an AMI, CABG, or SHFFT beneficiary who has qualified, or would qualify, for home health services when the visit was furnished. We expect that the visits by licensed 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 believe 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 EPM participants.

We also propose to waive current Medicare billing rules in order to allow the separate reporting of these post-discharge home visits during surgical global periods. The PFS 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 or, unless there is a transfer of care, by another practitioner. The current construction of the global packages included in PFS payments reflects a narrow view of surgical follow-up care that does not encompass broader, more comprehensive models of post-operative care, such as an episode payment model like the proposed AMI, CABG, and SHFFT models. 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 do not believe that the AMI, CABG, and SHFFT 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 PFS. Instead, we anticipate that the work of these post-discharge visits will be similar to the work furnished by the physician coordinating the patient's overall episode care. Therefore, we propose 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.

We plan to monitor utilization patterns of post-discharge home visits under EPMs to monitor for overutilization and significant reductions in medical home health services. We seek comments on the proposed waiver of the ''incident to'' rule to pay for a maximum number of post-discharge home visits to beneficiaries who do not qualify for home health services by licensed clinical staff under the general supervision of a physician.

5. Billing and Payment for Telehealth Services

As discussed in the previous section, we expect that the EPMs' design features will lead to greater interest on the part of hospitals and other providers and suppliers caring for EPM beneficiaries in furnishing services to beneficiaries in their homes or places of residence, including physicians' professional services. While physicians may furnish and be paid by Medicare for home visits under the PFS, few visits actually are furnished to Medicare beneficiaries because of the significant physician resources required for such visits and the general structure of most office-based physician practices. For example, in 2014, only 2.6 million physician or nonphysician practitioner home visits were furnished to Medicare beneficiaries, in contrast to almost 250 million office or other outpatient evaluation and management visits furnished by physicians or nonphysician practitioners. EPMs 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 understand that EPM participants may want to engage physicians in furnishing timely visits to homebound or non-homebound EPM beneficiaries in their homes or places of residence to address concerning symptoms or observations raised by beneficiaries themselves, clinicians furnishing home health services, or licensed clinical staff furnishing post-discharge home visits, while physicians committed to the proposed AMI, CABG, and SHFFT care redesign may not be able to revise their practice patterns to meet this home visit need for EPM 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 sections 1834(m)(4)(C)(i)(I) through (III) of the Act. Generally, for Medicare payment to be made for telehealth services under the PFS several conditions must be met, as set forth under § 410.78(b). Specifically, for a service to be eligible for payment, the individual receiving the services must be in an eligible

originating site, and the service must be—

- On the Medicare list of telehealth services; [103]
- Furnished via an interactive telecommunications system; and
- Furnished to a telehealth-eligible individual.

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.

Under section 1834(m)(4)(F)(ii) of the Act, CMS has 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.[104] In these 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 note 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-based payment models, such as BPCI Models 2 and 3 and the CJR model, we determined it was necessary to waive the geographic-site requirements of sections 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 the proposed EPMs—AMI, CABG, and SHFFT—we propose a waiver of this same provision as well as waiver of the requirement that the eligible telehealth individual be in an originating site when an 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 EPM 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. We believe that these waivers are essential to maximize the opportunity to improve the quality of care and efficiency for the proposed EPMs' episodes.

Specifically, like the telehealth waiver for the BPCI and CJR models, we propose to waive the geographic-site requirements of sections 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 to be 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–9 principal diagnosis code that is not excluded from the proposed EPMs episode definition (see section III.C. of this proposed rule) could be furnished to an EPM beneficiary, regardless of the beneficiary's geographic location. Under the proposed EPMs, this waiver would support care coordination and increasing timely access to high quality care for all EPM beneficiaries, regardless of geography. Additionally, we propose, only for the purpose of testing the proposed EPMs, waiving the originating site requirements of section 1834(m)(4)(C)(ii)(I)–(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 propose to waive the requirement only when telehealth services are being furnished in the EPM 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–9 principal diagnosis code that is not excluded from the applicable EPM's episode definition (see section III.C. of this proposed rule) could be furnished to an EPM 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 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 payment 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, we do 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 unspecified. Therefore, in order to create a mechanism to report E/M services accurately under the EPMs, we propose to create a specific set of HCPCS G-codes to describe the E/M services furnished to EPM beneficiaries in their homes via telehealth. Among the existing E/M visit services, we envision these services would be most similar to those described by the office and other outpatient E/M codes. Therefore, we propose 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 propose to create a parallel structure and set of descriptors currently used to report

[103] For the list of approved Medicare telehealth services, see the CMS Web site at *http://www.cms.gov/Medicare/Medicare-General-information/telehealth/*.

[104] Telehealth in an Evolving Health Care Environment: Workshop Summary (2012). Available at *http://www.ic4n.org/wp-content/uploads/2014/06/IoM-Telehealth-2012-Workshop-Summary.pdf*. Accessed on June 7, 2015.

office or other outpatient E/M services, (CPT codes 99201–99205 for new patient visits and CPT codes 99212–99215 for established patient visits). For example, the proposed G-code for a level 3 E/M visit for an established patient would be a remote in-home visit for the evaluation and management of an established patient, which requires at least two of the following three 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.

We note that we are not proposing a 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 qualified health professional. We also believe this would duplicate the home visits for non-homebound beneficiaries previously proposed in this section.

We propose 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 propose 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, we believe that the efficiencies of virtual presentation generally limit resource costs other than those related to the professional time, intensity, and malpractice risk to marginal levels. Therefore, we propose to adopt work and malpractice (MP) RVUs associated with the corresponding level of office/outpatient codes as the typical service because the practitioner's time and intensity and malpractice liabilities when conducting a visit via telehealth are comparable to the office visit.

We will include final RVUs under the CY 2016 PFS when we finalize the rules for EPMs. Additionally, we propose to update these values each year to correspond to final values established under the PFS. We considered whether each level of visit typically would warrant support by auxiliary licensed clinical staff within the context of the proposed EPMs. The cost of such staff and any associated supplies, for example, would be incorporated in the practice expense (PE) RVUs under the PFS. For the lower-level visits (levels 1–3 for new visits and levels 2 and 3 for established visits), we did not believe that visits necessarily would require auxiliary medical staff to be available in patients' homes. We anticipate these lower-level visits would be the most-commonly furnished and would serve as mechanisms for patients to consult quickly with practitioners for concerns that patients can easily describe and explain. We do not propose to include PE RVUs for these services, since we do not believe that virtual visits envisioned for EPMs typically incur the kinds of costs included in the PE RVUs under the PFS. 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 for the complete service to be furnished. We believe 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 beneficiaries in the proposed EPMs' episodes without licensed clinical staff support in the home.

However, we also note that the proposed EPMs already include 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 section of this proposed rule. Therefore, although we consider support by auxiliary clinical staff to be typical for levels 4 or 5 E/M visits furnished to EPM beneficiaries in the home via telehealth, we do not propose to incorporate these costs through PE RVUs. Given the anticipated complexity of these visits, we would expect to observe levels 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 propose 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 note that because the services described by the proposed G-codes, 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 note that because these home telehealth services are E/M services, all other coverage and payment rules regarding E/M services would continue to apply.

Under the proposed EPMs, 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.

With respect to home health services paid under the home health prospective payment system (HH PPS), we emphasize 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 cannot be furnished for EPM 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, can be furnished for EPM 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 nonphysician practitioner 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 post-acute care setting (from which the patient was directly admitted to home health) or an allowed nonphysician practitioner working in collaboration with or under

the supervision of the acute or post-acute care 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 are not proposing that the waiver of the telehealth geographic site requirement for telehealth services and the originating site requirement for telehealth services furnished in the EPM 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 is used to meet the requirement for home health certification, the usual Medicare telehealth rules apply with respect to geography and eligibility of the originating site. We expect that this policy will not limit EPM beneficiaries' access to medically-necessary home health services because beneficiaries receiving home health services during a proposed EPM episode will have had a face-to-face encounter with either the physician or an allowed nonphysician practitioner during their anchor hospitalization or a physician or allowed nonphysician practitioner during a post-acute facility stay prior to discharge directly to home health services.

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 EPM 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 pursuant to the telehealth waivers only during the proposed EPM episode.

We plan to monitor patterns of utilization of telehealth services under the proposed EPMs to monitor for overutilization or reductions in medically-necessary care, and significant reductions in face-to-face visits with physicians and nonphysician practitioners. We plan to specifically monitor the distribution of new telehealth home visits that we are proposing, as we anticipate greater use of lower level visits. Given our concern that auxiliary licensed clinical staff be present for level 4 and 5 visits, we will monitor our proposed requirement that these visits be billed on the same claim with the same date of service as a home nursing visit, during a period authorized home health care, or that the physician document the presence of auxiliary licensed clinical staff in the home or an explanation as to the specific circumstances precluding the need for auxiliary staff for the specific visit. We seek comments on the proposed waivers with respect to telehealth services, and the proposed creation of the home visit telehealth codes.

6. SNF 3-Day Rule

a. Waiver of SNF 3-Day Rule

Pursuant to section 1861(i) of the Act, a beneficiary must have a prior inpatient hospital stays 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 for Medicare SNF coverage under other episode payment models, including BPCI Model 2 and the CJR model. BPCI Model 2 awardees that request and are approved for the waiver can discharge Model 2 beneficiaries in fewer 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. Under the CJR model, we adopted a waiver of the SNF 3-day rule that applies beginning in performance year 2 as hospitals are not bearing risk in their first year. As discussed in section V.N. of this proposed rule with comment period, we are proposing to revise the effective date of the waiver of the SNF 3-day rule for the CJR model, and we are proposing that participant hospitals may begin using the waiver for episodes that begin on or after January 1, 2017.

We are proposing EPM payment policies, similar to CJR payment policies, in section III.D. of this proposed rule, which would require participating EPM hospitals to repay Medicare for excess episode spending beginning in performance year 2. Episode payment models like BPCI, CJR and those being proposed in this proposed rule 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 EPM lays the groundwork for offering EPM participants greater flexibility around the parameters that determine SNF stay coverage. BPCI participants considering the early discharge of a beneficiary pursuant to 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 episode-based payment models such as BPCI, the CJR model, or the EPMs in this proposed rule.

Because of the potential benefits we see for participating EPM hospitals, their provider partners, and beneficiaries, we propose to waive in certain instances, where it is clinically-appropriate, the SNF 3-day rule for coverage of a SNF stay following the anchor hospitalization under EPM for episodes that begin on or after April 1, 2018. While our intent is to align the effective date of the availability of this program waiver with performance year 2 (DR) of the model, when repayment responsibility for actual episode spending that exceeds the target price begins, we believe that an effective date based on the start of the episode will be clearer to participant hospitals, SNFs, and others in determining whether the waiver is available for an EPM beneficiary. We believe that clarity regarding whether a waiver applies to SNF services furnished to a particular beneficiary is important to help ensure compliance with the conditions of the waiver and also improve our ability to monitor waivers for misuse. We propose

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 EPM episode. We believe this waiver is necessary to the model test so that EPM participants can redesign care throughout the episode continuum of care extending to 90 days post-discharge from the anchor hospital stay in order to maximize quality and hospital financial efficiency, as well as reduce episode spending under Medicare. However, we are not proposing to waive this requirement in performance year 1, when EPM participants are not responsible for excess actual episode spending. We believe that there is some potential for early hospital discharge followed by a SNF stay to increase actual episode spending over historical patterns unless EPM participants are particularly mindful of this potential unintended consequence. Without participant repayment responsibility in performance year 1, we are 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. For EPM episodes beginning on or after April 1, 2018, we propose to waive the SNF 3-day rule, where clinically-appropriate, because participants will bear partial or full responsibility (capped at the proposed stop-loss limit described in section III.D.7.b. of this proposed rule) for excess episode actual spending, thereby providing a strong incentive in those years for participants 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 EPM beneficiaries in all performance years of the model.

In addition, for those proposed EPMs in this proposed rule and for future EPMs where this waiver is clinically-appropriate and the average LOS for Medicare beneficiaries hospitalized for certain EPM procedures without major complications or comorbidities may be already relatively short at 3 days we believe that we should protect immediate EPM beneficiary safety and optimizing health outcomes. Therefore, we propose to require that participants may only discharge an EPM beneficiary under this proposed waiver of the SNF 3-day rule to a SNF rated an overall 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 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 gives each SNF an overall rating of between 1 and 5 stars.[105] Those SNFs with 5 stars are considered to have much above average quality, and SNFs with 1 star are considered to have quality much below average. 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 an EPM episode, especially if that discharge occurs after fewer than 3 days in the hospital. Because of the potential greater risks following early inpatient hospital discharge, we believe it is appropriate that all EPM beneficiaries discharged from the EPM participant to a SNF in fewer 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 believe such a SNF would need to provide care of at least average overall quality, which would be represented by an overall SNF 3-star or better rating.

As discussed in the CJR final rule (80 FR 73457 through 73459), commenters expressed concern about the variation in the number of SNFs across the participating MSAs rated an overall 3 stars or better that would qualify for the SNF 3-day rule waiver under CJR. While we appreciate the variation in qualifying SNFs across the participating MSAs, we continue to believe that 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 note that all 294 MSAs that are eligible for selection for the AMI and CABG models under this proposed rule have at least one SNF that passed the 3 star requirement from June 2015 to May 2016 and would therefore qualify for the waiver under our proposal. Therefore, all EPM 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 proposed EPM waiver.

Thus, the participating hospital must discharge the beneficiary to a SNF that is qualified under the SNF 3-day rule waiver. We are proposing that to be qualified under the SNF 3-day rule waiver a SNF must be included in the most recent calendar year quarter Five-Star Quality Rating System listing for SNFs on the Nursing Home Compare Web site for the date of the beneficiary's admission to the SNF. The qualified SNF must be rated an overall 3 stars or better for at least 7 of the 12 months based on a review of the most recent rolling 12 months of overall star ratings. We propose to post on the CMS Web site the list of qualified SNFs in advance of the calendar quarter.

For the CJR model, we justified the waiver of the SNF 3-day rule by reviewing data specific to the characteristics of CJR beneficiaries, such as, the geometric mean hospital LOS for the MS–DRGs associated with lower extremity joint replacement (3 to 7 days) and the frequency and length of SNF usage (typically 30 days) for CJR beneficiaries. We stated in the CJR Final Rule that we believe this waiver is necessary to the model test so that CJR participant hospitals could redesign care throughout the episode continuum of care extending to 90 days post-discharge from the anchor hospital stay in order to maximize quality and hospital financial efficiency, as well as reduce episode spending under Medicare. However, the waiver does not apply in performance year 1, when CJR participant hospitals are not responsible for excess actual episode spending.

Based on our analysis of data discussed in section III.J.3. of this proposed rule, we believe some program and patient outcome vulnerabilities may exist with proposing to adopt the waiver of the SNF 3-day rule for the proposed AMI, CABG, and SHFFT models or under future EPMs. To mitigate these possible vulnerabilities, we believe it will be necessary to determine if this waiver applies to EPMs on a model-specific basis as follows:

- AMI Model—AMI beneficiaries have geometric mean hospital LOSs that are similar to CJR beneficiaries, 2.0–4.5 days (see Table 35). Most AMI beneficiaries, regardless of AMI medical treatment or PCI treatment for AMI, are

[105] *www.medicare.gov/NursingHomeCompare/.*

not discharged to post-acute care. There is no research that shows increased mortality associated with the hospital LOS. Therefore, we believe that is may be clinically-appropriate to propose to waive the SNF 3-day rule for the AMI model for episodes beginning on or after April 1, 2018, as participant hospitals are not bearing risk in their first performance year or performance year 2 (NDR).

We propose that the waiver be available for the AMI 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 AMI model participant, as the SNF would need to be in close communication with the EPM participant to ensure that the beneficiary is in the model at the time the waiver is used. We propose that where the beneficiary would be eligible for inclusion in an AMI 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. A beneficiary would be eligible to receive services furnished under the 3-day rule waiver only during the AMI episode.

- CABG Model—CABG beneficiaries have a geometric mean hospital LOS of 6.0 to 11.6 days (see Table 35), much longer than the CJR model's mean LOS. While most CABG beneficiaries are discharged to SNFs, a mean hospital LOS well above 3 days indicates that it would not be clinically-appropriate for early discharges provided with this waiver. Therefore, we are not proposing to waive the SNF 3-day rule for the CABG model.
- SHFFT Model—SHFFT beneficiaries have a geometric mean hospital LOS of 3.7–6.7 days (see Table 35), somewhat close to the CJR model's mean LOS. However, studies show that shorter than average hospital LOSs for hip fracture are associated with higher mortality.[106] While most SHFFT beneficiaries are discharged to SNFs, a mean hospital LOS above 3 days along with a higher mortality rates associated with shorter than average hospital LOSs indicates that it would not be clinically-appropriate for early discharges provided with this waiver. Therefore, we are proposing not to waive the SNF 3-day rule for the SHFFT model.

We plan to monitor patterns of SNF utilization under the EPM, particularly with respect to hospital discharge in fewer 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 seek comment on our proposal to waive the SNF 3-day stay rule for stays in SNFs rated overall as 3 stars or better following discharge from the anchor hospitalization in EPM episodes.

b. Additional Beneficiary Protections Under the SNF 3-Day Stay Rule Waiver

For those specific proposed EPMs, where we propose to allow the SNF 3-day rule waiver, we believe that it will be necessary to propose beneficiary protections against financial liability in addition to the beneficiary protections discussed elsewhere in this proposed rule. In proposing additional beneficiary protections that may be necessary to ensure proper use of the SNF 3-day rule waiver under the proposed EPMs, we note that there are existing, well-established payment and coverage policies for SNF services based on sections 1861(i), 1862(a)(1), and 1879 of the Act that include protections for beneficiaries from liability for certain non-covered SNF charges. These existing payment and coverage policies for SNF services continue to apply under the EPMs, including SNF services furnished pursuant to the SNF 3-day waiver. (For example, see section 70 in the Medicare Claims Processing Manual, Chapter 30—Financial Liability Protections on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c30.pdf*; and Medicare Coverage of Skilled Nursing Facility Care at *https://www.medicare.gov/Pubs/pdf/10153.pdf*; Medicare Benefit Policy Manual, Chapter 8—Coverage of Extended Care (SNF) Services Under Hospital Insurance at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c08.odf*). In general, CMS requires that the SNF inform a beneficiary in writing about services and fees before the beneficiary is discharged to the SNF (§ 483.10(b)(6)); a beneficiary cannot be required to request extra services as a condition of continued stay (§ 483.10(c)(8)(iii)(B)); and the SNF must inform a beneficiary that requests an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be (§ 483.10(c)(8)(iii)(C)). (See also Chapter 6 of Medicare Coverage of Skills Nursing Facility Care at *https://www.medicare.gov/Pubs/pdf/10153.pdf*.)

As discussed in the CJR final rule, commenters expressed concern regarding the lag between a CJR beneficiary's Medicare eligibility status change and a participant hospital's awareness of that change. There may be cases in which a SNF waiver is used by a participant hospital because the participant hospital believes that the beneficiary meets the criteria, based on the information available to the hospital and SNF at the time of the beneficiary's admission to the SNF, but in fact the beneficiary's Medicare eligibility status has changed and the hospital was unaware of it based on available information. We recognize that despite good faith efforts by participant hospitals and SNFs to determine a beneficiary's Medicare status for the model, it may occur that a beneficiary is not eligible to be included in the CJR model at the time the SNF waiver is used. In these cases, we will cover services furnished under the waiver when the information available to the provider at the time the services under the waiver were furnished indicated that the beneficiary was included in the model.

In addition, as discussed in the CJR final rule, we noted that we would continue to evaluate the waiver of the SNF 3-day rule, including further lessons learned from Innovation Center models in which a waiver of the SNF 3-day rule is being tested. We indicated that in the event we determine that additional safeguards or protections for beneficiaries or other changes were necessary, such as to incorporate additional protections for beneficiaries, we would propose the necessary changes through future rulemaking. In section V of this proposed rule, we are proposing to add certain beneficiary protection requirements under the CJR model in § 510.610.

We have continued to learn from implementation of the SNF 3-day rule waiver in the CJR model, other models, and the Shared Savings Program. Based on these experiences, we believe there are situations where it would be appropriate to require additional beneficiary financial protections under the SNF 3-day rule waiver for the applicable proposed EPMs. Specifically, we are concerned about potential beneficiary financial liability for non-covered Part A SNF services that might be directly related to use of the SNF 3-day waiver under the applicable EPMs. For instance, we are concerned that a beneficiary could be charged for non-covered SNF services if an EPM participant hospital discharges a beneficiary to a SNF that does not meet the quality requirement (3 stars or

[106] *http://www.ncbi.nlm.nih.gov/pubmed/19817664.*

higher in 7 of the last 12 months), and the beneficiary is not provided a discharge planning notice, as described in proposed § 512.450(b). Another scenario would be where the EPM participant hospital applies the SNF 3-day rule waiver for episodes that begin prior to April 1, 2018, when this waiver is not applicable, and payment to the qualified SNF for furnishing Medicare covered SNF services is denied. A third scenario would be if an EPM participant hospital applies the SNF 3-day rule waiver for a specific proposed EPM where the waiver is not allowed, such as proposed for the CABG and SHFFT models in this proposed rule. In any of these circumstances, we assume the participant EPM hospital's intent was to rely upon the SNF 3-day rule waiver, but the waiver requirements were not met. When this occurs, we are concerned that once the claim is rejected, the beneficiary may not be protected from financial liability under existing Medicare rules because the waiver would not be available, and the beneficiary would not have had a qualifying inpatient hospital stay. Thus, the EPM beneficiary could be charged by the SNF for non-covered SNF services that were a result of an inappropriate attempt to use the waiver. In these cases, Medicare would deny payment of the SNF claim, and the beneficiary could potentially be charged by the SNF for these non-covered SNF services, potentially subjecting such beneficiaries to significant financial liability. We believe that the rejection of the claim, in these cases, could easily have been avoided if the hospital had confirmed that the requirements for applying of the SNF 3-day waiver were satisfied.

Other models have addressed similar issues in which the beneficiary may be subject to financial liability for non-covered SNF services related to the waiver. The Next Generation ACO Model generally places the risk on the SNF, where the SNF did not qualify under the waiver or otherwise knew or reasonably could be expected to have known that payment would not be made for the non-covered SNF services. In such cases, CMS makes no payment for the services, and the SNF may not charge the beneficiary for the services and must return any monies collected from the beneficiary. Additionally, under the Next Generation ACO Model, the ACO must indemnify and hold the beneficiary harmless for the services. We believe it is appropriate to propose to adopt a similar policy under the EPMs. In contrast to the Next Generation ACO Model, however, we believe it is most appropriate to hold the EPM participant hospitals financially responsible for misusing the waiver in situations where waiver requirements are not met, because EPM participant hospitals are required to be aware of the 3-day waiver requirements. EPM participant hospitals are the entities financially responsible for episode spending under the proposed EPMs and will make the decision as to whether it is appropriate to discharge a beneficiary without a 3-day stay. In addition, we will clearly lay out the requirements for use of the SNF waiver in the EPM final rule. As we are proposing, EPM participant hospitals may begin using this waiver only for specific episodes beginning on or after April 1, 2018, and may only utilize the waiver to discharge a beneficiary to a SNF that meets the quality requirements. EPM participant hospitals are required to ensure the waiver requirements of proposed § 512.610 (a) and (b) are met. Therefore, we believe it is reasonable that the ultimate responsibility and liability for a non-covered SNF stay should rest with the EPM participant hospital. We considered holding the SNF responsible but decided that since hospitals, not SNFs, are the EPM participants, they therefore should be held responsible for complying with the SNF 3-day rule waiver conditions for the reasons stated previously.

To protect EPM beneficiaries from being charged for non-covered SNF charges in instances when the waiver was used inappropriately, we are proposing to add certain beneficiary protection requirements in proposed § 512.610. These requirements would apply for SNF services that would otherwise have been covered except for lack of a qualifying 3-day hospital stay. Specifically, we propose if, subsequent to an EPM participant hospital applying the SNF 3-day rule waiver, we determine that the following waiver requirements were not met then the EPM participant hospital will be financially liable for the SNF stay:

- The EPM participant hospital discharges a beneficiary that is in a specific EPM where the SNF 3-day rule waiver does not apply.
- The EPM participant hospital discharges a beneficiary prior to April 1, 2018, where the SNF 3-day rule waiver does not apply.
- The EPM participant hospital discharges a beneficiary to a SNF that does not meet the quality requirement (3 stars or higher in 7 of the last 12 months) and does not provide a discharge planning notice, as described in proposed § 512.450(b), to the beneficiary alerting them of potential financial liability.

In these preceding instances, we propose to apply the following rules:

- CMS shall make no payment to the SNF for such services.
- The SNF shall not charge the beneficiary for the expenses incurred for such services. and the SNF shall return to the beneficiary any monies collected for such services.
- The hospital shall be responsible for the cost of the uncovered SNF services furnished during the SNF stay.

In addition, if the EPM hospital discharges a beneficiary to a SNF that does not meet the quality requirement (3 stars or higher in 7 of the last 12 months) and a discharge planning notice, as described in proposed § 512.450(b), is provided to the beneficiary alerting them of potential financial liability then the hospital will not be financially liable for the cost of the SNF stay and the normal Medicare FFS rules for coverage of SNF services will apply.

The discharge notice absolves the hospital of liability. However, we are requiring hospitals to keep a record of discharge planning notice distribution to EPM beneficiaries. We will monitor participant hospitals' use of discharge notification letters to protect EPM beneficiaries from potential abuse of the waiver. Nevertheless, we recognize there are some situations in which a beneficiary may wish to be discharged before a qualifying 3-day stay and may accept financial liability for a non-qualifying stay, in which case the participant hospital will not be held financially liable for the SNF stay. Therefore, when the EPM participant hospital has discharged a beneficiary to a SNF that does not qualify under the conditions of the waiver, we believe it is reasonable that the ultimate responsibility and financial liability for a non-covered SNF stay should rest with the EPM participant hospital. We will communicate with hospitals and SNFs about how a hospital would pay SNFs for non-qualifying services provided.

We seek comment on these proposals. Specifically, we seek comment on whether it is reasonable to: (a) Cover services furnished under the SNF waiver based on the EPM participant hospital's knowledge of beneficiary eligibility for the applicable proposed EPMs, as determined by Medicare status, at the time the services under the waiver were furnished; and (b) to hold the EPM participant hospital financially responsible for rejected SNF claims as a result of lack of a qualifying inpatient hospital stay in cases where the EPM participant hospital discharge a

beneficiary to a SNF that did not qualify for waiver use and did not provide the beneficiary with a discharge planning notice. We seek comment on whether SNFs instead of, or in addition to, the EPM participant hospital should be held liable for such claims and under what circumstances. Finally, we seek comment on any other related issues that we should consider in connection with these proposal to protect beneficiaries from significant financial liability for non-covered SNF services related to the waiver of the SNF 3-day rule under the proposed EPMs. We may address those issues through future notice and comment rulemaking.

7. Waivers of Medicare Program Rules To Allow Reconciliation Payment or Repayment Actions Resulting From the Net Payment Reconciliation Amount

In order to make a reconciliation payment to or carry out recoupment from a participant that results from the NPRA calculation for each performance year as discussed in section III.D.5. of this proposed rule, we believe we would need to waive certain Medicare program rules. Therefore, in accordance with the authority in section 1115A(d)(1) of the Act, we propose 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 this proposed payment model for EPM participants selected in accordance with CMS's proposed selection methodology. In addition, our proposals on reconciliation payments or repayments would 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. We therefore would 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 an EPM participant. We seek comment on our proposed waivers related to repayment and recoupment actions as a result of the NRPA calculated.

8. New Waiver for Providers and Suppliers of Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Services Furnished to EPM Beneficiaries During an AMI or CABG Episode

A cardiac rehabilitation (CR) program, as defined in § 410.49(a) of the regulations, means a physician-supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, psychosocial assessment, and outcomes assessment. An intensive cardiac rehabilitation (ICR) program, as defined in § 410.49(a) of the regulations, means a physician-supervised program that furnishes cardiac rehabilitation and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in § 410.49(c).

Services provided under CR and ICR programs may be furnished to EPM beneficiaries during the proposed AMI and CABG episodes. We note that all EPM beneficiaries in an AMI or CABG episode would meet CMS's coverage criteria for CR and ICR services.

Section 410.49(f) describes the limitations of coverage of cardiac rehabilitation programs. The coverage requirements of CR limits the number of cardiac rehabilitation program sessions to a maximum of 2 one-hour sessions per day for up to 36 sessions over a period up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the MAC under section 1862(a)(1)(A) of the Act. Intensive cardiac rehabilitation program sessions are limited to 72 one-hour sessions (as defined in section 1848(b)(5) of the Act), up to 6 sessions per day, over a period of up to 18 weeks. In section VI of this proposed rule, we are proposing to make a payment adjustment under the AMI and CABG models to account for and possibly incentivize the provision of CR and ICR services beyond what has historically been provided during AMI and CABG episodes. In addition, we believe that waiving certain CR/ICR program requirements may also increase the use of these beneficial services under the AMI and CABG models.

We reviewed the following physician functions required under § 410.49 in furnishing CR/ICR services:

- Medical director—defined at § 410.49(a) as a physician that oversees or supervises the cardiac rehabilitation or intensive rehabilitation program at a particular site.
- Supervising physician—defined at § 410.49(a) as a physician that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under cardiac rehabilitation and intensive cardiac rehabilitation programs.
- Physician-prescribed exercise—defined at § 410.49(a) as aerobic exercise combined with other types of exercise (that is, strengthening, stretching) as determined to be appropriate for individual patients by a physician.
- Individualized treatment plan—defined at § 410.49(a) as a written plan tailored to each individual patient that, under § 410.49(b)(2)(v), must be established, reviewed, and signed by a physician every 30 days.

Under § 410.49(a), and § 1861(r)(1) of the Act, a physician is defined as a doctor of medicine or osteopathy. Section 410.49(b)(3) states that Medicare Part B pays for CR/ICR in a physician's office or in a hospital outpatient setting. All settings must have a physician immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician meets the requirements for direct supervision for physician office services, at § 410.26 of this subpart; and for hospital outpatient services at § 410.27 of this subpart.

To provide greater program flexibility that might increase the availability of CR and ICR services furnished to EPM beneficiaries in AMI and CABG episodes, we are proposing to provide a waiver to the definition of a physician to include a nonphysician practitioner (defined for the purposes of this waiver as a physician assistant, nurse practitioner, or clinical nurse specialist as authorized under sections 1861(s)(2)(K)(i) and (ii) of the Act and defined in section 1861(aa)(5) of the Act, or in §§ 410.74, 410.75, and 410.76 of the regulations). Thus, this waiver will allow, in addition to a physician, a nonphysician practitioner to perform the functions of supervisory physician, prescribing exercise, and establishing, reviewing, and signing an individualized treatment plan for a provider or supplier of CR and ICR services furnished to an EPM beneficiary during an AMI or CABG episode. We do not believe a nonphysician practitioner is qualified to act in the capacity of a medical director. Thus, we are specifically excluding the medical director function from this proposed waiver. In addition, all other definitions and requirements related to a physician or supervising physician under § 410.49 continue to apply. This proposed waiver is codified at proposed § 512.630.

For an EPM beneficiary in an AMI or CABG episode, this proposed waiver will apply to any provider or supplier that furnishes CR and ICR services to that beneficiary. We anticipate monitoring outcomes of care for EPM beneficiaries that receive CR and ICR services under this proposed waiver during an AMI or CABG episode. The

monitoring may involve an analysis of all or a sample of claims, medical records, or other clinical data for AMI and CABG EPM beneficiaries and providers or suppliers of CR and ICR services. We are soliciting comments on approaches we may take to monitor this waiver to ensure this program flexibility does not have a negative effect on how beneficiaries receive CR and ICR services which then may affect the outcome of the EPM beneficiary's care.

We also reviewed other program requirements, such as waiving beneficiary cost-sharing, allowing home nursing visits/home monitoring, and allowing telehealth visits in the home under the AMI and CABG models. We did not find clinical data and literature that we believed sufficient to support proposing any additional waivers to the CR/ICR program requirements in this proposed rule. We are soliciting comments on the proposed CR/ICR waiver to allow nonphysician practitioners to perform the aforementioned physician functions specified for the provision of CR/ICR services, as well as comments on possible other CR/ICR program requirement waive.

K. Data Sharing

1. Overview

In section III.D.2.of this proposed rule, we propose models similar to the CJR model, to financially incentivize EPM participants 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. Consistent with the CJR model, we are proposing retrospective bundled payment models that provide financial incentives for EPM participants to work with other health care providers and suppliers to improve the quality and efficiency of care for Medicare beneficiaries by paying EPM participants or holding them responsible for repaying Medicare based on EPM participants' performance with respect to the quality and spending for AMI, CABG, and SHFFT episodes.

In addition to the CJR model, we have experience with a range of efforts designed to improve care coordination for Medicare beneficiaries through financial incentives similar to those currently proposed, including the Shared Savings Program, the Pioneer ACO model and the BPCI initiative, all of which make certain data available to participants to better enable them to achieve their goals. For example, participants in the 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 ACOs receive certain beneficiary-identifiable claims information in accordance with our regulations. As noted in the June 9, 2015 Medicare Shared Savings Program final rule (80 FR 32733), ACOs participating in the Shared Savings Program have reported that the beneficiary-identifiable claims data that they receive from CMS are being used effectively to better understand the FFS beneficiaries that are receiving services from their providers. As stated in that rule, these data give ACOs valuable insight into patterns of care for their beneficiary population and enable them to improve care coordination among and across providers and suppliers and sites of care. 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 claims data regarding their own patients, both for the historical period 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 post-acute care spending for beneficiaries that could have initiated an episode of care at that BPCI participant.

Based on our experience with these efforts, we believe that making certain data available to EPM participants can have a salutary effect on their performance and is necessary for them to, among other things, adequately structure their care pathways, coordinate care for beneficiaries, make practice changes supported under the models, identify services furnished to beneficiaries receiving services under the models, and estimate spending across provider types within EPM episodes. Further, we believe that providing EPM participants with certain claims and summary information on beneficiaries in accordance with applicable privacy and security laws and established privacy and security protections would improve their ability to monitor their performance and understand the totality of care provided during an episode of care. With this greater awareness and understanding, we anticipate that EPM participants would be better equipped to evaluate and modify their practice patterns and actively manage care delivery so that care for beneficiaries is better coordinated, quality and efficiency are improved, and payments are aligned more appropriately to the medically necessary services beneficiaries have a right to receive.

Accordingly, we propose to provide EPM participants in the proposed AMI, CABG, and SHFFT models with beneficiary-level claims data for the historical period used to calculate their episode benchmark and quality-adjusted target prices as well as with ongoing quarterly beneficiary-identifiable claims data in response to their request for such data in accordance with our regulations. Given that we are also proposing to incorporate regional pricing in the calculation of benchmark and quality-adjusted target prices, we also propose to provide EPM participants with aggregate regional data. Our proposal to make these data available to EPM participants is included in § 512.350. We note that, consistent with CJR, the EPM participant with whom we would share data is the acute care hospital that is held accountable for spending during the episode of care. We believe our proposal to share data as we do under the CJR model would be the most effective approach under the proposed AMI, CABG, and SHFFT models, and that proposing different processes for these models would increase administrative complexity for CMS and model participants as well as create confusion, especially given that we are proposing in section III.B. that some of the hospitals participating in CJR will also participate in the proposed EPMs. We request comments on these proposals, particularly regarding possible ways, if any, to further align our proposed policies with those finalized under the CJR model, as well as any appropriate bases for treating these models differently.

2. Beneficiary Claims Data

Based on our experience with BPCI and CJR participants, we recognize that EPM participants could vary with respect to the kinds of beneficiary claims information that would be most helpful. For example, we believe that while many EPM participants might have the ability to analyze raw claims

data, other EPM participants could find it more useful to have a summary of these data. Given this, we propose to make beneficiary claims information for AMI, CABG, and SHFFT episodes available through two formats both for the baseline period and on an ongoing basis during their participation in the model as we do for CJR.

First, for EPM participants that lack the capacity to analyze raw claims data, we propose to provide summary beneficiary claims data reports on beneficiaries' use of health care services during the baseline and performance periods upon request and in accordance with applicable privacy and security laws and established privacy and security protections. Such summary reports would 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 EPM participant reflects that, relative to their peers, a certain provider is associated with significantly higher rates of inpatient readmissions than the rates experienced by other beneficiaries with similar care needs, that may be evidence that the EPM participant could consider, among other things, the appropriateness of 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.

Such reports would allow EPM participants to assess summary data on their relevant beneficiary population without requiring a more complicated analysis of raw claims data. Therefore, for both the baseline period and on a quarterly basis during an EPM participant's performance period, we propose to provide EPM participants with an opportunity to request summary claims data that would encompass the total expenditures and claims for episodes under the proposed AMI, CABG, and SHFFT models in which they are participating, 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, post-acute care, and physician services for the EPM participant's beneficiaries with an anchor diagnosis at discharge that is included under one of the proposed AMI, CABG, or SHFFT models.

We also propose that these summary claims data reports, at a minimum, would also contain payment information, based upon the following categories for each episode initiated under the models:

- Inpatient.
- Outpatient.
- Skilled Nursing Facility.
- Home Health.
- Hospice.
- Carrier/Part-B.
- Durable Medical Equipment.

These files would provide summary spending data such as episode counts, total average spending for each episode, and a breakdown of the episode counts and spending averages by each of the most common categories listed previously (for example, Inpatient, Outpatient, etc.). These reports should allow participants to assess summary data on their relevant beneficiary population without requiring analysis of raw claims data.

Alternatively, for EPM participants with the capacity to analyze raw claims data, we propose to make more detailed beneficiary-level information available upon request and in accordance with applicable privacy and security laws and established privacy and security protections. These files would be much more detailed and include all beneficiary-level raw claims for all of the categories listed for each episode payment model episode. In addition, they would include episode summaries, indicators for excluded episodes, diagnosis and procedure codes, and enrollment and dual eligibility information for beneficiaries that initiate AMI, CABG, and SHFFT episodes. Through analysis, these detailed claims data would provide EPM participants with information to improve their ability to coordinate and target care strategies as well as to monitor, understand, and manage utilization and expenditure patterns. Such data would also aid them in developing, targeting, and implementing quality improvement programs and initiatives. We propose that the data files would be packaged and sent to a data portal (to which the EPM participants must request and be granted access) in a ''flat'' or binary format for the EPM participant to retrieve. We would also note that, for both the summary and more detailed claims data, information that is subject to the regulations governing the confidentiality of alcohol and drug abuse patient records (42 CFR part 2) would be excluded from the data shared with an EPM participant. Our proposal to make available to EPM participants, through the most appropriate means, data that CMS determines may be useful to EPM participants to determine appropriate ways to increase the coordination of care, improve quality, enhance efficiencies in the delivery system, and otherwise achieve the goals of the proposed episode payment models is included in § 512.350. Further, CMS will make beneficiary-identifiable data available to an EPM participant in accordance with applicable privacy and security laws and only in response to the EPM participant's request for such data for a beneficiary who has been furnished a billable service by the participant corresponding to the episode definitions for AMI, CABG, and SHFFT episodes.

We request comments on this proposal.

3. Aggregate Regional Data

As discussed in section III.D. of this proposed rule, we propose to incorporate regional pricing data when establishing target prices for EPM participants as we do in the CJR model pricing methodology. As indicated in the CJR final rule (80 FR 73510), we finalized our proposal to share regional pricing data with CJR participants because it was a factor affecting target prices. Given the similarities between the CJR model and the EPMs proposed in this proposed rule, particularly our proposal to incorporate regional pricing data when establishing target prices under the model, we propose to provide aggregate expenditure data available for all claims associated with AMI, CABG, and SHFFT episodes for the U.S. Census Division in which the EPM participant is located, as we similarly provide to hospitals participating in the CJR model.

Specifically, we propose to provide EPM participants with aggregate data on the total expenditures during an acute inpatient stay and 90-day post-discharge period for all Medicare FFS beneficiaries who would have initiated an episode under our proposed episode definitions in section III.C. of this proposed rule. This data will be provided at the regional level; that is, we propose that an EPM participant would receive, if requested from CMS, aggregate regional data for potential episode payment model AMI, CABG, and/or SHFFT episodes initiated in the U.S. Census Division where the EPM participant is located.

These regional data would be in a format similar to the proposed summary claims data reports and would provide summary information on the average episode spending for AMI, CABG, and SHFFT episodes in the U.S. Census Division in which the EPM participant is located. Our proposal to provide aggregate regional data is included in § 512.350. We seek comments on our proposal to provide these data to EPM participants.

4. Timing and Period of Baseline Data

We recognize that providing the ability to request certain baseline data will be important for EPM participants to be able to estimate episode spending, coordinate care, and identify areas for practice transformation, and that early release of this data can facilitate their efforts to do so. Also, as discussed in section III.D. of this proposed rule, episode benchmark and quality-adjusted target prices will be calculated using an EPM participant's historical episode spending during their baseline period. Further, we believe that EPM participants will view the episode payment model effort as one involving continuous improvement. As a result, changes initially contemplated by an EPM participant could be subsequently revised based on updated information and experiences.

Therefore, as with CJR and BPCI, we propose to make 3 years of baseline data available to EPM participants and intend to make these data available upon request prior to the start of the first episode payment model performance year and in accordance with applicable privacy and security laws and established privacy and security protections. We believe that 3 years of baseline data is sufficient to reflect both an EPM participant's most recent performance and recent performance trends. Moreover, making data available for a 3-year period aligns with our proposal to set a target price based on a 3-year period of baseline data in section III.D. of this proposed rule. We believe that if an EPM participant has access to baseline data for the 3-year period used to set its episode benchmark and quality-adjusted target prices, then it would be better able to assess its practice patterns, identify cost drivers, and ultimately redesign its care practices to improve efficiency and quality.

Therefore, we propose that the 3-year period utilized for the baseline period match the baseline data used to create EPM participants episode benchmark and quality-adjusted target prices, as discussed in section III.D. Specifically, we propose that the baseline beneficiary-level and summary data (both EPM participant-level and regional summary data) would be available for episodes that began January 1, 2013 through December 31, 2015. We request comments on these proposals.

5. Frequency and Period of Claims Data Updates for Sharing Beneficiary-Identifiable Claims Data During the Performance Period

In addition to baseline data, we believe that the availability of periodically updated beneficiary-identifiable claims data (both summary and beneficiary-level) will assist EPM participants in the proposed AMI, CABG, and SHFFT models 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 and frequency for making updated claims information available to EPM participants, while complying with the HIPAA Privacy Rule's ''minimum necessary'' standard.

We believe that, as is the case with CJR, making 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, would be representative of total spending and useful to hospitals as they consider long-term practice changes. We note that we intend for the data for this model to be consistent with our proposed performance year of January 1 through December 31 (July 1 through December 31 for performance year 1). To accomplish this for the first year of the models (2017), we propose to provide, upon request and in accordance with the HIPAA Privacy Rule, claims data from July 1, 2017 to June 30, 2018 on as frequently as a running quarterly basis, as claims were available. For each quarter and extending through June 30, 2018, we propose that participants during that first year would receive data for up to the current quarter and all of the previous quarters going back to July 1, 2017. These data sets would contain all claims for all potential episodes that were initiated on or after July 1, 2017 and capture a sufficient amount of time for relevant claims to have been processed. We note 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.

Accordingly, we propose to make updated claims data available to EPM participants, representing up to 6 quarters of data, upon receipt of a request for such information that meets CMS's requirements to ensure the applicable HIPAA conditions for disclosure have been met. Also, consistent with our procedures for CJR, we propose to make these data available as frequently as on a quarterly basis. Given that we have received requests in other initiatives to make data available on a more frequent basis, we also propose to eventually make these data available on as frequently as a monthly basis if practicable. In addition, we propose that for an EPM participant to receive data on episode spending, they will only need to make a single initial request rather than multiple periodic requests for data. CMS would make data available to the EPM participant for the duration of their participation or until they notify CMS that they no longer wish to receive these data.

Our proposal to make the minimum data necessary for EPM participants to conduct quality assessment and improvement activities and effectively coordinate care of its patient population as frequently as on a quarterly basis throughout the EPM participant's participation or until they notify CMS that they no longer wish to receive these data is included at § 512.350(b)(2). We seek comments on this proposal.

6. Legal Permission To Share Beneficiary-Identifiable Data

As we have stated previously (see 80 FR 73513), 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. Here, the HIPAA Privacy Rule allows for the proposed disclosure of individually identifiable health information by CMS.

In this proposed rule, we propose to make EPM participants financially responsible for services that may have occurred outside of the hospital during the 90-day post-discharge period. Although we expect EPM participants to be actively engaged in post-discharge planning and other care during the 90-day post-discharge period for beneficiaries receiving services under the proposed AMI, CABG, and SHFFT models, we believe that it is necessary for the purposes of these models to provide EPM participants 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 for episodes included under the proposed models 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, EPM participants would be using the data on their patients to evaluate the performance of the participant 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 an EPM participant 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 to a ''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 EPM's 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.

We note that, as is the case with CJR, in this proposed rule, we propose to disclose beneficiary-identifiable data to only the hospitals that are bearing risk for an AMI, CABG, or SHFFT episode and not with their collaborators. As stated in the final CJR rule (80 FR 73515), we believe that the hospitals that are specifically held financially responsible for an episode should make the determination as to which data are needed to manage care and care processes with their collaborators as well as which data they might want to re-disclose, if any, to their collaborators provided they are in compliance with the HIPAA Privacy Rule. We note that beneficiaries have the right to request restrictions on the use of their data in accordance with the HIPAA Privacy Rule, but covered entities are not required to agree to such requests.

We believe our data sharing proposals are permitted by and are consistent with the authorities and protections available under the aforementioned statutes and regulations. We seek comments on our proposals regarding the authority to share beneficiary-identifiable data.

7. Data Considerations With Respect to EPM and CJR Collaborators

As noted earlier in this section and as is the case with CJR (80 FR 73515), we propose to disclose beneficiary-identifiable data to only the EPM participants that are bearing risk for an AMI, CABG, or SHFFT episode and not with their collaborators because we believe that the EPM participants that are specifically held financially responsible for an episode should make the determination as to which data are needed to manage care and care processes with their collaborators as well as which data they might re-disclose in accordance with applicable privacy and security laws. Based on our experience in implementing the CJR, however, we understand that some CJR collaborators under that model believe that not having comparable data poses challenges to their ability to assess their own performance in the context of the model and the region in which they operate. As such, these collaborators believe that it would helpful to have additional data with which they could better assess their own performance, including information about care patterns within their region.

We are considering ways in which to address the concerns raised by these CJR collaborators and potentially similar future concerns that could arise among EPM collaborators as well as what additional data might be helpful for

these purposes and which could be disclosed in accordance with existing statutory and regulatory requirements. As previously discussed, EPM participants, like CJR participants, may share data with their EPM (or CJR) collaborators provided they are ''business associates'' in compliance with the HIPAA Privacy Rule, and we encourage them to make data available to their EPM collaborators to the extent they deem it appropriate and in compliance with these strictures.

In addition, given our view that the HIPAA Privacy Rule limits our ability to share beneficiary-identifiable data with non-EPM (or non-CJR) participants, we are considering whether it would be feasible and appropriate to make additional non-beneficiary-identifiable aggregate data publicly available through some means. For example, we are exploring whether it would be helpful to make available aggregate summary data organized by anchor MS–DRG, provider type, and region for care that would be included in episodes that would meet the criteria for inclusion in the regional component of EPM (or CJR) episode benchmark prices as described in section III.D.4.b. of this proposed rule (or 80 FR 73337 with respect to CJR), assuming all IPPS hospitals nationally were EPM (or CJR) participants. We will refer to these episodes as simulated episodes later in this section. We are interested in whether information such as the following would be helpful to EPM (or CJR) collaborators:

- Number of simulated episodes and number of hospitals with each anchor MS–DRG at discharge in the simulated episodes.
- For AMI model anchor MS–DRGs, the number of simulated episodes with chained anchor admissions by the price MS–DRG that would have been assigned to the simulated episode.
- For AMI model anchor MS–DRGs, the number of simulated episodes with readmissions resulting in discharge under a CABG MS–DRG by the CABG MS–DRG.
- Average (mean and median) and standard deviation of total spending on those simulated episodes.
- Number of simulated episodes with and mean acute care payments for the anchor hospitalization and readmission.
- Number of simulated episodes with and mean Part B payments.
- Number of simulated episodes with and mean inpatient rehabilitation facility payments.
- Number of simulated episodes with and mean skilled nursing facility payments.
- Number of simulated episodes with and mean home health payments.
- Proportion of total simulated episode spending attributable to acute care payments for the anchor hospitalization and readmissions.
- Proportion of total simulated episode spending attributable to Part B payments.
- Proportion of total simulated episode spending attributable to inpatient rehabilitation facility payments.
- Proportion of total simulated episode spending attributable to skilled nursing facility payments.
- Proportion of total simulated episode spending attributable to home health payments.

To assist us as we consider future options for potentially increasing the availability of data to collaborators under the EPMs or similar models such as CJR, we seek comments on what kinds of actions and data would be most helpful to EPM, or similar model (such as CJR) collaborators, and which could be disclosed in accordance with the existing statutory and regulatory requirements for sharing data.

L. 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 proposed EPMs are intended to enable CMS to better understand the effects of episode payments approaches on a broader range of Medicare providers and suppliers than would choose to participate in a voluntary model such as is currently being tested under BPCI. Obtaining information that is representative of a wide and diverse group of episode initiators will best inform us on how such a payment model might function were it to be more fully integrated within the Medicare program. The proposed CR incentive model is intended to enable CMS to assess whether the proposed incentive improves patient quality and access to this covered benefit without increasing overall payments. All CMS models, which would include the proposed EPMs and CR incentive 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. Outlined in the following section are the proposed design and evaluation methods, the data collection methods, key evaluation research questions, and the evaluation period and anticipated reports for the proposed EPMs.

B. Design and Evaluation Methods

Our evaluation methodology for the EPMs and CR incentive model would be consistent with the standard Innovation Center evaluation approaches we have taken in other projects such as the BPCI initiative, the Continuous Care for Joint Replacement (CJR) model,[107] the Acute Care Episode (ACE) Demonstration, Pioneer ACO model, and other Innovation Center models. Specifically, the evaluation design and methodology would be designed to allow for a comparison of historic patterns of care among the participant to any changes made in these patterns in response to the proposed models. In addition, the overall design would include a comparison of participants in EPM or CR areas with a matched comparison group in areas not participating in a specific episode to help us discern simultaneous and competing provider and market level forces that could influence our findings. Comparison group members for the EPMs would be selected based on how well they match the EPM participants along a variety of measurable dimensions, such as size, expenditures, and other provider characteristics and market characteristics. The random method of selection for participating MSAs will allow the evaluation to observe the operation of the model in a variety of circumstances and among providers and suppliers who may not otherwise choose to participate in a voluntary payment model.

We plan to use a range of analytic methods, including regression and other multivariate methods, and difference-in-differences methods 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. With these methodologies, we would be able to examine the experience over time relative to those in the comparison groups controlling for as many of the relevant confounding factors as is possible. 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 proposed models at the geographic unit level, the

[107] *https://innovation.cms.gov/initiatives/cjr.*

hospital level, and at the patient level. We are also considering various statistical methods to address factors that could confound or bias our results. For example, we would use 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. Thus, in our analysis, if 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 biased estimates and mistaken inferences. Finally, we plan to use various statistical techniques to examine the effects of the proposed models while also taking into account the effects of other ongoing interventions such as BPCI, Pioneer ACOs, and the Shared Savings Program. For example, we are considering additional regression techniques to help identify and evaluate the incremental effects of adding the EPMs 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 proposed EPM and CR Incentive models. We expect to base much of our analysis on secondary data sources such as the Medicare FFS claims. The beneficiary claims data would provide information such as use of CR, expenditures in total and by type of provider and service as well as whether or not there was an inpatient hospital readmission or a subsequent AMI. In conjunction with the secondary data sources mentioned previously, we are considering a CMS-administered survey of beneficiaries who received a qualifying procedure during the performance period in the EPM evaluation. This survey would be administered to beneficiaries who were in the EPM qualifying episode or similar patients selected as part of a control group. The primary focus of this survey would be to obtain information on the beneficiary's experience in EPMs' episodes relative to usual care. The administration of this beneficiary survey would be coordinated with administration of the HCAHPS survey so as to not conflict with or compromise HCAHPS efforts. For the evaluation of both the EPMs and the CR incentive model, we are considering a survey administered by CMS and guided interviews conducted by CMS with providers and suppliers including, but not limited to, initiating and transfer hospitals, physicians, and post-acute care providers participating in the proposed models. These surveys would provide insight on providers' experience under the model and further information on the care redesign strategies undertaken.

In addition, we are considering CMS evaluation contractor administered site visits and focus groups with selected hospitals, physicians, and post-acute care providers in EPM and CR evaluation efforts. We believe that these qualitative methods would provide contextual information that would help us better understand the dynamics and interactions occurring among participants. 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 program nuances as well as identify factors that are associated with successful interventions and distinguish the effects of multiple interventions that may be occurring, such as simultaneous ACO and bundled payment participation.

We anticipate that secondary data sources will be the source of most if not all data collection for the FFS-non CR control group; however, we may initiate some data collection from primary data sources for this group if warranted.

D. Key Evaluation Research Questions

Our evaluation would assess the impact of the proposed models 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, quality, and access. Our key evaluation questions would include, but would not be limited to, the following:

- PAYMENT. Is there a reduction in Medicare expenditures in absolute terms? By subcategories? Do the participants reduce or eliminate variations in utilization and/or expenditures 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 and for specific types of services? How do these patterns compare to matched comparators, 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? For example, in the AMI and CABG episodes, what changes to hospital transfer patterns, if any, could be seen under the models? Has there been any changes to utilization of cardiac rehabilitation services and does this appear to be associated with access to the cardiac rehabilitation incentive payment, participation in the cardiac EPMs or a combination of the two?
- REFERRAL PATTERNS AND MARKET IMPACT. How has the behavior in the selected MSAs changed under the models? Have the referral patterns of type and specific providers changed?
- OUTCOMES/QUALITY. Is there either a negative or positive impact on quality of care and/or better patient experiences of care? Did the incidence of relevant clinical outcomes including but not limited to complications, mortality, readmissions and other subsequent clinically relevant events, and beneficiary pain, functioning, and independence experiences remain constant or decrease? Were there changes in beneficiary outcomes under the models compared to appropriate comparison groups? Was there an impact on quality during the episode/CR care period or in the period immediately preceding or following the episode/CR care period? Was there an impact on measures of relevant long term quality such as mortality at one year after the initiating event?
- UNINTENDED CONSEQUENCES. Did the proposed models result in any unintended consequences, including adverse selection of patients, access problems, cost shifting beyond the episode/CR care period, evidence of delay or stinting of appropriate care, anti-competitive effects on local health care markets, or 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 and how did this compare to regional and national patient populations? What were the characteristics of impacted markets, providers, and patients and to what extent were they reflective of the national sample? Were EPMs and/or the CR incentive model more successful in reducing payments and improving quality in certain types of markets, providers, or patients? To what extent would the results be able to be extrapolated to similar markets and/or nationally?
- EXPLANATIONS FOR VARIATIONS IN IMPACT. What factors are associated with the pattern of results

stated previously? Specifically, are they related to—

++ Characteristics of the administrative features of the models including variations by year and factors such as presence of downside risk;

++ The EPM or CR participant's specific features and structure, including such factors as the number of relevant cases, whether they have ability to handle complex cases, profit status, proportion of dually eligibility patients served, and other considerations;

++ The EPM or CR participant's care redesign or other interventions and their ability to carry out their proposed intervention;

++ The characteristics of the providers and suppliers serving patients during the entirety of the episode or CR care period and the nature of the interaction of these providers and suppliers with the EPM or CR participants;

++ The characteristics of the markets and MSAs, and

++ The clinical and socio-demographic characteristics associated with the patient populations served.

E. Evaluation Period and Anticipated Reports

As discussed in section III.B, the proposed models have a 5-year performance period. The evaluation periods would encompass this entire 5-year period and up to 2 years after. We plan to evaluate the proposed models on an annual basis. We recognize, however, that interim results are subject to issues such as sample size and random fluctuations in practice patterns. Hence, while CMS intends to have internal periodic summaries to offer useful insight during the course of the effort, a final analysis after the end of the 5-year performance period will be important for ultimately synthesizing and validating results.

We seek comments on our design, evaluation, data collection methods, and research questions.

V. Comprehensive Care for Joint Replacement Model

A. Participant Hospitals in the CJR Model

In the CJR proposed rule (80 FR 41207), we proposed to require that all hospitals paid under the IPPS that are physically located in a county in an MSA selected for participation in the CJR model would be required to participate. In the final rule (80 FR 73288), we finalized this proposal, noting that we would use the primary physical address associated with a hospital's CCN to identify whether or not a given hospital was physically located in an MSA selected for participation. In response to a commenter's inquiry as to whether all hospitals under a CCN would be required to participate in CJR if a CCN included multiple hospital campuses and some of these campuses were physically located in the MSA while others were not, we stated that since CMS tracks and identifies hospitals using the CCN, all hospital locations associated with that CCN would be required to participate in the model. In order to identify hospitals located in the MSAs selected to participate in the CJR model, we utilize the primary physical address associated with the CCN. In cases where a CCN is associated with multiple hospital campuses, if the primary CCN address is located in a selected MSAs, all hospital campuses associated with that CCN would be required to participate in CJR unless otherwise excluded. We also noted that our initial analysis of the acute care hospitals in the MSAs selected to participate in CJR indicated that none of the CCNs in the MSAs selected for CJR included multiple campuses crossing MSA boundaries. That is, none of the CCNs with a primary physical address in one of the selected MSAs had multiple campuses physically located in different MSAs that would result in inclusion of a hospital campus not physically located in a selected MSA.

We are not aware of any participant hospitals currently in the CJR model that are not physically located in one of the 67 MSAs chosen to participate in CJR. However, given the comments we received from the public on the CJR proposed rule (80 FR 41207) and questions from stakeholders during our implementation of the CJR model, we note here that if a hospital that is not physically located in one of the 67 MSAs participating in CJR bills under a CCN with a primary address in one of the 67 CJR MSAs, whether through a merger or other organizational change, that hospital will be considered a CJR participant as of the date in which the hospital began to bill under the CCN address located within the 67 MSAs. This policy has been in effect since the start of the CJR model on April 1, 2016 and is laid out at 42 CFR 510.2 (definition of participant hospital).

B. Inclusion of Reconciliation and Repayment Amounts When Updating Data for Quality-Adjusted Target Prices

In response to the CJR proposed rule, commenters encouraged us to include reconciliation payments in updated historical episode spending totals when calculating quality-adjusted target prices for performance years 3 and 4 (based on spending for episodes beginning in years 2014 through 2016) and performance year 5 (based on spending for episodes beginning in 2016 through 2018). (Note that we propose to replace the term ''target price'' with the term ''quality-adjusted target price,'' as described further in section V.C.) Commenters were concerned that if we excluded those payments, we would not account for care coordination services that are not paid for under Medicare FFS, but that participant hospitals paid for using reconciliation payments. As a result, we would underestimate hospital costs and prices by not accounting for care coordination services paid for with reconciliation payments. We finalized our proposal to exclude reconciliation payments from expenditure data, noting our view that including reconciliation payments would result in Medicare paying participant hospitals their quality-adjusted target price, regardless of whether the participant hospital's expenditures were above or below that price. We also noted that we had not proposed an alternative in our proposed rule, and that we might consider including reconciliation payments in updating the set of historical years used to calculate quality-adjusted target prices through future rulemaking (80 FR 73332).

Based upon our further consideration, we propose to include both reconciliation payments and repayments in our calculations when updating quality-adjusted target prices for performance years 3 and 4 and performance year 5. We want to encourage hospitals to invest in novel ways of coordinating care and improving quality, and we recognize that such activities are not directly reimbursed by Medicare. We agree that including reconciliation payments would more fully recognize the total costs of care under an episode payment model than would excluding those payments. The number of comments we previously received on this topic indicates that excluding reconciliation payments could discourage such investment, due to concerns that quality-adjusted target prices would underestimate the true cost of care. Although including the entire reconciliation payment in our updated quality-adjusted target price calculations could result in overpaying for care coordination services, the impact of including these payments on quality-adjusted target prices will decrease as we move to regional pricing. In addition, we believe our proposal to also include repayment amounts when

updating historical data used to calculate quality-adjusted target prices would mitigate any potential overpayment for care coordination services.

In addition, we propose to include in regional historical episode payments any reconciliation payments and repayment amounts from historical BPCI LEJR episodes initiated at regional hospitals in order to most fully capture the total costs of care under episode payment models. If we included reconciliation payments and repayment amounts for CJR episodes but not BPCI LEJR episodes, we would likely underestimate the regional total costs of care to hospitals, which would result in artificially lowered quality-adjusted target prices for participant hospitals, in effect penalizing participant hospitals. By including these amounts from both initiatives we will avoid distorting the regional component of historical LEJR episode spending, which will be especially important once we move to setting prices based on 100 percent regional episode data in performance year 4 of the model. This policy mirrors our proposal to include these reconciliation payments and repayment amounts when updating the historical periods used for EPM quality-adjusted target prices; we refer readers to section III.D.3.e. of this proposed rule for further discussion of our rationale for proposing this approach.

We propose to amend our regulations to add a new subsection § 510.3(b)(8) to reflect this proposal. We seek comment on our proposal.

C. Quality-Adjusted Target Price

We propose to change the term we use to refer to a CJR participant hospital's episode benchmark price incorporating the effective discount factor based on the participant hospital's quality category to ''quality-adjusted target price.'' This term will replace our prior term, ''episode target price,'' which referred to the episode benchmark price with a 3 percent discount applied. The term quality-adjusted target price would represent the price used at reconciliation to determine whether a CJR participant hospital is eligible for a reconciliation payment or repayment, and the amount of the reconciliation payment or repayment. To clarify, this change would be a change of terminology to more accurately reflect the impact of quality scores on the reconciliation process, and would not change the actual data that hospitals receive. In addition, our proposal to replace the term ''episode target price'' with ''quality-adjusted target price'' mirrors the terminology for the proposed EPMs and would reduce confusion for hospitals participating in more than one model.

In accordance with 42 CFR 510.300(b)(7), CMS provides prospective prices to CJR participant hospitals prior to the performance period in which they apply, incorporating the 3 percent discount that would apply if the hospital is eligible for a reconciliation payment and achieves an ''Acceptable'' composite quality score category. As discussed in the CJR final rule, a hospital's effective discount percentage may be reduced at reconciliation to account for quality performance (80 FR 73378). At the conclusion of a performance year, CMS will calculate a composite quality score for each hospital, which determines the effective discount percentage at reconciliation. The CJR final rule outlines the relationship between the composite quality score and the effective discount percentage (80 FR 73365). That is, a participant hospital may be eligible to earn a greater reconciliation payment or have a lower repayment amount as a result of its quality performance under the model (80 FR 73378). Hospitals are therefore aware that a different effective discount factor, and thus different quality-adjusted target price, may be utilized at reconciliation to reflect their quality performance under the model, and they could easily estimate the range of potential quality-adjusted target prices that could apply at reconciliation.

We also wish to clarify the terminology we use to describe the discount factor included in the quality-adjusted target price. The discount factor included in the quality-adjusted target price based on the quality score is referred to as the ''effective discount factor.'' In contrast, the discount factor used to determine repayment amounts in performance years 2 and 3, during which repayment responsibility is being phased in and a lower discount factor applies for purposes of calculating repayment amounts will be referred to as the ''applicable discount factor.'' In performance years 2 and 3, the effective discount factor would continue to apply for hospitals that qualify for and earn a reconciliation payment; the applicable discount factor would only be applied in those cases where a hospital exceeded expected episode spending and would be responsible for repayment.

We propose to implement these terminology changes in all communications with participant hospitals 60 days after the change is finalized. We propose to establish these definitions in the regulations at § 510.2 and update our regulations at § 510.300 and § 510.315 to reflect our use of the term ''quality-adjusted target price'' in lieu of ''episode target price'' and our use of the term ''applicable discount factor.''

D. Reconciliation

1. Hospital Responsibility for Increased Post-Episode Payments

As discussed in the CJR final rule, participant hospitals will be responsible for repaying Medicare for post-episode spending that exceeds 3 standard deviations from the regional mean (80 FR 73408). We refer readers to the CJR final rule (80 FR 73407) for further discussion of our rationale for holding participant hospitals financially accountable for significant increases in Medicare Parts A and B spending during the 30 days after a CJR episode ends. We also finalized a policy to include the result of our post-episode spending calculation (the amount exceeding 3 standard deviations above the regional mean) in a participant hospital's NPRA for a given performance year; as a result, a hospital's financial responsibility for post-episode spending would be subject to the stop-loss and stop-gain limits we finalized for the CJR model (80 FR 73398).

We propose to modify our policy to hold hospitals responsible for post-episode payments that exceed 3 standard deviations from the regional mean. First, we propose to calculate post-episode payments using the same timeframes we use for the subsequent reconciliation calculation, not when we conduct the initial reconciliation for a performance year (80 FR 73383). Given that we will begin reconciliation calculations 2 months after the conclusion of a performance year, we do not believe there would be sufficient time for claims run-out in order to set a reliable regional threshold for determining post-episode spending. Since in all cases any responsibility for post-episode payments would decrease a participant hospital's reconciliation payment or increase its repayment amount, our proposed change would more accurately and fairly hold hospitals accountable for increased post-episode spending. We believe instances in which a CJR participant hospital is responsible for post-episode spending repayment will be rare, given our belief that hospitals in the CJR model will focus on care redesign during the LEJR episode and our other monitoring efforts under the CJR model. Our intent is to prevent hospitals from delaying services or care until the conclusion of a CJR episode by

monitoring for cases in which hospitals have significantly increased spending in the 30 days following the episode. Assessing post-episode spending when we have more complete claims information would allow a more accurate assessment of hospitals' behavior under the model and prevent potentially high fluctuations in results that may occur if we calculate regional thresholds and hold hospitals responsible for post-episode spending beginning 2 months after the conclusion of a performance year. We propose that this modified timeline would be applied to our reconciliation of the first CJR performance year and all performance years thereafter. That is, we would assess post-episode spending for the first performance year (episodes beginning and ending between April 1, 2016 and December 31, 2016) when we conduct the reconciliation for the second CJR performance year (2017) in early 2018.

We also propose that hospital responsibility for post-episode spending will not be subject to the stop-loss and stop-gain limits. Although we believe, as noted previously, that hospital responsibility for post-episode spending will be rare, we also believe that in those cases where a hospital has financial responsibility for post-episode spending, such hospitals should be responsible in full for these amounts. The CJR model includes stop-loss limits, including more generous limits for certain types of hospitals (80 FR 73403), which are designed to limit a participant hospital's responsibility for episode spending above the quality-adjusted target price during the anchor hospitalization and 90-day post-discharge period. The stop-loss limits are not intended to protect hospitals that engage in inappropriate behavior or shifting of care beyond the episode from financial responsibility for such actions.

We propose to implement this policy change when we conduct the subsequent reconciliation calculation for performance year 1 of the model in the first 2 quarters of 2018 and for all performance years thereafter. That is, when we conduct the reconciliation for performance year 1 in early 2017, we would not assess post-episode spending for performance year 1 at that time. Although hospitals would not have been aware of these proposed changes to our reconciliation process during performance year 1 of the model, the proposed changes will not impact the performance year 1 NPRA.

We propose to amend our regulations at § 510.305(e), § 510.305(h)(6), and add a new paragraph § 510.305(j)(2) to reflect these proposals. We seek comment on our proposal.

2. ACO Overlap and Subsequent Reconciliation Calculation

In the CJR final rule, we finalized a policy to account for overlap in situations where a portion of the CJR discount percentage is paid out as savings to an ACO participating in the Shared Savings Program or specified ACO models. We refer readers to the CJR final rule for further discussion of this policy and our rationale for this approach (80 FR 73395–73398). We propose a modification to how we will account for such cases of overlap in the CJR model at reconciliation. In the final CJR rule, we specified that the results of this overlap calculation would be included in the subsequent reconciliation calculation that occurs 14 months after the conclusion of a performance year (80 FR 73383). We propose that the subsequent reconciliation calculation not include the results of this ACO overlap calculation; that is, the subsequent reconciliation calculation will only include calculating the prior performance year's episode spending a second time with more complete claims data and comparing it to the quality-adjusted target price. The ACO overlap calculation will be a separate calculation from the subsequent reconciliation (although both calculations will occur concurrently) and added with the NPRA, subsequent reconciliation calculation, and post-episode spending calculation to determine the reconciliation payment or repayment amount at reconciliation. The effect of this proposal will be that these overlap amounts will not be subject to the stop-loss or stop-gain limits that apply to the calculation of the NPRA and subsequent reconciliation calculation. We believe this change is appropriate because the subsequent reconciliation calculation is intended to account for claims run-out and canceled episodes, and to reassess CJR episode spending during the model performance years. The stop-loss limit, therefore, is intended to ensure that participant hospitals that do not reduce actual episode payments below the quality-adjusted target price have a limit on the amount they must repay Medicare due to spending during CJR episodes. The stop-gain limit, conversely, is intended to place judicious limits on the degree to which hospitals can be rewarded based on responsible stewardship of CMS resources. In contrast, the ACO overlap calculation is intended to account for cases in which a portion of the CJR discount percentage is paid out to an ACO as shared savings, and does not hinge upon a participant hospital's performance in the CJR model. If ACO overlap amounts are included in calculations of the stop-loss limit, CMS could in some cases pay twice for the same cost-reducing activities, thereby skewing the model results. We believe the stop-loss and stop-gains should provide limits on the amount a hospital could earn or lose due to episode spending, not limit CMS's ability to adjust for overlap between models. For these reasons, we do not believe our policy to avoid paying out savings twice for the same beneficiary during the same period should be subject to the stop-loss or stop-gain limits. More details on how this proposed modification will impact the steps involved in the reconciliation process are provided further in this section.

We propose to implement this proposed policy change when we conduct the subsequent reconciliation calculation for performance year 1 of the model in the first 2 quarters of 2018 and for all performance years thereafter. Although hospitals would not have been aware of these proposed changes to our reconciliation process during performance year 1 of the model, we believe this timeframe is reasonable for the following reasons. First, if CMS must recoup a portion of the CJR discount percentage paid out as shared savings, this calculation must occur during the same timeframe as the subsequent reconciliation calculation for a given performance year to ensure that the ACO models and program have already completed their financial reconciliation for a given performance year. Second, this policy change (that is, not including the ACO overlap calculation in assessing whether a hospital has met the stop-loss or stop-gain limit for a given year) will not impact the performance year 1 NPRA.

We propose to add a new paragraph to our regulations at § 510.305(i). We seek comment on our proposal.

3. Stop-Loss and Stop-Gain Limits

In the CJR final rule, we finalized our proposal to limit the amount a CJR participant hospital will be required to repay Medicare or could earn as a reconciliation payment under the CJR model. Specifically, we stated that CJR participant hospitals would be subject to the following stop-loss limits: 5 percent in performance year 2, 10 percent in performance year 3, and 20 percent in performance years 4 and 5. Similarly, we finalized symmetrical stop-gain limits: 5 percent in performance years 1 and 2, 10 percent in performance year 3, and 20 percent

in performance years 4 and 5 (80 FR 73401 through 73402). We finalized separate limits to provide additional financial protections for rural hospitals, Medicare-dependent hospitals, rural referral centers, and sole community hospitals (80 FR 73406). These limits are intended to provide financial protections for CJR participant hospitals, who may have varying levels of experience with episode payment models. We finalized symmetrical stop-gain limits to ensure hospitals do not have an incentive to excessively reduce services provided during episodes or shift services outside the CJR episode (80 FR 73398). As noted previously in this section, we are proposing a modification to our application of the stop-loss and stop-gain limits for the CJR model by excluding the post-episode spending amount and situations in which the CJR discount percentage is paid out to an ACO as shared savings.

In light of our proposal to exclude the ACO overlap and post-episode spending adjustments from the stop-loss and stop-gain limits, to calculate the stop-loss and stop-gain limits, we would use a hospital's quality-adjusted target price at reconciliation. For example, a hospital with benchmark episode spending of $30,000 and a composite quality score of ''excellent,'' would have an effective discount percentage of 1.5 percent and a quality-adjusted target price of $29,550 at reconciliation. The hospital's stop-loss and stop-gain limits for year 2 (assuming for simplicity that the hospital has only 1 episode) would be 5 percent of the quality-adjusted target price, or $1,477.50. This is consistent with our proposed calculation of stop-loss and stop-gain limits for the proposed EPMs described in section III.C. of this proposed rule. This approach is also consistent with our regulations at § 510.305(e)(1)(v)(A) and § 510.305(e)(1)(v)(B) to calculate stop-loss and stop-gain based on the effective discount factor at reconciliation.

In order to determine whether a participant hospital has reached the stop-loss or stop-gain limits, we would compare actual episode payments during the performance year to the quality-adjusted target price to calculate the NPRA. In the example previously noted, if the participant hospital had actual episode spending of $35,000 during performance year 2, this would be compared against its quality-adjusted target price of $29,550. The difference between the quality-adjusted target price and actual episode spending is $5,450, but since the applicable stop-loss limit is $1,477.50, the hospital would need to repay Medicare $1,477.50. In this example, any post-episode spending amount or adjustment for ACO overlap from the prior performance year (performance year 1 in this example) would not be included in determining whether a hospital has met the stop-loss or stop-gain limit for a performance year, but rather would be added, unadjusted, to the performance year 2 NPRA in order to calculate the reconciliation payment or repayment amount. Therefore, if the hospital in this example owed $1,000 due to post-episode spending in performance year 1, and we determined that $2000 represented the CJR discount percentage that was paid out as shared savings for performance year 1, the full $3000 would be added to the hospital's performance year 2 NPRA regardless of stop-loss, resulting in a repayment of $4,477.50. In addition, when performing the subsequent reconciliation calculation for performance year 2, which would be done simultaneously with the calculation of NPRA for performance year 3, we would apply the results of the performance year 2 subsequent reconciliation calculation to the year 2 stop-loss limit of $1,477.50 to ensure that, aggregated across all episodes in the performance year, the participant hospital is not responsible for repaying Medicare more for episode spending above the quality-adjusted target price than the stop-loss limit for that performance year. Thus, if the subsequent reconciliation calculation determined that the hospital in our example had actually spent $36,000 during performance year 2, resulting in a larger difference between actual spending and the quality-adjusted target price, the higher amount of $6,450 would still be subject to the stop-loss limit of $1,477.50, so the hospital would not be responsible for the additional $1,000 of episode spending beyond the quality-adjusted target price.

As discussed previously in this section, we are proposing to implement these changes to our reconciliation process beginning with the reconciliation for performance year 1.

We are proposing to amend our regulations at § 510.305(e), § 510.305(f), and add a new paragraph (j) to reflect these proposals. We also propose to streamline § 510.305(i)(2) for clarity.

We seek comment on our proposal.

4. Proposed Modifications to Reconciliation Process

As previously discussed in this section, we are proposing several modifications to how we conduct the reconciliation process for participant hospitals in the CJR model for all performance years. We propose here how these steps would modify the CJR reconciliation process we finalized in the CJR final rule (80 FR 73383).

The following example illustrates our proposed modifications to the reconciliation process, reflecting our proposals to compare actual episode payments to the quality-adjusted target price; calculate post-episode spending beginning 14 months after the conclusion of a performance year; calculate post-episode spending amounts and the ACO overlap calculation separately from the NPRA and subsequent reconciliation calculation; and apply the stop-loss and stop-gain limits only to calculations of NPRA and the subsequent reconciliation calculation (that is, exclude post-episode spending amounts and the ACO overlap calculation) for a given performance year:

Beginning 2 months after the conclusion of performance year 2, CMS would compare actual episode payments to the quality-adjusted target prices for the episodes at a CJR participant hospital. The quality-adjusted target price that applies at reconciliation would be based on a participant hospital's composite quality score for performance year 2. We would aggregate episodes at each CJR participant hospital and calculate the hospital's NPRA. The NPRA would be the difference between the quality-adjusted target price times the number of episodes and actual episode payments times the number of episodes during the performance year. We would apply the stop-gain and stop-loss limits of 5 percent of the quality-adjusted target price to determine if a hospital reached the limit.

We would simultaneously perform the subsequent reconciliation calculation for performance year 1, to account for claims run-out and canceled episodes from performance year 1. At this time, we would reapply the stop-gain limit for performance year 1, by summing the result of the subsequent reconciliation calculation for performance year 1 and the performance year 1 NPRA (which was calculated during the prior reconciliation). For example, if the participant hospital's NPRA for performance year 1 was greater than the stop-gain limit and the result of the subsequent reconciliation calculation for performance year 1 was positive, the subsequent reconciliation calculation would not be added to the reconciliation payment made to the participant hospital in the second quarter of 2018, because the stop-gain limit had already been reached for performance year 1.

Concurrently with our subsequent reconciliation calculation, we would also determine if a participant hospital is responsible for post-episode spending from performance year 1, as well as determine any potential amount of the CJR discount percentage that was paid out as savings to an ACO entity as previously described in this section during performance year 1. In this example, the results of all three calculations (the subsequent reconciliation calculation for performance year 1—subject to the stop-loss and stop-gain limits—and the post-episode spending calculation and ACO overlap calculation) would be added to the NPRA calculated for performance year 2 in order to create the reconciliation payment or repayment amount. (The exception to this pattern will be performance year 5, as the subsequent reconciliation, post-episode spending, and ACO overlap calculations will occur in 2022 without a concurrent NPRA calculation.)

We note that this approach mirrors the reconciliation process we are proposing for the AMI, CABG, and SHFFT models at III.D.5. of this proposed rule. We refer readers to that section for additional discussion of our approach.

E. Use of Quality Measures and the Composite Quality Score

1. Hospitals Included in Quality Performance Distribution

As finalized in the CJR final rule, 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. We propose to compute quality performance points for each quality measure based on the participant hospital's performance relative to the distribution of performance of all ''subsection (d)'' hospitals reporting the measure that are eligible for payment under IPPS and meet the minimum patient case or survey count for that measure. This approach is similar to the methodologies of other CMS programs, such as the HVBP Program. In addition, comparing CJR participant hospitals' quality performance to IPPS-eligible subsection (d) hospitals' quality performance on the same measures is a fairer comparison of quality performance, as CJR participant hospitals are all IPPS-eligible subsection (d) hospitals. Defining and limiting the relative distribution in this way will minimize variability due to factors that are unrelated to quality, thereby increasing the validity of the quality performance score.

We propose to amend the regulations at § 510.315(c) to reflect this change. We are also proposing a technical change to the regulations to renumber certain subparagraphs. We seek comment on our proposals.

2. Quality Improvement Points

As finalized in the CJR final rule, quality improvement points for each measure are added to the composite quality score if the hospital's score on that quality measure increases by at least 3 deciles on the performance percentile scale compared to the previous performance year. We propose to clarify that, for performance year 1, we will compare the hospital's performance percentile with the corresponding time period in the previous year, not the previous performance year. We are proposing this clarification because there is no performance year preceding performance year 1. For performance years 2 through 5, we will still compare the hospital's performance percentile with the previous performance year. We also propose to modify this policy to define quality measure improvement as an increase of at least 2 deciles on the performance percentile scale compared to the previous performance year. Reducing the threshold for improvement from 3 deciles to 2 deciles will increase the number of CJR participant hospitals eligible for quality improvement points and provide CJR participant hospitals at all current levels of quality performance, including those historically lagging, with significant incentives to achieve improvement in the quality of care. Quality improvement points can contribute up to 1.8 points toward a CJR participant hospital's composite quality score, so increasing the number of CJR participant hospitals that are eligible for these points may also increase the number of CJR participant hospitals that are eligible for a reduced quality-adjusted target price. As defined in section V.C. of this proposed rule, the quality-adjusted target price is the price used at reconciliation to determine whether a CJR participant hospital is eligible for a reconciliation payment or repayment and the amount of the reconciliation payment or repayment. This mirrors the approach we are proposing for the proposed EPMs at III.E.3.c. of this proposed rule.

We propose to amend our regulations at § 510.315(d) to reflect these changes. We seek comment on our proposal.

3. Relationship of Composite Quality Score to Quality Categories

As finalized in the CJR final rule, CMS will place participant hospitals into one of four quality categories to determine reconciliation payment eligibility and, if applicable, the value of the effective discount percentage at reconciliation. We refer readers to the CJR final rule for a full discussion of our approach (80 CFR 73363–73381). We describe here a technical correction to our composite quality scores that will determine reconciliation payment eligibility and the effective discount percentage at reconciliation. We note that this technical correction does not affect our estimation of savings due to the CJR model, because the measure distribution used for such calculations in the CJR final rule was the correct one we describe here.

Participant hospitals will be required to achieve a minimum composite quality score of greater than or equal to 5.0 to be eligible for a reconciliation payment if actual episode spending is less than the target price. Participant hospitals with a composite quality score less than 5.0 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. Participant hospitals with a composite quality score greater than or equal to 5.0 and less than 6.9 will be assigned to the ''Acceptable'' quality category and will be eligible for a reconciliation payment if actual episode spending is less than the target price. Participant hospitals in the ''Acceptable'' quality category will not be eligible to receive a reduced effective discount percentage at reconciliation. Participant hospitals with a composite quality score greater than or equal to 6.9 and less or equal to 15.0 will be assigned to the ''Good'' quality category and will be eligible for a reconciliation payment if actual episode spending is less than the target price. Participant hospitals in the ''Good'' quality category will be eligible to receive a reduced effective discount percentage (80 FR 73378). Participant hospitals with a composite quality score greater than 15.0 will be assigned to the ''Excellent'' quality category and will be eligible for a reconciliation payment if actual episode spending is less than the target price. Participant hospitals in the ''Excellent'' quality category will be eligible to receive a reduced effective discount percentage (80 FR 73378).

4. Maximum Composite Quality Score

As finalized in the CJR final rule, a participant hospital could be awarded a

maximum composite quality score of 21.8 if the hospital received maximum quality performance points for each quality measure, maximum quality improvement points for each quality measure, and successfully submitted voluntary patient-reported outcomes and limited risk variable data. We propose to award up to 10 percent of the maximum measure performance score on the THA/TKA Complications and HCAHPS Survey measures, and impose a cap on the CJR model composite quality score at 20 points. This change would bring calculation of the CJR composite quality score into greater alignment with existing CMS programs, such as the HVBP Program, by reducing the number of participants who receive both the highest quality performance score on a measure and the maximum points for measure improvement.

We propose to amend our regulations at § 510.315(d) to reflect this change. We seek comment on our proposal.

5. Acknowledgement of Voluntary Data Submission

Our regulations at 42 CFR 510.400(c)(3) state that although we do not publicly report the voluntary patient-reported outcomes and limited risk variable data during the CJR model, we do indicate whether a hospital has voluntarily submitted such data. We propose to amend § 510.400(c)(3) to clarify that we would acknowledge only CJR participant hospitals that successfully submit voluntary patient-reported outcomes and limited risk variable data, in accordance with § 510.400(b). We seek comment on our proposal.

6. Calculation of the HCAHPS Linear Mean Roll-Up (HLMR) Score

We propose to calculate the HCAHPS Linear Mean Roll-up (HLMR) score by taking the average of the linear mean scores (LMS) for 10 of the 11 publicly reported HCAHPS measures for IPPS hospitals with 100 or more completed HCAHPS surveys in a 4-quarter period. The HLMR will summarize HCAHPS performance on all of the publicly reported measures, except for Pain Management. We propose this change because removal of Pain Management from the HVBP Program has been proposed in the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (81 FR 45603).

This mirrors the approach we are proposing for the proposed EPMs at III.E.4.d.(1)(f) of this proposed rule. Our regulations do not include the methods to calculate the HLMR, so we refer readers to III.E.4.d.(1)(f) of this proposed rule for additional discussion of our approach.

We propose to implement the proposed changes to hospitals included in the quality performance distribution, the maximum number of points in the composite quality score, the change from 3 to 2 deciles for assessing quality improvement, and calculation of the HLMR score starting with the reconciliation for performance year 1 of the CJR model, when we calculate each participant hospital's composite quality score for year 1.

F. Accounting for Overlap With CMS ACO Models and the Shared Savings Program

The CJR final rule details our policies to address cases of overlap in which beneficiaries that are aligned or attributed to an ACO model or Shared Savings Program participant are also included in a CJR episode. We recognize that there will be circumstances in which a Medicare beneficiary in a CJR episode is also aligned or attributed to an ACO participating in the Shared Savings Program or a CMS ACO model. In the CJR final rule, we finalized an approach to allow for such cases of overlap and minimize any double counting of savings through the following policies. We will conduct our annual reconciliation prior to the ACO reconciliation process, and make our reconciliation payments and repayment amounts available for the ACO models and program to take into account when performing their reconciliation, as their financial methodologies permit. In addition, in cases where a portion of the CJR discount percentage is paid out as shared savings to a participant hospital that participates in an ACO as a participant or provider/supplier, we would make an adjustment to the participant hospital's reconciliation results. We refer readers to the CJR final rule for a full discussion of our approach and the options we considered (80 FR 73387).

Given commenters' concerns about our approach, which are summarized in the final rule (80 FR 73387) we have continued to consider alternative options for accounting for overlap between the ACO models and program and the CJR model. Specifically, we have considered, as some commenters suggested, attributing savings achieved during CJR episodes in which beneficiaries are also aligned or attributed to an ACO accepting downside risk to the ACO entity, not the participant hospital. We recognize that ACOs are engaged in care management activities for beneficiaries across the spectrum of care, which may also include care redesign during acute episodes. As a result, we are proposing to cancel (or never initiate) a CJR episode for beneficiaries that are prospectively aligned to a Next Generation ACO or ESRD Seamless Care Organization (ESCO) in the Comprehensive ESRD Care initiative in tracks with downside risk for financial losses. While the CJR model excludes beneficiaries whose eligibility for Medicare is on the basis of end stage renal disease, not all beneficiaries aligned to ESCOs meet this criterion. Thus, some beneficiaries aligned to ESCOs could be included in the CJR model.

We propose to implement this policy for episodes beginning on or after July 1, 2017, to align with the timeframe for implementation of the proposed AMI, CABG, and SHFFT models which propose the same exclusion of beneficiaries aligned to Next Generation ACOs and ESCOs in downside risk tracks. We propose this change to how we determine episodes included in CJR because these ACOs and ESCOs are accepting a high level of financial risk for the total cost of care for their aligned beneficiaries; for example, Next Generation ACOs are held to as much as 80 percent to 100 percent of first dollar losses. In addition, beneficiaries are prospectively aligned to ACOs in both initiatives. We believe that if we were to implement a policy where we would cancel CJR episodes based on a given beneficiary's ACO alignment status, we would do so only in those cases where the ACO alignment is prospective and does not change during a performance year. In such cases, CJR participant hospitals could be aware of a beneficiary's ACO alignment status, reducing uncertainty as to whether a given beneficiary is included in the CJR model. We note that we are proposing elsewhere in this proposed rule to exclude beneficiaries prospectively aligned to a Next Generation ACO model participant or an ESCO in the Comprehensive ESRD Care Initiative in a downside risk track from the proposed AMI, CABG, and SHFFT model episodes because we wish to test this alternative approach to ACO overlap. We are not proposing to exclude beneficiaries assigned to Shared Savings Program Track 3 ACOs at this time, however, because we intend to test the approach of excluding prospectively-aligned ACO beneficiaries from the CJR model with the limited number of beneficiaries assigned to Next Generation ACOs and ESCOs in a downside risk track. We do not seek to disrupt the operations of our large,

permanent ACO program at this time to test this novel approach for accounting for overlap. The Shared Savings Program is a national program; we do not believe that testing a new approach to addressing overlap in a national program would be appropriate at this time prior to testing such an approach with a smaller population. However, we seek comment on whether we should extend this proposed policy—that is, excluding from CJR beneficiaries who are prospectively assigned to an ACO—to beneficiaries who are assigned to a Track 3 Shared Savings Program ACO. We refer readers to section III.D.6.c. of this proposed rule for further discussion of our proposed approach and rationale, including details on how we would operationalize such an approach if finalized for CJR or the proposed EPMs.

In cases where a beneficiary is in a CJR episode and also aligned to a Pioneer ACO, Medicare Shared Savings Program ACO, or ESCO not participating in a downside risk track, we would not cancel the CJR episode. The policies we previously finalized for accounting for such overlap would continue to apply. We refer readers to the CJR final rule (80 FR 73391 through 73398) for additional discussion of our policies. Because the Pioneer ACO model ends on December 31, 2016, no adjustments are necessary to account for overlap between beneficiaries in the proposed AMI, CABG, and SHFFT models and the Pioneer ACO model. However, since the first CJR performance year began in April 2016, we will make an adjustment for overlap between the two models during the first performance year of the CJR model.

Finally, we note that we are proposing elsewhere in this proposed rule to allow ACOs to be CJR collaborators. Our proposal, which is discussed in detail in section V.J.1.a. of this proposed rule, would allow for gainsharing arrangements between ACOs and CJR participant hospitals. This proposal would allow such partnerships in regions where such relationships could be mutually beneficial for ACOs and CJR participant hospitals. We believe these proposals will mitigate concerns about the limited opportunities for collaboration between ACOs and CJR participant hospitals that are often caring for the same beneficiaries. We refer readers to section V.J.1.a. of this proposed rule for additional detail on this proposed policy.

The proposal for addressing overlap between the CJR model and CMS's ACO models and program is included in § 510.305(j)(1). We seek comment on our proposal to exclude beneficiaries aligned to a Next Generation ACO or ESCO downside risk track from the CJR model beginning with episodes that are initiated on or after July 1, 2017.

G. Appeals Process

The CJR final rule provides that participant hospitals may dispute a 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, if the hospital wishes to dispute such calculation. Unless the participant hospital provides a written notice of the error, the CJR reconciliation report is deemed final 45 calendar days after it is issued, and CMS will then proceed with the payment or repayment process as applicable. In order to further specify our timeline for this process, we propose that a timely notice of a calculation error means a notice received by CMS within 45 calendar days of CMS issuing a participant hospital's reconciliation report.

In continuing our efforts to be clear and concise, we propose to add language to our regulations highlighting the available appeals process for a participant hospital that receives a notice of termination from the CJR model. We previously described this appeals process for notice of termination in the CJR final rule at § 510.310(c), by using the notice of termination as an example of an exception to a participant hospital having to provide CMS with notice of calculation error. A notice of calculation error continues not to be required by participant hospitals that receive a notice of termination, as this matter does not involve an issue contained in, or a calculation that contributes to, a CJR reconciliation report. We propose that if a participant hospital receives notification that it has been terminated from the CJR model and wishes to appeal such termination, it must provide a written request for reconsideration to CMS requesting review of the termination within 10 calendar days of the notice. Following receipt of the participant hospital's timely written request, CMS would have 30 days to respond to the participant hospital's request for review. If the participant hospital fails to notify CMS, the termination would be deemed final.

We propose to amend the regulations at § 510.310 to reflect these proposals, and to correct a technical error in paragraph (d)(6) (which would be renumbered (e)(6)). We also propose to delete § 510.310(a)(3) in the current regulations as it is duplicative with § 510.310(a)(1). We seek comment on our proposal.

H. Beneficiary Notification

Currently, CMS requires participant hospitals and CJR collaborators to provide written notice to any Medicare beneficiary that meets certain criteria in § 510.205 of his or inclusion in the CJR model detailing the structure of the model, existence of providers and suppliers with whom the participant hospital has a sharing arrangement, and that the beneficiary retains the freedom of choice. We refer readers to the CJR final rule (80 FR 73516–73521) for further discussion of this requirement. We propose to amend § 510.405 to include all CJR collaborators in the requirements for delivery of beneficiary notices and streamline our current regulations. We seek comments on all aspects of this proposal.

1. Physician, Nonphysician Practitioner, and PGP Provision of Notice

We propose to amend § 510.405(b)(2), which specifies that a physician who is a CJR collaborator must provide notices to CJR beneficiaries, to include PGPs. The CJR final rule included a requirement that physician collaborators provide notice to beneficiaries, but did not include a requirement that PGP collaborators or nonphysician practitioners also do so. Since PGPs and nonphysician practitioners may also be CJR collaborators, we believe it is important for PGPs and nonphysician practitioners to have a distinct notification requirement as well as physicians that are CJR collaborators. Requiring these collaborators to notify beneficiaries of the CJR model will help to ensure that beneficiaries are aware of the model and its potential effect on their care.

We propose to amend our regulations at § 510.405(b)(2) to reflect this change. We seek comment on our proposal.

2. Other CJR Collaborators Provision of Notice

Given that we are proposing in V.J.1.a. of this proposed rule to add hospitals, ACOs, and CAHs to our definition of CJR collaborator (see section V.J.1 of this proposed rule), we also propose to require that all CJR collaborators other than physicians and PGPs (ACOs, CAHs, hospitals, and post-acute care providers) provide notice of the model to CJR beneficiaries. We propose that in the case of ACOs, the ACO would require the ACO participants for which the ACO has an ACO distribution arrangement to provide the written notification. We propose that a

participant hospital must require any CJR collaborator to provide written notice of the structure of the model and the existence of the hospital's 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 CJR collaborator or their collaboration agent during the CJR episode. We propose to amend our regulations at § 510.405(b)(4) to reflect this change.

3. Beneficiary Notification Compliance and Records

We propose that participant hospitals and CJR collaborators must be able to, upon request by CMS, demonstrate compliance with the applicable beneficiary notification requirements. The participant hospital or CJR collaborator, as applicable, would be required to provide CMS or its designee with a list of beneficiaries that have received such notification, including the date the notification was given. We note that the method employed to document beneficiary notification may vary. For example, some hospitals and collaborators may retain a list of all beneficiaries that received the notification. Others may document in the medical record that the beneficiary received the beneficiary notification, add a barcode to the notification form to be scanned into the medical record, or employ another method of recordkeeping. Regardless of the method used by the individual hospital or collaborator for recordkeeping, the entity must be able to provide CMS or our designee with a list of all beneficiaries that received the notification materials within the time period specified in the request. This requirement will aid CMS in monitoring participant hospitals for compliance with the CJR requirements.

We propose to amend our regulations at § 510.405(b)(1) through § 510.405(b)(5) and § 510.405(b)(7) to reflect this change. We seek comment on our proposal.

4. Compliance With § 510.110

We propose elsewhere in this rule to consolidate and streamline our requirements for record retention (see section V.L. of this proposed rule for further details). As part of that proposed change, we also propose to require that participant hospitals and CJR collaborators, as applicable retain such records as are necessary to demonstrate the sufficiency of CJR beneficiary notifications.

I. Compliance Enforcement

We propose numerous amendments to the regulations in § 510.410. The amendments are largely to align terminology so that the CJR model regulations mirror the proposed EPM regulations at § 512.460 in order to avoid confusion for hospitals that are participating in CJR and one or more of the proposed EPMs. Our proposed changes reflect that the requirements and rules regarding compliance enforcement under the CJR model would stay mostly the same. However, we are proposing the following changes in § 510.410 to adapt it to our proposal to amend the regulations at § 510.500 and § 510.505, as well as the addition of § 510.506. We propose to replace the term 'collaborator agreement' with the term 'sharing arrangement' since we propose further in section V.J.1.b. of this proposed rule to consolidate the requirements of a collaborator agreement into requirements of a sharing arrangement, and to delete the term 'collaborator agreement' from part 510.

1. Failure To Comply

Currently, CMS may take remedial action against a participant hospital if a participant hospital or any of the hospital's CJR collaborators are noncompliant with CJR requirements in any of the ways listed in § 510.410(b)(1). As discussed in section V.J.1.a. of this proposed rule, the proposed addition of ACOs and hospitals, including CAHs, as CJR collaborators, and the proposed modification of the financial arrangements available under the CJR model, would require collaboration agents and downstream collaboration agents to comply with the CJR model requirements as well. We believe that because we are allowing additional entities and individuals to be CJR collaborators, collaboration agents, or downstream collaboration agent, we must ensure that all such entities and individuals comply with all requirements of the CJR model, such as notifying beneficiaries of the model and maintaining access to care. We believe that CJR participant hospitals should ensure that their sharing arrangements and the distribution arrangements and downstream distribution arrangements of their collaborators, collaboration agents, and downstream collaboration agents comply with the model requirements and safeguard program integrity. Therefore, we propose that CMS may take remedial actions against the participant hospital if any collaboration agent of such participant hospital's CJR collaborators, or any downstream collaboration agent of such CJR collaboration agent is not compliant with applicable requirements in any of the ways listed in of § 510.410(b)(1). Further, we propose that CMS may take remedial actions against a participant hospital if a participant hospital or any of the participant hospital's CJR collaborators, any collaboration agent of such CJR collaborators or any downstream collaboration agent has signed a sharing arrangement, distribution arrangement, or downstream distribution arrangement that is noncompliant with the requirements of part 510.

We propose to amend the regulations at § 510.410 to include these requirements. We seek comment on our proposal.

J. Financial Arrangements Under the CJR Model

Currently, participant hospitals may engage in financial arrangements under the CJR model. The arrangements published in the CJR final rule (80 FR 73412 through 73437) allow participant hospitals and providers and suppliers caring for CJR beneficiaries to share in the financial risks and rewards under the CJR model, to engage in care redesign and CJR beneficiary care management, and to establish close partnerships with these individuals and entities to promote accountability for the quality, cost, and overall care for CJR beneficiaries. In order to ensure that goals of the CJR model are met, and to ensure program integrity and protect from abuse, the CJR model has many requirements for financial arrangements. The sections further discuss and propose amendments to these requirements and safeguards, as well as amendments to align the CJR model with the proposed regulations of the EPMs. We propose a full replacement for the prior CJR regulations at § 510.500 and § 510.505 in order to streamline and consolidate our regulations in line with the proposed financial arrangements for the EPMs at § 512.500 and § 512.505. Our proposed changes are largely organizational in nature, not changes to policy or requirements. However, in several cases we are proposing new financial arrangements policies and/or requirements for the CJR model; we discuss these proposed policies in detail later in this section. We also refer readers to section III.J. of this proposed rule for further discussion and rationale behind our proposed approach.

We propose that all amendments to regulations discussed in this section would be effective beginning July 1, 2017, in order to align with the beginning of the first performance year

of the proposed EPMs. We seek comment on all proposals discussed further in this section.

1. Definitions Related to Financial Arrangements

a. Addition to the Definition of CJR Collaborators

In order to align with the proposed financial arrangements for the EPMs and to provide further opportunity for coordination between participant hospitals and their partners in care redesign, we propose to allow the following entities to be CJR collaborators: ACOs (with the limitations discussed later in this section), hospitals, and CAHs. We believe this proposal would allow for increased care coordination opportunities across the spectrum of care for beneficiaries in CJR episodes. Given that our proposals in this section mirror those proposed for the EPMs in section III.I.3. of this proposed rule, we refer readers to that section for further discussion of our rationale for allowing ACOs, hospitals, and CAHs to be collaborators.

Many ACOs and other stakeholders have expressed strong interest in being collaborators in episode payment models such as CJR. In the CJR final rule, we did not include ACOs in the definition of CJR collaborators, responding that we decided to limit the testing of gainsharing relationships to solely those between hospitals and providers and suppliers enrolled in Medicare because we expected enrolled providers and suppliers to be most directly and specifically engaged with the CJR participant hospital in care redesign and episode care for beneficiaries who had surgery at the participant hospitals (80 FR 73417). We also noted that a number of scenarios discussed by commenters to support their request to allow ACOs to be CJR collaborators could be achieved outside of the context of gainsharing relationships between the participant hospital and ACOs. However, with the steady growth in the number of ACOs and ACO-attributed beneficiaries, we have further considered the potential for ACOs to be CJR collaborators, especially given ACO expertise in care coordination and accountability for the quality and expenditures for health care for ACO-attributed beneficiaries over an annual period. In addition, we note that the challenges of attributing savings and changes in the quality of care for beneficiaries simultaneously in CJR and total cost-of-care models or programs, such as ACOs, remain not fully resolved, as discussed in section III.D.6. of this proposed rule.

We propose that ''ACOs,'' meaning accountable care organizations, as defined at § 425.20 of regulations of this chapter, that participate in the Medicare Shared Savings Program, be permitted to be CJR collaborators. This proposal would allow locally variable financial arrangements that could account for the way CJR episode care is coordinated and managed in communities, and ensure that entities with appropriate skills and experience are permitted to share in the risks and rewards with participant hospitals. Our proposal would not allow any entities that are not providers or suppliers to be CJR collaborators other than ACOs. Medicare has a close relationship with these ACOs who are regulated by CMS, so we can verify that these ACOs meet current Shared Savings Program requirements that could make them suitable for a role as CJR collaborators.

We also propose to allow participant hospitals to enter into financial arrangements with other hospitals and CAHs that care for CJR beneficiaries. We believe it is important to allow participant hospitals to enter into financial arrangements with other hospitals and CAHs that care for CJR beneficiaries, in order to align the financial incentives of such other hospitals and CAHs with the CJR model's goals of improving the quality and efficiency of CJR episodes and to align with the proposed financial arrangements for the EPMs.

In summary, we propose that the following providers, suppliers, and other entities be added to the list of permissible CJR collaborators: ACOs, hospitals, and CAHs.

We seek comment on our proposal to include ACOs, hospitals, and CAHs in the definition of CJR collaborators.

b. Deletion of Term 'Collaborator Agreements'

In order to reduce duplicative language in § 510.500 and streamline the regulations for financial arrangements between CJR participant hospitals and CJR collaborators, we propose to delete the term ''collaborator agreement'' in § 510.2 and transition the requirements of collaborator agreements to requirements of sharing arrangements. Overall, this proposal would allow CMS to align the CJR financial arrangements with those of the proposed EPMs, and provide consistent regulations to potential parties that may participate in both the CJR model and the EPMs.

We recognize that current participant hospitals and CJR collaborators already have existing collaborator agreements. However, as noted further in this section, although we propose to change several terms, the proposed sharing arrangements policies are largely similar to the current policies regarding collaborator agreements.

We seek to amend the regulations at § 510.2 by deleting the term collaborator agreement in Part 510. We seek comment on our proposals.

c. Addition of CJR Activities

We propose to use the term ''CJR activities'' to identify certain obligations of parties in a sharing arrangement that are currently described as ''changes in care coordination or delivery'' in the CJR regulations governing the contents of the written agreement memorializing the sharing arrangement. In addition to the quality of care provided during episodes, we believe the activities that would fall under this proposed definition of CJR activities would encompass the totality of activities upon which it would be appropriate for certain financial arrangements under the CJR model to be based in order to value the contributions of providers, suppliers, and other entities toward meeting the CJR model's goals of improving the quality and efficiency of episodes. Therefore, for purposes of financial arrangements under the CJR model, we propose to define CJR activities as activities related to promoting accountability for the quality, cost, and overall care for CJR beneficiaries, including managing and coordinating care; encouraging investment in infrastructure, enabling technologies, and redesigned care processes for high quality and efficient service delivery; the provision of items and services during a CJR episode in a manner that reduces costs and improves quality; or carrying out any other obligation or duty under the CJR models. Sections V.J.2. through V.J.4. of this proposed rule further provide more detail as to how the addition of CJR activities affect other proposals in this part.

We propose to amend § 510.2 by adding the term 'CJR activities.' We seek comment on our proposal to add CJR activities as an inclusive and comprehensive framework for capturing direct care and care redesign for CJR episodes that contribute to improving the quality and efficiency of these episodes.

2. Sharing Arrangements

As discussed previously in this section, we propose to delete the term 'collaborator agreement' and include all requirements of a financial arrangement

between a participant hospital and a CJR collaborator under sharing arrangements. Given the magnitude of this terminology change, we propose a complete revision of § 510.500. We believe the proposed amendments to this section will provide participant hospitals and CJR collaborators with more revised, organized, and streamlined regulations.

a. General

With the exception of adding ''past or anticipated'' to the selection criteria for CJR collaborators, and replacing 'collaborator agreement' with 'sharing arrangement' the following proposed criteria are similar to the current requirements of the CJR model as finalized in prior regulations at § 510.500. We discuss here the proposed requirements for sharing arrangements, including our continuation of policies we finalized in the CJR final rule, as well as several new proposals. We propose that participant hospitals must develop, maintain, and use a set of written policies for selecting individuals and entities to be CJR collaborators, and that the selection criteria must include the quality of care delivered by the potential CJR collaborator. The selection criteria cannot be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent. By adding ''past or anticipated'', all previous and future referrals between or among participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent would be encompassed. We do not believe it would be appropriate for sharing arrangements to be based on criteria that include the volume or value of past or anticipated referrals because the sole purpose of sharing arrangements is to create financial alignment between participant hospitals and CJR collaborators toward the CJR model's goals of improving the quality and efficiency of episode care. Thus, we continue to require that CJR participant hospitals select CJR collaborators based on criteria that include the quality of care furnished by the potential CJR collaborator to ensure that the selection of CJR collaborators takes into consideration the likelihood of their future performance in improving the quality of episode care.

In summary, we propose to amend § 510.500(a) as follows:

- A participant hospital may enter into a sharing arrangement with a CJR collaborator to make a gainsharing payment, or to receive an alignment payment, or both.
- A participant hospital must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement.
- A sharing arrangement must comply with the provisions of this section and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.
- Participant hospitals must develop, maintain, and use a set of written policies for selecting individuals and entities to be CJR collaborators. These policies must contain criteria related to, and inclusive of, the quality of care delivered by the potential CJR collaborator. The selection criteria cannot be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.
- If a participant hospital enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the CJR model.

We propose to amend the regulations at § 510.500(a). We seek comment on our proposal.

b. Requirements

Currently, there are a number of specific requirements for sharing arrangements under the CJR model. However, with our proposal to delete the term 'collaborator agreement,' the existing requirements under collaborator agreements would now be streamlined under sharing arrangements. Though many of the proposed requirements under sharing arrangements are largely similar to the current requirements under collaborator agreements, we discuss these requirements in detail further in this section in order to ensure current and future participant hospitals and CJR collaborators are aware of all requirements.

We propose that the sharing arrangement must be in writing, signed by the parties, and entered into before care is furnished to CJR beneficiaries under the sharing arrangement. In addition, participation in a sharing arrangement must be voluntary and without penalty for nonparticipation. We propose that the sharing arrangement must require the CJR collaborator and its employees, contractors, and subcontractors to comply with certain requirements that are important for program integrity protections under the arrangement. We note that the terms contractors and subcontractors, respectively, include collaboration agents and downstream collaboration agents as defined later in this section.

The sharing arrangement must require all of the individuals and entities in this group to comply with the applicable provisions of Part 510, 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, because these individuals and entities all would play a role in CJR care redesign and be part of financial arrangements under the CJR model. The sharing arrangement must also require all individuals and entities in the group to comply with the applicable Medicare provider enrollment requirement at § 424.500, including having a valid and active TIN or NPI, during the term of the sharing arrangement. This is to ensure that the individuals and entities have the required enrollment relationship with CMS under the Medicare program, although we note that they are not responsible for complying with requirements that do not apply to them. Finally, the sharing arrangement must require individuals and entities to comply with all other applicable laws and regulations.

We propose that the sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care so that financial relationships between participant hospitals and CJR collaborators do not negatively impact beneficiary protections under the CJR.

Further we propose that sharing arrangements must require the CJR collaborator to have a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the CJR, just as we would require participant hospitals to have a compliance plan for this purpose as a program integrity safeguard. We note that the CJR

compliance program requirement does not mandate that a CJR collaborator's compliance program take a particular form or include particular components.

It is necessary that participant hospitals have adequate oversight over sharing arrangements to ensure that all arrangements meet the requirements of this section and provide program integrity protections. Therefore, we propose that the board or other governing body of the CJR participant hospital have responsibility for overseeing the participant hospital's participation in the CJR model, its arrangements with CJR collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the CJR. We propose that the written agreement memorializing a sharing arrangement must specify a number of parameters of the arrangement, including the following:

- The purpose and scope of the sharing arrangement.
- The identities and obligations of the parties, including specified CJR activities and other services to be performed by the parties under the sharing arrangement.;
- Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out CJR activities.
- The date of the sharing arrangement.
- The financial or economic terms for payment, including—

++ Eligibility criteria for a gainsharing payment;

++ Eligibility criteria for an alignment payment;

++ Frequency of gainsharing or alignment payment;

++ Methodology and accounting formula for determining the amount of a gainsharing payment that is substantially based on quality of care and the provision of CJR activities; and

++ Methodology and accounting formula for determining the amount of an alignment payment.

Finally, we propose to require that the terms of the sharing arrangement must not induce the participant hospital, CJR collaborator, or any employees, contractors, or subcontractors of the participant hospital or CJR collaborator to reduce or limit medically necessary services to any Medicare beneficiary or 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. These requirements are to ensure that the quality of care for CJR beneficiaries is not negatively affected by sharing arrangements under the CJR.

In summary, we propose the following requirements for sharing arrangements:

- A sharing arrangement must be in writing and signed by the parties, and entered into before care is furnished to CJR beneficiaries under the sharing arrangement.
- Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.
- The sharing arrangement must require the CJR collaborator and its employees, contractors (including collaboration agents), and subcontractors (including downstream collaboration agents) to comply with the following:

++ 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).

++ All applicable Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the sharing arrangement.

++ All other applicable laws and regulations.

- The sharing arrangement must require the CJR collaborator to have a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the CJR model.
- The sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.
- 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, its receipt of alignment payments, and its use of beneficiary incentives in the CJR model.
- The written agreement memorializing a sharing arrangement must specify the following:

++ The purpose and scope of the sharing arrangement.

++ The obligations of the parties, including specified CJR activities and other services to be performed by the parties under the sharing arrangement.

++ Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out CJR activities.

++ The financial or economic terms for payment, including—

—Eligibility criteria for a gainsharing payment;

—Eligibility criteria for an alignment payment;

—Frequency of gainsharing or alignment payment;

—Methodology and accounting formula for determining the amount of a gainsharing payment or alignment payment.

- The sharing arrangement must not—

++ Induce the participant hospital, CJR collaborator, or any employees, contractors, or subcontractors of the participant hospital or CJR collaborator to reduce or limit medically necessary services to any Medicare beneficiary; or

++ 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.

We propose to amend the requirements for sharing arrangements at § 510.500(b). We seek comment on our proposals.

c. Gainsharing Payment, Alignment Payment, and Internal Cost Savings Conditions and Restrictions

Under the CJR model, we place a number of conditions and limitations on gainsharing payments, alignment payments, and internal cost savings. Our proposal to amend these limitations and conditions would allow us to reorganize and clarify current policies, account for the addition of ACOs, CAHs, and hospitals as CJR collaborators, and align the CJR model with the proposed financial arrangements for the EPMs. Though many of the proposed requirements under sharing arrangements are largely similar to the current requirements under gainsharing payments, alignment payments, and internal cost savings conditions and restrictions, we discuss these requirements in detail further in this section in order to ensure current and future participant hospitals and CJR collaborators are aware of such requirements, in particular those that we are proposing to change.

We propose that to be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator other than a PGP or an ACO must have directly furnished a billable item or service to an CJR beneficiary during an CJR episode that occurred in the same performance year for which the participant hospital has calculated a gainsharing payment or been assessed a repayment amount. For purposes of this requirement, we

consider a hospital, CAH, or post-acute care provider to have ''directly furnished'' a billable service if one of these entities billed for an item or service for a CJR beneficiary during a CJR episode that occurred in the same performance year for which the CJR participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. The phrase ''performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount'' does not mean the year in which the gainsharing payment was made. These requirements ensure that there is a required relationship between eligibility for a gainsharing payment and the quality of direct care for CJR beneficiaries during CJR episodes for these CJR collaborators. We believe the provision of direct care is essential to the implementation of effective care redesign, and the requirement provides a safeguard against payments to CJR collaborators other than a PGP or an ACO that are unrelated to direct care for CJR beneficiaries during CJR episodes.

Further, we propose to establish similar requirements for PGPs and ACOs that vary because these entities do not themselves directly furnish billable services. To be eligible to receive a gainsharing payment or required to make an alignment payment, a 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 an CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. Further, we propose that to be eligible to receive a gainsharing payment or required to make an alignment payment, an ACO must have had an ACO provider/supplier that directly furnished, or an ACO participant that billed for, an item or service that was rendered to an CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. With respect to ACOs, an ''ACO participant'' and ''ACO provider/supplier'' have the meaning set forth in § 425.20 of regulations. Like the proposal for CJR collaborators that are not PGPs or ACOs, these proposals also require a linkage between the CJR collaborator that is the PGP or ACO and the provision of items and services to CJR beneficiaries during CJR episodes by PGP members or ACO participants or ACO providers/suppliers, respectively.

Moreover, we further propose that because PGPs and ACOs do not directly furnish items and services to beneficiaries, in order to be eligible to receive a gainsharing payment or be required to make an alignment payment, the PGP or ACO must have contributed to CJR activities and been clinically involved in the care of CJR beneficiaries during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. For example, a PGP or ACO or might have been clinically involved in the care of CJR beneficiaries by providing care coordination services to CJR beneficiaries during and/or after inpatient admission; engaging with a participant hospital in care redesign strategies, and actually performing a role in implementing such strategies that are designed to improve the quality of care for CJR episodes and reduce CJR episode spending; or in coordination with providers and suppliers (such as members of the PGP, ACO participants, ACO providers/suppliers, the participant hospital, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of CJR beneficiaries.

Because internal cost savings may be shared through gainsharing payments with CJR collaborators, we have certain requirements for their calculation as a safeguard against fraud and abuse. We propose that the internal cost savings reflect care redesign under the CJR in order to be eligible to be shared through gainsharing payments, the methodology used to calculate internal cost savings must reflect the actual, internal cost savings achieved by the participant hospital through the documented implementation of CJR activities identified by the participant hospital and must exclude any savings realized by any individual or entity that is not the participant hospital and ''paper'' savings from accounting conventions or past investment in fixed costs. Unlike the current CJR model policy where we require that sharing arrangements document the 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 collaborator, we are proposing a revised policy to not require in the CJR model that the calculation of internal cost savings be tied to the activities of any specific CJR collaborator. We believe this proposed change would recognize that multiple collaborators and collaboration agents contribute to internal cost savings and provide participant hospitals with flexibility to focus on overall internal cost savings due to model activities, rather than the activities of any specific collaborator or collaboration agent. Rather, we believe it is appropriate for participant hospitals to calculate internal cost savings based on the implementation of CJR activities and then provide gainsharing payments to CJR collaborators that may include internal cost savings, reconciliation payments, or both, based on a methodology that meets the requirements described later in this section.

We propose that the amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities. Further, we propose the methodology may take into account the amount of such CJR activities provided by a CJR collaborator relative to other CJR collaborators. While we emphasize that financial arrangements may not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent, so that their sole purpose is to align the financial incentives of the participant hospital and CJR collaborators toward the CJR goals of improved CJR episode care quality and efficiency, we believe that accounting for the relative amount of CJR activities by CJR collaborators in the determination of gainsharing payments does not undermine this objective. Rather, this proposed requirement allows flexibility in the determination of gainsharing payments where the amount of a CJR collaborator's provision of CJR activities (including direct care) to CJR beneficiaries during CJR episodes may contribute to both the internal cost savings and participant hospital's reconciliation payment that may be available for making a gainsharing payment. We refer readers to section III.I.4. of this proposed rule for additional discussion of our rationale.

We seek comment on this proposal for gainsharing payments, where the methodology could take into account the amount of CJR activities provided by a CJR collaborator relative to other CJR collaborators. In addition we invite comment on whether additional safeguards or a different standard is needed to allow for greater flexibility to provide certain performance-based payments consistent with the goals of program integrity, protecting against abuse and ensuring the goals of the model are met.

In the CJR model, we continue to have certain limitations on alignment payments. Currently for a performance 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. In addition, the aggregate amount of all alignment payments from a CJR collaborator to the participant hospital may not be greater than 25 percent of the participant hospital's repayment amount for a CJR collaborator that is not an ACO and we propose 50 percent of the participant hospital's repayment amount for a CJR collaborator that is an ACO. We propose to allow a higher percentage of the participant hospital's repayment amount to be paid by an ACO than by CJR collaborators that are not ACOs in recognition that some ACOs are sizable organizations with significant financial and other resources. In addition, their expertise in managing the cost and quality of care for Medicare beneficiaries over a period of time may make some ACOs uniquely capable of sharing a higher percentage of downside risk under the CJR with the participant hospital under a sharing arrangement between the ACO and CJR participant hospital that meets all requirements for such arrangements, including that participation in the sharing arrangement must be voluntary and without penalty for nonparticipation as discussed previously. We seek comment on the proposed limitation that would apply to ACOs that are CJR collaborators.

Additionally, we propose that all gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction. This is different from the current CJR model policy which requires gainsharing payments and alignment payments to be made by electronic funds transfer. Here, we propose to revise this requirement this requirement in the CJR model in order to provide additional flexibility for entities making gainsharing payments and alignment payments. We believe our proposal would mitigate the administrative burden that the EFT requirement would place on the financial arrangements between certain participant hospitals and CJR collaborators, especially individual physicians and nonphysician practitioners and small PGPs, which could discourage participation of those suppliers as CJR collaborators. We seek comment on the effect of this proposal on reducing the administrative barriers to individual physician and nonphysician practitioner and small PGP participation in the CJR as CJR collaborators.

In summary, we propose the following conditions and restrictions on gainsharing payments, alignment payments, and internal cost savings:

- Gainsharing payments, if any, must—

++ Be derived solely from reconciliation payments, or internal cost savings, or both;

++ Be distributed on an annual basis (not more than once per calendar year);

++ Not be a loan, advance payment, or payment for referrals or other business; and

++ Be clearly identified as a gainsharing payment at the time it is paid.

- To be eligible to receive a gainsharing payment, a CJR collaborator must meet quality of care criteria for the performance year for which the CJR participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment. The quality of care criteria must be established by the participant hospital and directly related to the CJR episode.

- To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator other than a PGP or an ACO must have directly furnished a billable item or service to a CJR beneficiary during a CJR episode that occurred in the same performance year for which the CJR participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount.

- To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator that is a PGP 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 same performance year for which the participant hospital has calculated a gainsharing payment or been assessed a repayment amount.

++ The PGP must have contributed to CJR activities and been clinically involved in the care of CJR beneficiaries during the same performance year for which the participant hospital has calculated a gainsharing payment or been assessed a repayment amount. For example, a PGP might have been clinically involved in the care of CJR beneficiaries by—

—Providing care coordination services to beneficiaries during and/or after inpatient admission;

—Engaging with a participant hospital in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care for CJR episodes and reduce CJR episode spending; or

—In coordination with other providers and suppliers (such as members of the PGP, the participant hospital, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of CJR beneficiaries.

- To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator that is an ACO must meet the following criteria:

++ The ACO must have had an ACO provider/supplier that directly furnished, or an ACO participant that billed for, an item or service that was rendered to a CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital has calculated a gainsharing payment or been assessed a repayment amount.

++ The ACO must have contributed to CJR activities and been clinically involved in the care of CJR beneficiaries. For example, an ACO might be have been clinically involved in the care of CJR beneficiaries by—

—Providing care coordination services to CJR beneficiaries during and/or after inpatient admission;

—Engaging with a participant hospital in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care and reduce spending for CJR episodes; or

—In coordination with providers and suppliers (such as ACO participants, ACO providers/suppliers, the participant hospital, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of CJR beneficiaries.

- The methodology for accruing, calculating and verifying 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 used to calculate internal cost savings must reflect the actual, internal cost savings achieved by the participant hospital through the documented implementation of CJR activities identified by the participant hospital and must exclude—

++ Any savings realized by any individual or entity that is not the participant hospital; and

++ ''Paper'' savings from accounting conventions or past investment in fixed costs.

• The total amount of a gainsharing payment for a performance year paid to a CJR collaborator must not exceed the following:

++ In the case of a CJR collaborator who is a physician or nonphysician practitioner, 50 percent of the Medicare-approved amounts under the PFS for items and services furnished by that physician or nonphysician practitioner to the participant hospital's CJR beneficiaries during CJR episodes that occurred during the same performance year in which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made.

++ In the case of a CJR collaborator that is a PGP, 50 percent of the Medicare-approved amounts under the PFS for items and services billed by the PGP and furnished to the participant hospital's CJR beneficiaries by members of the PGP during CJR episodes that occurred during the same performance year in which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made.

• The amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities. The methodology may take into account the amount of such CJR activities provided by a CJR collaborator relative to other CJR collaborators.

• For a performance year, the aggregate amount of all gainsharing payments that are derived from a reconciliation payment must not exceed the amount of the reconciliation payment the participant hospital receives from CMS.

• No entity or individual, whether a party to a sharing arrangement 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 past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.

• 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.

• The sharing arrangement must require the participant hospital to recoup any gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation report or was based on the submission of false or fraudulent data.

• 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 by CMS of a repayment amount reflected in a reconciliation report;

++ Loans, advance payments, or payments for referrals or other business; or

++ Assessed by a participant hospital if it does not owe a repayment amount.

• The participant hospital must not receive any amounts from a CJR collaborator under a sharing arrangement that are not alignment payments.

• For a performance 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.

• The aggregate amount of all alignment payments from a CJR collaborator to the participant hospital may not be greater than—

++ With respect to a CJR collaborator other than an ACO, 25 percent of the participant hospital's repayment amount; and

++ With respect to a CJR collaborator that is an ACO, 50 percent of the participant hospital's repayment amount.

• The methodology for determining alignment payments must not directly account for the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.

• All gainsharing payments and any alignment payments must be administered by the participant hospital in accordance with generally accepted accounting principles.

• All gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction.

We propose to amend the regulations at § 510.500(c). We seek comment on our proposal, including the feasibility of implementing the proposed safeguards in the context of the current regulatory framework applicable to ACOs and whether additional or different safeguards are reasonable, necessary or appropriate to ensure the goals of program integrity, protecting against abuse and ensuring the goals of the model are met.

d. Documentation

We propose revisions to § 510.500(d) for organization and formatting purposes, and to align with the proposed regulations of the EPMs. Besides the proposed definitional changes and our proposal related to the determination of qualified practitioners under the Quality Payment Program, these revisions would not change any policies under the current documentation section of the CJR model.

In summary we propose the following requirements for documentation:

• Participant hospitals must—

++ Document the sharing arrangement contemporaneously with the establishment of the arrangement;

++ Maintain accurate current and historical lists of all CJR collaborators, including collaborator names and addresses; update such lists on at least a quarterly basis; and publicly report the current and historical lists of CJR collaborators on a Web page on the participant hospital's Web site as well as provide such lists to CMS; and

++ Maintain and require each CJR collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum the—

—Nature of the payment (gainsharing payment or alignment payment);

—Identity of the parties making and receiving the payment;

—Date of the payment;

—Amount of the payment; and

—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 its potential and current CJR collaborators' eligibility to participate in Medicare.

++ Its 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.

++ Its plan to track gainsharing payments and alignment payments.

• The participant hospital must retain and provide access to, and must require each CJR collaborator to retain and provide access to, the required documentation in accordance with § 510.110.

In the proposed § 510.500(d)(3), we propose that participant hospitals must retain and provide access to the required documentation in accordance with § 510.110 and must obligate CJR collaborators to do the same. We propose to add a new section, § 510.110, to the CJR regulations, which would apply all records access and retention requirements under the CJR model, including those for financial arrangements as well as beneficiary notifications and beneficiary incentives. Because we propose to consolidate all records access and retention requirements in one place in the regulations, we propose to delete § 510.500(e) from the current CJR regulations. We discuss further our proposal to consolidate the requirements under the CJR model for access to records and record retention and apply them more broadly in the model. This approach mirrors our proposed records retention policies for the EPMs, which are discussed in detail in section III.H. of this proposed rule. We refer readers to that section for further discussion of our proposed policies and rationale.

We propose to amend these regulations at § 510.500(d). We seek comment on our proposals.

3. Distribution Arrangements

Though we propose a complete revision of the regulations in § 510.505, these changes are mainly to accommodate our proposals to add ACOs as CJR collaborators, add the term 'collaboration agent,' consolidate the requirements under the previous term 'collaborator agreement' with sharing arrangements, and to mirror the proposed EPM regulations at § 512.505 to avoid confusion for hospitals that are participating in CJR as well as one or more of the proposed EPMs. Our proposed changes to the regulations reflect that the requirements and rules regarding distribution arrangements under the CJR model would stay largely the same.

a. General

We propose that certain financial arrangements between CJR collaborators and other individuals or entities called ''collaboration agents'' be termed ''distribution arrangements.'' A distribution arrangement is a financial arrangement between a CJR collaborator that is an ACO or PGP and a collaboration agent for the sole purpose of sharing a gainsharing payment received by the ACO or PGP. A collaboration agent is an individual or entity that is not a CJR collaborator and that is either a PGP member that has entered into a distribution arrangement with the same PGP in which he or she is an owner or employee or an ACO participant or ACO provider/supplier that has entered into a distribution arrangement with the same ACO in which it is participating. Where a payment from a CJR collaborator to a collaboration agent is made pursuant to a distribution arrangement, we propose to define that payment as a ''distribution payment.'' A collaboration agent may only make a distribution payment in accordance with a distribution arrangement which complies with the provisions of § 510.505 and all other applicable laws and regulations, including the fraud and abuse laws. We solicit comment on whether requirements for distribution payments by ACOs under this proposal are reasonable, necessary and appropriate to promote program integrity, prevent fraud and abuse, and achieve the goals of the model. In addition, we solicit comment on how the regulation of the financial arrangements this proposal may interact with how these or similar financial arrangements are regulated under the Medicare Shared Savings Program.

b. Requirements

We propose to amend the requirements for distribution payments in § 510.505 as discussed in this section.

We propose the opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent. With the exception of adding ''past or anticipated'', this proposed requirement is similar to the existing requirement in the CJR model. By adding this language, all previous and future referrals between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent are encompassed.

Currently, 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, any collaboration agent, any downstream collaboration agent, and any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent. We propose to change this requirement as follows.

Like our proposal for gainsharing payments discussed previously, we propose a more flexible standard for the determination of the amount of distribution payments from ACOs and PGPs for the same reasons we propose this standard for the determination of gainsharing payments. Specifically, for ACOs we propose that the amount of any distribution payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities and that may take into account the amount of such CJR activities provided by a collaboration agent relative to other collaboration agents. We believe that the amount of a collaboration agent's provision of CJR activities (including direct care) to CJR beneficiaries during a CJR episode may contribute to the participant hospital's internal cost savings and reconciliation payment that may be available for making a gainsharing payment to the CJR collaborator with which the collaboration agent has a distribution arrangement. Greater contributions of CJR activities by one collaboration agent versus another collaboration agent that result in different contributions to the gainsharing payment made to the CJR collaborator with which those collaboration agents both have a distribution arrangement may be appropriately valued in the methodology used to make distribution

payments to those collaboration agents. Accordingly, we believe this is the appropriate standard for determining the amount of distribution payments from an ACO to its collaboration agents.

We note that for distribution payments made by a PGP to PGP members, the requirement that the amount of any distribution payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities may be more limiting in how a PGP pays its members than is allowed under existing law. Therefore, to retain existing flexibility for distribution payments by a PGP to PGP members, we propose that the amount of the distribution payment from a PGP to PGP members must be determined either using the methodology previously described for distribution payments from an ACO or in a manner that complies with § 411.352(g). This proposal would allow a PGP the choice either to comply with the general standard that the amount of a distribution payment must be substantially based on quality of care and the provision of CJR activities or to provide its members a financial benefit through the CJR without consideration of the PGP member's individual quality of care. In the latter case, PGP members who are not collaboration agents (including those who furnished no services to CJR beneficiaries) would be able receive a share of the profits from their PGP that includes the monies contained in a gainsharing payment. We believe that our proposal to modify the current CJR regulations to allow the amount of the distribution payment from a PGP to a PGP member to be determined in a manner that complies with § 411.352(g) is an appropriate exception to the general standard for determining the amount of distribution payment under the CJR model from a PGP to a PGP member. CMS has determined under the physician self-referral law that payments from a group practice as defined under § 411.352 to its members that comply with § 411.352(g) are appropriate. This proposal would allow a PGP the choice either to comply with the general standard that the amount of a distribution payment must be substantially based on quality of care and the provision of CJR activities or to provide its members a financial benefit through the CJR model without consideration of the PGP member's individual quality of care. This approach mirrors our proposed policies for distribution arrangements for the EPMs, which are discussed in detail in section III.I.5. of this proposed rule.

We propose to amend the regulations at § 510.505(b)(4) and (b)(5). We seek comment on this proposal and specifically whether additional safeguards or a different standard is needed to allow for greater flexibility in calculating the amount of distribution payments consistent with the goals of promoting program integrity, protecting against abuse, and ensuring that the goals of the model are met. In addition, we solicit comment on the proposal to allow distribution payments by a PGP to its members that comply with § 411.352(g) or whether additional/different safeguards are reasonable, necessary, and appropriate.

Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g), we propose to continue the limits in the current CJR regulations on the total amount of distribution payments to physicians, nonphysician practitioners, and PGPs as we propose for gainsharing payments. Specifically, in the case of a collaboration agent that is a physician or nonphysician practitioner, absent the alternative safeguards afforded by compliance with § 411.352(g), we would limit the total amount of distribution payments paid for a performance year to the collaboration agent to 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the collaboration agent to the CJR participant hospital's CJR beneficiaries during CJR episodes that occurred during the same performance year for which the CJR participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed. In the case of a collaboration agent that is a PGP, the limit would continue to be 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by the PGP for items and services furnished by members of the PGP to the CJR participant hospital's CJR beneficiaries during CJR episodes that occurred during the same performance year for which the CJR participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

We propose that all distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction. This proposal would provide additional flexibility for entities making distribution payments as well as would mitigate the administrative burden that the EFT requirement previously placed on the financial arrangements between certain participant hospitals and CJR collaborators, especially individual physicians and nonphysician practitioners and small PGPs, which could discourage participation of those suppliers as CJR collaborators.

We propose to amend the regulations at § 510.505(b)(10). We seek comment on this proposal.

Finally, we propose that CJR collaborators must retain and provide access to the required documentation in accordance with § 510.110 and must require each collaboration agent to do so as well. We discuss further our proposal to consolidate the requirements under the CJR model for access to records and record retention and apply them more broadly in the model. This approach mirrors our proposed records retention policies for the EPMs, which are discussed in detail in section III.H. of this proposed rule. We refer readers to that section for further discussion of our proposed policies and rationale.

We propose to amend the regulations at § 510.505(b)(14). We seek comment on our proposals.

4. Downstream Distribution Arrangements Under the CJR Model

a. General

We propose that the CJR model allow for certain financial arrangements within an ACO between a PGP and its members. We discuss here our proposals for downstream distribution arrangements, which mirror our proposals for the proposed EPMs described in section III.I.6. of this proposed rule. Specifically, we propose that certain financial arrangements between a collaboration agent that is both a PGP and an ACO participant and other individuals termed ''downstream collaboration agents'' be termed a ''downstream distribution arrangement.'' A downstream distribution arrangement is a financial arrangement between a collaboration agent that is a both a PGP and an ACO participant and a downstream collaboration agent for the sole purpose of sharing a distribution payment received by the PGP. A downstream collaboration agent is an individual who is not a CJR collaborator or a collaboration agent and who is a PGP member that has entered into a downstream distribution arrangement with the same PGP in which he or she is an owner or employee, and where the PGP is a collaboration agent. Where a payment from a collaboration agent to a downstream collaboration agent is made pursuant to a downstream distribution arrangement, we define that payment as

a ''downstream distribution payment.'' A CJR collaboration agent may only make a downstream distribution payment in accordance with a downstream distribution arrangement which complies with the requirements of this section and all other applicable laws and regulations, including the fraud and abuse laws.

The proposals for the general provisions for downstream distribution arrangements under the CJR model are included in § 510.506. These provisions mirror those proposed for the proposed EPMs in § 512.510(a). We seek comment on our proposals for these general provisions, as well as any alternatives to this structure.

b. Requirements

We propose a number of specific requirements for downstream distribution arrangements to help ensure that their sole purpose is to create financial alignment between collaboration agents that are PGPs which are also ACO participants and downstream collaboration agents toward the goal of the CJR model to improve the quality and efficiency of CJR episodes. We refer readers to section III.I.6.(b) of this proposed rule for further discussion of our proposals regarding downstream distribution arrangements and our rationale for each proposal. Our proposed requirements largely parallel those proposed in § 510.510(b) and § 510.505(b) for sharing and distribution arrangements and gainsharing and distribution payments based on similar reasoning for these three types of arrangements and payments.

As listed in § 510.506 and described in detail in III.I.6(b) of this proposed rule, we propose requirements addressing the agreements governing downstream distribution arrangements, eligibility for receipt of downstream distribution payments, a cap on the amount of such payments, the methodologies used to determine the amount of downstream distribution payments, and documentation regarding downstream distribution arrangements. Specifically, we propose that all downstream distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and entered into before care is furnished to CJR beneficiaries under the distribution arrangement. We propose that participation must be voluntary and without penalty for nonparticipation, and the downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

As with our proposals for gainsharing and distribution payments, we propose that the opportunity to make or receive a downstream distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent. In determining the amount of downstream distribution payments we propose a more flexible approach, as we have with the proposed EPMs. We propose that the amount of any downstream distribution payments must be determined either in a manner that complies with § 411.352(g) or that is substantially based on quality of care and the provision of CJR activities and that may take into account the amount of CJR activities provided by a downstream collaboration agent relative to other downstream collaboration agents. Just as we propose an alternative to a methodology that is substantially based on quality of care and the provision of CJR activities for determining the amount of a distribution payment from a PGP to a PGP member, we similarly propose an alternative that the amount of a downstream distribution payment from a PGP to a PGP member may be determined in a manner that complies with § 411.352(g).

Similar to our proposed requirements for distribution arrangements for those EPM collaborators that are PGPs, we propose that, except for a downstream distribution arrangement that complies with § 411.352(g), a downstream collaboration agent is eligible to receive a downstream distribution payment only if the PGP billed for an item or service furnished by the downstream collaboration agent to a CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprise the gainsharing payment from which the ACO made the distribution payment to the PGP that is an ACO participant. This approach mirrors our proposed requirements for distribution arrangements between collaborators and collaboration agents, as well as the proposed approach for the EPMs.

With regard to limitations on the amount of downstream distribution payments made to downstream collaboration agents, we propose the same limit as that proposed for distribution payments by CJR collaborators that are PGPs. With the exception of downstream distribution payments that comply with § 411.352(g), we propose to limit the total amount of downstream distribution payments paid for a performance year to a downstream collaboration agent to 50 percent of the total Medicare-approved amounts under the PFS for services billed by the PGP and furnished by the downstream collaboration agent to the participant hospital's CJR beneficiaries during CJR episodes that occurred during the same performance year in which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment from which the ACO made the distribution payment to the PGP. We further propose that the total amount of all downstream distribution payments made to downstream collaboration agents must not exceed the amount of the distribution payment received by the collaboration agent (PGP that is an ACO participant) from the ACO that is a CJR collaborator. In addition, all downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction, as with our proposed approach for gainsharing, alignment, and distribution payments. Finally, the distribution arrangement must not induce the downstream collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary or reward the provision of items and services that are medically unnecessary.

We propose that the PGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 510.110, including:

- The relevant written agreements;
- The date and amount of any downstream distribution payment(s);
- The identity of each downstream collaboration agent that received a downstream distribution payment; and
- A description of the methodology and accounting formula for determining the amount of any downstream distribution payment.

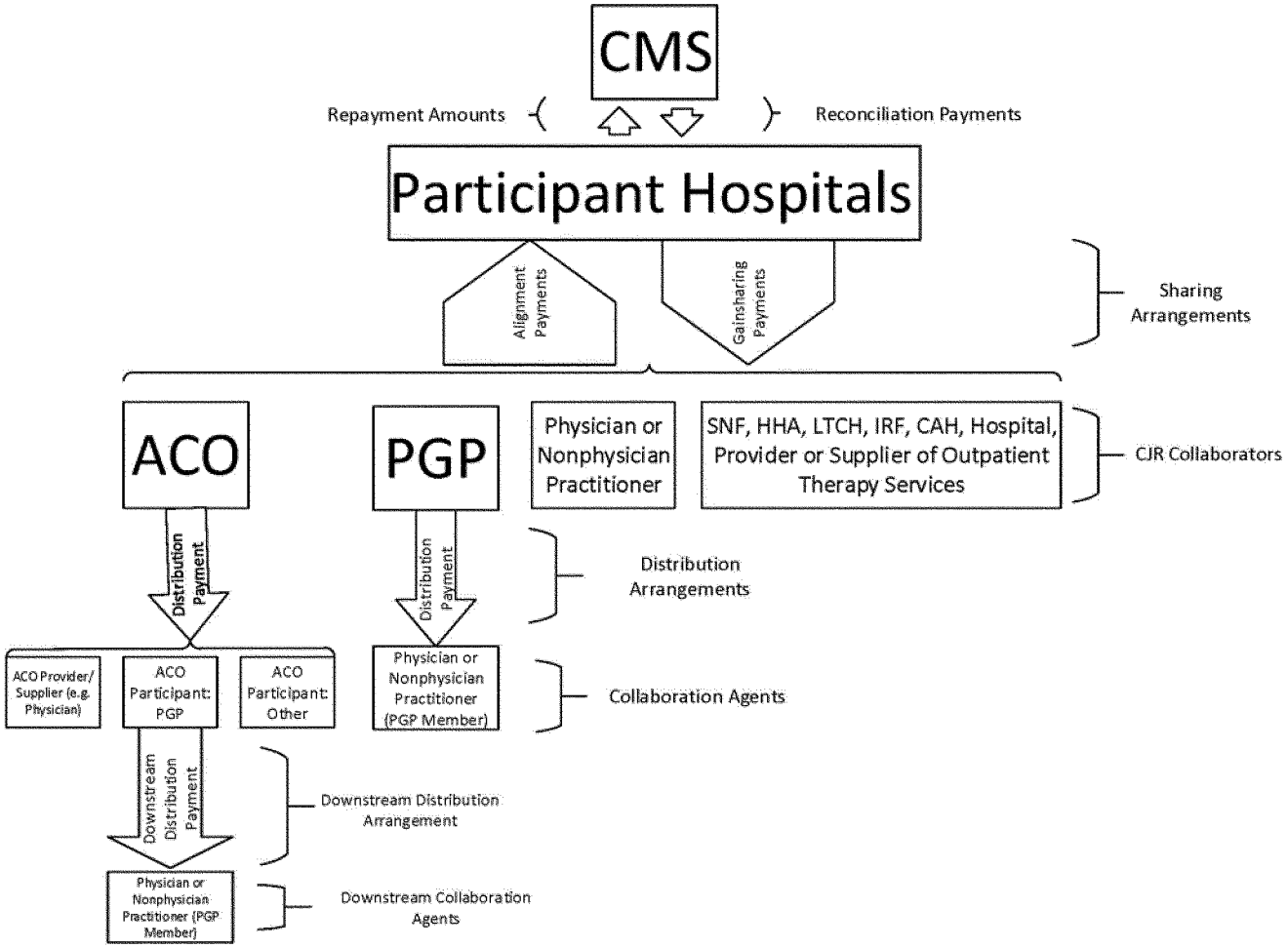
We propose that the PGP may not enter into a downstream distribution arrangement with any PGP member who has a sharing arrangement with a participant hospital or distribution arrangement with the ACO in which the PGP is a participant. Finally, we propose that the PGP must retain and provide access to, and must require downstream collaboration agents to retain and provide access to, the required documentation in accordance with § 510.110.

The proposals for downstream distribution arrangement requirements are included in § 510.506. We seek comment on our proposals.

5. Summary of Proposals for Sharing, Distribution, and Downstream Distribution Arrangements Under the CJR Model.

Figure 3 summarizes the proposals for the defined terms and financial arrangements discussed in section V.J. of this proposed rule.

Figure 3: PROPOSED CJR FINANCIAL ARRANGEMENTS



K. Beneficiary Incentives Under the CJR Model

We propose numerous amendments to the regulations in § 510.515. These are mainly for organizational purposes, to more clearly specify our policies, and for the CJR model regulations to mirror the proposed EPM regulations at § 512.525 to avoid confusion for hospitals that are participating in CJR as well as one or more of the proposed EPMs. Our proposed changes to the regulations reflect that the requirements and rules regarding the use of beneficiary incentives under the CJR model would stay largely the same. However, we are proposing several changes in order to ensure adequate documentation of beneficiary incentives by participant hospitals and to align with our proposed requirements for the EPMs.

First, as a program safeguard against misuse of beneficiary incentives under the CJR model, we would clarify our existing requirements for documentation of beneficiary incentives. Documentation regarding items of technology exceeding $100 in retail value must also include contemporaneous documentation of any attempt to retrieve the technology at the end of a CJR episode. Documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

We also propose to add as a requirement that participant hospitals retain and provide access to required documentation pertaining to beneficiary incentives as discussed throughout section V.L. of this proposed rule and proposed in § 510.110 of the regulations. Participant hospitals retaining and providing access to documentation in accordance with § 510.110 would promote parallel record retention for all CJR model requirements and further enable successful monitoring efforts by CMS. As discussed in section V.L., the proposed section § 510.110 would apply to beneficiary incentives as well as financial arrangements and beneficiary notification requirements under the CJR model; therefore, we are proposing to delete § 510.515(e) to avoid duplicative requirements and language and to align the applicable CJR model regulations

with the proposed regulations of the EPMs.

We propose to include these requirements in the regulations at § 510.515(d)(3) and § 510.515(d)(4). We seek comment on our proposal. We also seek comment on the proposed additional requirements for compliance with proposed section § 510.110 and the deletion of § 510.515(e).

L. Access to Records and Record Retention

We propose to consolidate the requirements under CJR for access to records and record retention and apply them more broadly in the model. This approach mirrors our proposed records retention policies for the EPMs, which are discussed in detail in section III.H. of this proposed rule. We refer readers to that section for further discussion of our proposed policies and rationale.

We propose to add § 510.110 to the CJR regulations, which would apply to documentation regarding beneficiary notifications, financial arrangements, and beneficiary incentives. Because we propose to consolidate all of the existing records access and retention requirements in one place, we propose to delete § 510.500(e) and § 510.515(c). We further propose to require participant hospitals, CJR collaborators, collaboration agents, downstream collaboration agents and any other individuals or entities performing CJR activities to allow the Government, including CMS, OIG, HHS and the Comptroller General or their designees, scheduled and unscheduled access to all books, contracts, records, documents and other evidence sufficient to enable the audit, evaluation, inspection or investigation of the individual or entity's compliance with CJR model requirements, the calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments, the obligation to repay any reconciliation payments owed to CMS, the quality of the services furnished to a CJR beneficiary during a CJR episode, and the sufficiency of CJR beneficiary notifications.

In general, we propose that such documents be maintained 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.

We believe these safeguards regarding access to records and record retention are necessary to ensure program integrity and protect against abuse, in view of the CJR model's design and requirements. We believe that by providing access to CJR records, we promote transparency of activities in the CJR model. Further, the proposed access to records and record retention requirements would ensure that the compliance of participant hospitals, CJR collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities performing CJR activities can be monitored and assessed. Also, these records may be necessary in the event that a participant hospital appeals any matter that is subject to dispute resolution through CMS. As such, CMS would have the resources necessary to prepare and respond to any such appeal. Finally, we propose to establish CEHRT use attestation for CJR participant hospitals so that a CJR participant hospital could be in Track 1 of the CJR model that meets the proposed requirements in the Quality Payment Program proposed rule to be an Advanced APM as discussed in section III.A.2. of this proposed rule. Thus, we propose to require access to records and record retention about the accuracy of each Track 1 CJR model participant hospital's submissions under CEHRT use requirements. Specifically, attestation to CEHRT use and submission of clinician financial arrangements lists are key requirements for Track 1 of the CJR model that is an Advanced APM, and the access to records and record retention requirements provide a program integrity safeguard by allowing us to assess the completeness and accuracy of the participant hospital's compliance with the requirements for those submissions.

In summary, we propose in § 510.110 that participant hospitals, CJR collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities performing providing CJR activities must allow the Government, including CMS, OIG, HHS 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, distribution arrangements, downstream distribution arrangements and the documentation required under § 510.500(d) and § 510.525(c)) sufficient to enable the audit, evaluation, inspection or investigation of the following:

- Individual's or entity's compliance with CJR model requirements.
- The calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments
- The obligation to repay any reconciliation payments owed to CMS.
- The quality of the services furnished to a CJR beneficiary during a CJR episode.
- The sufficiency of CJR beneficiary notifications.
- The accuracy of the CJR participant hospital's submission under CEHRT use requirements.

Further, we propose that participant hospitals, CJR collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities performing providing CJR activities 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 CMS determines a particular record or group of records should be retained for a longer period and notifies the participant hospital at least 30 calendar days before the disposition date or there has been a dispute or allegation of fraud or similar fault against the participant hospital, CJR collaborator, collaboration agents, downstream collaboration agents, or any other individual or entity performing CJR activities related to the CJR model. In this case, the records must be maintained for 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

We seek comment on our proposals, including whether additional or different requirements are appropriate to promote program integrity, prevent fraud and abuse and promote the goals of the model.

M. Waivers of Medicare Program Rules To Allow Reconciliation Payment or Repayment Actions Resulting From the Net Payment Reconciliation Amount

In order to correct a technical error in the CJR final rule (42 CFR 510.620), we propose to waive the requirements of section 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 proposed this policy in the CJR proposed rule (80 FR 41274) and received no comments from the public on our proposal; the proposal was finalized in the CJR final rule. We

refer readers to the CJR final rule (80 FR 73460 and 73461) for further discussion.

We propose to amend our regulations at § 510.620 to reflect this change.

N. SNF 3-Day Waiver Beneficiary Protections

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. Under 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. In the November 2015 final rule (80 FR 73454 through 73460), we provided hospitals in CJR with additional flexibility to attempt to increase quality and decrease costs by allowing a waiver of the SNF 3-day rule for beneficiaries in a CJR episode beginning on or after January 1, 2017. Program requirements for this waiver are codified at § 510.610. Specifically, under § 510.610, for SNFs that meet all specified requirements, we waive the requirement in section 1861(i) of the Act for a 3-day inpatient hospital stay prior to a Medicare covered post-hospital extended care service for eligible beneficiaries in a CJR episode. The CJR SNF waiver will only be available to participant hospitals that are active participants in the CJR model. If a participant hospital no longer participates in the CJR model, due to a merger or other reason, it cannot continue to use the CJR SNF waiver. All other provisions of the statute and regulations regarding Medicare Part A post-hospital extended care services continue to apply.

We believe that clarity regarding whether a waiver applies to SNF services furnished to a particular beneficiary is important to help ensure compliance with the conditions of the waiver and also improve our ability to monitor waivers for misuse. Therefore, in the CJR final rule (80 FR 73454 through 73460), we discussed how the waiver can be utilized when a beneficiary is in a CJR episode at the time when the waiver is applied. In addition, at § 510.405 we require participant hospitals to provide a discharge planning notice to beneficiaries in cases where there is potential beneficiary liability for the SNF stay (80 FR 73548 through 73549).

Based on our experiences under BPCI Model 2, the Pioneer ACO Model, and other initiatives, we established certain requirements under § 510.610 for hospitals and SNFs with respect to the SNF 3-day rule waiver under the CJR model. As discussed in the CJR final rule, commenters expressed concern about beneficiary liability in cases whether the beneficiary's eligibility status has changed but the hospital is unaware of the change at the time it uses the waiver. We noted that we would continue to evaluate the waiver of the SNF 3-day rule, including further lessons learned from Innovation Center models in which a waiver of the SNF 3-day rule is being tested. We indicated that in the event we determine that additional safeguards or protections for beneficiaries or other changes were necessary, such as to incorporate additional protections for beneficiaries, we would propose the necessary changes through future rulemaking.

In considering additional beneficiary protections that may be necessary to ensure proper use of the SNF 3-day waiver under the CJR model, we note that there are existing, well-established payment and coverage policies for SNF services based on sections 1861(i), 1862(a)(1), and 1879 of the Act that include protections for beneficiaries from liability for certain non-covered SNF charges. These existing payment and coverage policies for SNF services continue to apply under the model, including SNF services furnished pursuant to the SNF 3-day waiver. (For example, see section 70 in the Medicare Claims Processing Manual, Chapter 30—Financial Liability Protections on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c30.pdf*; and Medicare Coverage of Skilled Nursing Facility Care at *https://www.medicare.gov/Pubs/pdf/10153.pdf*; Medicare Benefit Policy Manual, Chapter 8—Coverage of Extended Care (SNF) Services Under Hospital Insurance at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c08.odf*). In general, CMS requires that the SNF inform a beneficiary in writing about services and fees before the beneficiary is discharged to the SNF (§ 483.10(b)(6)); the beneficiary cannot be charged by the SNF for items or services that were not requested (§ 483.10(c)(8)(iii)(A)); a beneficiary cannot be required to request extra services as a condition of continued stay (§ 483.10(c)(8)(iii)(B)); and the SNF must inform a beneficiary that requests an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be (§ 483.10(c)(8)(iii)(C)). (See also section 6 of Medicare Coverage of Skilled Nursing Facility Care at *https://www.medicare.gov/Pubs/pdf/10153.pdf*.)

As we discussed in the CJR final rule (80 FR 73454 through 73460), commenters expressed concern regarding the lag between a CJR beneficiary's Medicare coverage or eligibility status change and a participant hospital's awareness of that change. There may be cases in which a SNF waiver is used by a participant hospital because the participant hospital believes that the beneficiary meets the inclusion criteria, based on the information available to the hospital and SNF at the time of the beneficiary's admission to the SNF, but in fact the beneficiary's Medicare coverage has changed and the hospital was unaware of it based on available information. We recognize that despite good faith efforts by participant hospitals and SNFs to determine a beneficiary's Medicare status for the model, it may occur that a beneficiary is not eligible to be included in the CJR model at the time the SNF waiver is used. In these cases, we will cover services furnished under the waiver when the information available to the provider at the time the services under the waiver were furnished indicated that the beneficiary was included in the model.

Since publication of our final rule, we have continued to learn from implementation and refinement of the SNF 3-day waiver in other models and the Shared Savings Program. Based on these experiences, we believe there are situations where it would be appropriate to require additional beneficiary financial protections under the SNF 3-day waiver for the CJR model. Specifically, we are concerned about potential beneficiary financial liability for non-covered Part A SNF services that might be directly related to use of the SNF 3-day waiver under the CJR model. We are concerned that there could be scenarios where a beneficiary could be charged for non-covered SNF services that were a result of a participant hospital's inappropriate use of the SNF waiver. Specifically, we are concerned that a beneficiary could be charged for non-covered SNF services if a participant hospital discharges a beneficiary to a SNF that does not meet the quality requirement (3 stars or higher in 7 of the last 12 months), and payment for SNF services is denied for lack of a qualifying inpatient hospital stay. We recognize that requiring a discharge planning notice (§ 510.405) will help mitigate concerns about beneficiaries' potential financial liability for non-covered services. Nevertheless, we are concerned that in this scenario, once the claim is rejected, the beneficiary may not be protected

from financial liability under existing Medicare rules because the waiver would not be available, and the beneficiary would not have had a qualifying inpatient hospital stay. Thus, the CJR beneficiary could be charged by the SNF for non-covered SNF services that were a result of an inappropriate attempt to use the waiver. In this scenario, Medicare would deny payment of the SNF claim, and the beneficiary could potentially be charged by the SNF for these non-covered SNF services, potentially subjecting such beneficiaries to significant financial liability. In this circumstance, we assume the participant hospital's intent was to rely upon the SNF 3-day waiver, but the waiver requirements were not met. We believe that in this scenario, the rejection of the claim could easily have been avoided if the hospital had confirmed that the requirements for use of the SNF 3-day waiver were satisfied or if the beneficiary had been provided the discharge planning notice and elected to go to a SNF that met the quality requirement.

Other models have addressed similar issues in which the beneficiary may be subject to financial liability for non-covered SNF services related to the waiver. The Next Generation ACO Model generally places the risk on the SNF, where the SNF did not qualify under the waiver or otherwise knew or reasonably could be expected to have known that payment would not be made for the non-covered SNF services. In such cases, CMS makes no payment for the services, and the SNF may not charge the beneficiary for the services and must return any monies collected from the beneficiary. Additionally, under the Next Generation ACO Model, the ACO must indemnify and hold the beneficiary harmless for the services. We believe it is appropriate to propose to adopt a similar policy under the CJR model. In contrast to the Next Generation ACO Model, however, we believe it is most appropriate to hold the participant hospitals financially responsible for misusing the waiver in situations where waiver requirements are not met, because participant hospitals are required to be aware of the 3-day waiver requirements. Participant hospitals are the entities financially responsible for episode spending under the model and will make the decision as to whether it is appropriate to discharge a beneficiary without a 3-day stay. In addition, we clearly laid out the requirements for use of the SNF waiver in the CJR final rule. Participant hospitals may begin using the waiver for episodes that begin on or after January 1, 2017, and may only utilize the waiver to discharge a beneficiary to a SNF that meets the quality requirements. CMS will post on the public Web site a list of qualifying SNFs (those with a 3-star or higher rating for 7 of the last 12 months). Participant hospitals are required to consult the published list of SNFs prior to utilizing the SNF waiver. As described later in this section, we propose that when the hospital provides the beneficiary with the discharge notice in accordance with the requirements of 510.405(b)(4), the hospital would not have financial liability for non-covered SNF services that result from inapplicability of the waiver. In other words, when the participant hospital has discharged a beneficiary to a SNF that does not qualify under the conditions of the waiver, and has not provided the required notice so that the beneficiary is aware that he or she is accepting financial liability for non-covered SNF services as a result of not having a qualifying inpatient stay, we believe it is reasonable that the ultimate responsibility and financial liability for the non-covered SNF stay should rest with the participant hospital. For this reason, we are proposing to require hospitals to keep a record of discharge planning notice distribution to CJR beneficiaries. We will monitor participant hospitals' use of discharge planning notices to assess the potential for their misuse. We also considered holding the SNF responsible but decided that since hospitals, not SNFs, are the CJR model participants, they therefore should be held responsible for complying with the 3-day waiver conditions for the reasons stated previously in this section.

To protect CJR beneficiaries from being charged for non-covered SNF charges in instances when the waiver was used inappropriately, we are proposing to add certain beneficiary protection requirements in § 510.610. These requirements would apply for SNF services that would otherwise have been covered except for lack of a qualifying hospital stay. Specifically, we propose that beginning with episodes that are initiated on or after January 1, 2017, when the SNF waiver is available, if a participant hospital discharges a beneficiary without a qualifying 3-day inpatient stay to a SNF that is not on the published list of SNFs that meet the CJR SNF waiver quality requirements as of the date of admission to the SNF, the hospital will be financially liable for the SNF stay if no discharge planning notice is provided to the beneficiary, alerting them of potential financial liability. If the participant hospital provides a discharge planning notice in compliance with the requirements of § 510.405(b)(4), the participant hospital will not be financially liable for the cost of the SNF stay and the normal Medicare FFS rules for coverage of SNF services will apply. In cases where the participant hospital provides a discharge planning notice in compliance with the requirements of § 510.405(b)(4) and the beneficiary chooses to obtain care from a non-qualified SNF without a qualifying inpatient stay, the beneficiary assumes financial liability for services furnished (except those that are covered by Medicare Part B during a non-covered inpatient SNF stay).

In the event a CJR beneficiary is discharged to a SNF without a qualifying 3-day inpatient stay, but the SNF is not on the qualified list as of the date of admission to the SNF, and the participant hospital has failed to provide a discharge planning notice, as specified in § 510.405(b)(4), we propose that CMS apply the following rules:

- CMS shall make no payment to the SNF for such services.
- The SNF shall not charge the beneficiary for the expenses incurred for such services; and the SNF shall return to the beneficiary any monies collected for such services.
- The hospital shall be responsible for the cost of the uncovered SNF stay.

In addition, we propose to amend our regulations to clarify that the SNF 3-day waiver will be available in performance years 2 through 5 for those episodes beginning on or after January 1, 2017. In the CJR final rule, we discussed how the SNF 3-day waiver will be available beginning in performance year 2. We propose to clarify here that the waiver does begin in performance year 2, but only for those episodes that begin on or after January 1, 2017 when the waiver goes into effect.

We seek comment on these proposals. Specifically, we seek comment on whether it is reasonable to—(1) cover services furnished under the SNF waiver based on participant hospital knowledge of beneficiary eligibility for the CJR model as determined by Medicare coverage status at the time the services under the waiver were furnished; and (2) to hold the participant hospital financially responsible for rejected SNF claims if a CJR beneficiary is discharged to a SNF without a qualifying 3-day inpatient stay, but the SNF is not on the qualified list as of the date of admission to the SNF, and the participant hospital has failed to provide a discharge planning notice as specified in § 510.405(b)(4).

We seek comment on whether SNFs instead of, or in addition to, the participant hospital should be held liable for such claims and under what circumstances. Finally, we seek comment on any other related issues that we should consider in connection with these proposal to protect beneficiaries from significant financial liability for non-covered SNF services related to the waiver of the SNF 3-day rule under the CJR model. We may address those issues through future notice and comment rulemaking.

We propose to amend our regulations at § 510.610 to reflect this change. We also propose to clarify the language in § 510.610 to reflect that the CJR SNF waiver will be available for use for episodes that begin on or after January 1, 2017.

O. Advanced Alternative Payment Model Considerations

1. Overview for CJR

The MACRA created two paths for eligible clinicians to link quality to payments: The MIPS and Advanced APMs. These two paths create a flexible payment system called the Quality Payment Program as proposed by CMS in the Quality Payment Program proposed rule (81 FR 28161 through 28586).

As proposed in the Quality Payment Program proposed rule, an APM must meet three criteria to be considered an Advanced APM (81 FR 28298). First, the APM must provide for payment for covered professional services based on quality measures comparable to measures described under the performance category described in section 1848(q)(2)(B)(i) of the Act, which is the MIPS quality performance category. Under the Quality Payment Program proposed rule, we proposed that the quality measures on which the Advanced APM bases payment for covered professional services (as that term is defined in section 1848(k)(3)(A) of the Act) must include at least one of the following types of measures, provided that they have an evidence-based focus and are reliable and valid (81 FR 28302):

- Any of the quality measures included on the proposed annual list of MIPS quality measures.
- Quality measures that are endorsed by a consensus-based entity.
- Quality measures developed under section 1848(s) of the Act.
- Quality measures submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act.
- Any other quality measures that CMS determines to have an evidence-based focus and be reliable and valid.

As we discussed in the Quality Payment Program proposed rule, because the statute identifies outcome measures as a priority measure type and we wanted to encourage the use of outcome measures for quality performance assessment in APMs, we further proposed in that rule, that in addition to the general quality measure requirements, an Advanced APM must include at least one outcome measure if an appropriate measure is available on the MIPS list of measures for that specific QP Performance Period, determined at the time when the APM is first established (81 FR 28302 through 28303).

Second, the APM must either require that participating APM Entities bear risk for monetary losses of a more than nominal amount under the APM or be a Medical Home Model expanded under section 1115A(c) of the Act. Except for Medical Home Models, we proposed in the Quality Payment Program proposed rule that, for an Advanced APM to meet the nominal amount standard, the specific level of marginal risk must be at least 30 percent of losses in excess of expected expenditures; a minimum loss rate, to the extent applicable, must be no greater than 4 percent of expected expenditures; and total potential risk must be at least 4 percent of expected expenditures (81 FR 28306).

Third, the APM must require participants to use CEHRT (as defined in section 1848(o)(4) of the Act), as specified in section 1833(z)(3)(D)(i)(I) of the Act, to document and communicate clinical care with patients and other health care professionals. Specifically, where the APM participants are hospitals, the APM must require each hospital to use CEHRT (81 FR 28298 through 28299).

In this proposed rule, we propose to adopt two different tracks for CJR—Track 1 in which CJR and its participant hospitals would meet the criteria for Advanced APMs as proposed in the Quality Payment Program proposed rule, and Track 2 in which CJR and its participant hospitals would not meet those proposed criteria. The CJR model incorporates a pay-for-performance methodology including quality measures that we believe would meet the proposed Advanced APM quality measure requirements in the Quality Payment Program proposed rule. Both of the required quality measures in the CJR model are NQF-endorsed, have an evidence-based focus, and are reliable and valid. We believe they would meet the proposed Advanced APM general quality measure requirements.

The CJR pay-for-performance methodology includes one outcome measure that is NQF-endorsed, has an evidence-based focus, and is reliable and valid. The pay-for-performance methodology incorporates the Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550) (Hip/Knee Complications) outcome measure. Thus, we believe the CJR model would meet the requirement proposed for Advanced APMs in the Quality Payment Program proposed rule for use of an outcome measure that also meets the general quality measure requirements.

In terms of the proposed nominal risk criteria for Advanced APMs, beginning in performance year 2 for episodes ending between January 1, 2017 and December 31, 2017, participant hospitals would begin to bear downside risk for excess actual CJR episode spending above the quality-adjusted target price. The marginal risk for excess actual CJR episode spending above the quality-adjusted target price would be 100 percent over the range of spending up to the stop-loss limit, which would exceed 30 percent marginal risk, and there would be no minimum loss rate. As a result, we believe the CJR model would meet the marginal risk and minimum loss rate elements of the nominal risk criteria for Advanced APMs proposed in the Quality Payment Program proposed rule. Total potential risk for most CJR participant hospitals is 5 percent of expected expenditures in performance year 2, and increasing in subsequent performance years. Therefore, we believe the total potential risk applicable to most participant hospitals, with the lowest total potential risk being 5 percent for CJR episodes ending on or after January 1, 2017 in performance year 2, would meet the total potential risk element of the nominal risk amount standard for Advanced APMs proposed in the Quality Payment Program proposed rule because it is greater than the value of at least 4 percent of expected expenditures.

We note that participant hospitals that are rural hospitals, sole community hospitals (SCHs), Medicare Dependent Hospitals (MDHs) and Rural Referral Centers (RRCs) will have a stop-loss limit of 3 percent in performance year 2. Because 3 percent is less than the proposed threshold of at least 4 percent of expected expenditures for total potential risk proposed for Advanced APMs in the Quality Payment Program proposed rule, those rural hospitals, SCHs, MDHs, and RRCs that are CJR participant hospitals subject to special

protections would be in Track 2 of the CJR model and would not meet the proposed nominal risk standard for Advanced APMs for performance year 2. We recognize that this proposal might initially limit the ability of rural hospitals, SCHs, MDHs, and RRCs to be in an Advanced APM for performance year 2. We believe this potential limitation on rural hospitals, SCHs, MDHs, and RRCs is appropriate for the following reasons: (1) Greater risk protections for these hospitals under the CJR model beginning in performance year 2 and subsequent performance years compared to other participant hospitals are necessary, regardless of their implications regarding Advanced APMs based on the nominal risk standard proposed in the Quality Payment Program proposed rule, because these hospitals have unique challenges that do not exist for most other hospitals, such as being the only source of health care services for beneficiaries or certain beneficiaries living in rural areas or being located in areas with fewer providers, including fewer physicians and post-acute care facilities; and (2) under the CJR risk arrangements, these hospitals would not bear an amount of risk in performance year 2 that we determined to be more than nominal in the Quality Payment Program proposed rule. However, we seek comment on whether we should allow participant hospitals that are rural hospitals, SCHs, MDHs, or RRCs to elect a higher stop-loss limit performance year 2 where downside risk applies in order to permit these hospitals to be in Track 1 of the CJR model for performance year 2. We note that by performance year 3, the stop-loss limit for these hospitals with special protections under the CJR model would increase to 5 percent under our proposal, so these hospitals could be in Track 1 based on the nominal risk standard proposed in the Quality Payment Program proposed rule.

As addressed in the Quality Payment Program proposed rule, it is necessary for an APM to require the use of CEHRT in order to meet the criteria to be considered to be an Advanced APM. Therefore, according to the requirements proposed in the Quality Payment Program proposed rule, so that the CJR model may meet the proposed criteria to be an Advanced APM, we propose to require participant hospitals to use CEHRT (as defined in section 1848(o)(4) of the Act) to participate in Track 1 of the CJR model. We propose that Track 1 participant hospitals must use certified health IT functions, in accordance with the definition of CEHRT under our regulation at 42 CFR 414.1305, to document and communicate clinical care with patients and other health care professionals as proposed in the Quality Payment Program proposed rule (81 FR 28299). We believe this proposal would allow Track 1 of CJR to be able to meet the proposed criteria to be an Advanced APM.

Without the collection of identifying information on eligible clinicians (physicians, nonphysician practitioners, physical and occupational therapists, and qualified speech-language pathologists) who would be considered affiliated practitioners as proposed in the Quality Payment program proposed rule under the CJR model, CMS would not be able to consider participation in the model in making determinations as to whom could be considered a QP (81 FR 28320). As detailed in the Quality Payment Proposed rule, these determinations are based on the whether the eligible clinician meets the QP threshold under either the Medicare Option starting in payment year 2019 or the All-Payer Combination Option, which is available starting in payment year 2021 (81 FR 28165). Thus, we make proposals in the following sections to specifically address these issues that might otherwise preclude the CJR model from being considered an Advanced APM, or prevent us from operationalizing it as an Advanced APM. Based on the proposals for Advanced APM criteria in the Quality Payment Program proposed rule, we seek to align the design of the CJR model with the proposed Advanced APM criteria and enable CMS to have the necessary information on eligible clinicians to make the requisite QP determinations.

2. CJR Participant Hospital Tracks

To be considered an Advanced APM, the APM must require participants to use CEHRT (as defined in section 1848(o)(4) of the Act), as specified in section 1833(z)(3)(D)(i)(I) of the Act. We propose that all participant hospitals must choose whether to meet the CEHRT use requirement. Participant hospitals that do not meet and attest to the CEHRT use requirement would be in Track 2 of the CJR model. Participant hospitals selecting to meet the CEHRT use requirement would be in Track 1 of the CJR model and would be required to attest in a form and manner specified by CMS to their use of CEHRT that meets the definition in our regulation at section 414.1305 to document and communicate clinical care with patients and other health professionals, consistent with the proposal in the Quality Payment Program proposed rule for the CEHRT requirement for Advanced APMs (81 FR 28299). Participant hospitals choosing not to meet and attest to the CEHRT use requirement would not be required to submit an attestation.

We believe that the selection by the participant hospital to meet and attest to the CEHRT use requirement would create no significant additional administrative burden on participant hospitals. Moreover, the choice of whether to meet and attest to the CEHRT use requirement would not otherwise change any participant hospital's requirements or opportunity under the CJR model. However, to the extent the eligible clinicians who enter into financial arrangements related to Track 1 CJR participant hospitals are considered to furnish services through an Advanced APM, those services could be considered for purposes of determining whether the eligible clinicians are QPs.

The proposals for CEHRT use and attestation for participant hospitals are included in § 510.120(a). We seek comment on our proposals for CJR tracks and participant hospital requirements.

3. Clinician Financial Arrangements Lists Under the CJR Model

In order for CMS to make determinations as to eligible clinicians who could be considered QPs based on services furnished under the CJR model (to the extent the model is determined to be an Advanced APM), we require accurate information about eligible clinicians who enter into financial arrangements under Track 1 of CJR under which the Affiliated Practitioners support the participant hospitals' cost or quality goals as discussed in section V.J. of this proposed rule. We note that eligible clinicians could be CJR collaborators engaged in sharing arrangements with a CJR participant hospital; PGP members who are collaboration agents engaged in distribution arrangements with a PGP that is a CJR collaborator; or PGP members who are downstream collaboration agents engaged in downstream distribution arrangements with a PGP that is also an ACO participant in an ACO that is a CJR collaborator. These terms as they apply to individuals and entities with financial arrangements under CJR are discussed in section V.J. of this proposed rule. A list of physicians and nonphysician practitioners in one of these three types of arrangements could be considered an Affiliated Practitioner List of eligible clinicians who are

affiliated with and support the Advanced APM Entity in its participation in the Advanced APM as proposed in the Quality Payment Program proposed rule. Therefore, this list could be used to make determinations of who would be considered for a QP determination based on services furnished under the CJR model (81 FR 28320).

Thus, we propose that each participant hospital that chooses to meet and attest to the CEHRT use requirement must submit to CMS a clinician financial arrangements list in a form and manner specified by CMS on a no more than quarterly basis. The list must include the following information for the period of the CJR performance year specified by CMS:

- For each CJR collaborator who is a physician, nonphysician practitioner, or provider of outpatient therapy services during the period of the CJR performance year specified by CMS—

++ The name, tax identification number (TIN), and national provider identifier (NPI) of the CJR collaborator; and

++ The start date and, if applicable, end date, for the sharing arrangement between the CJR participant hospital and the CJR collaborator.

- For each collaboration agent who is a physician or nonphysician practitioner of a PGP that is a CJR collaborator during the period of the CJR performance year specified by CMS—

++ The TIN of the PGP that is the CJR collaborator, and the name and NPI of the physician or nonphysician practitioner; and

++ The start date and, if applicable, end date, for the distribution arrangement between the CJR collaborator that is a PGP and the physician or nonphysician practitioner who is a PGP member.

- For each downstream collaboration agent who is a physician or nonphysician practitioner member of a PGP that is also an ACO participant in an ACO that is a CJR collaborator during the period of the CJR performance year specified by CMS—

++ The TIN of the PGP that is the ACO participant, and the name and NPI of the physician or nonphysician practitioner; and

++ The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent that is both PGP and an ACO participant and the physician or nonphysician practitioner who is a PGP member.

- If there are no individuals that meet the requirements to be reported as CJR collaborators, collaboration agents, or downstream collaboration agents, the participant hospital must attest in a form and manner required by CMS that there are no individuals to report on the clinician financial arrangements list.

As discussed in the Quality Payment program proposed rule, those physicians or nonphysician practitioners who are included on the Affiliated Practitioner List as of December 31 of a performance period would be assessed to determine whether they qualify for APM Incentive Payments (81 FR 28320).

While the submission of this required information may create some additional administrative requirements for certain participant hospitals, we expect that Track 1 participant hospitals could modify their contractual relationships with their CJR collaborators and, correspondingly, require those collaborators to include similar requirements in their contracts with collaboration agents and in the contracts of collaboration agents with downstream collaboration agents.

The proposal for the submission of a clinician financial arrangements list by participant hospitals that meet and attest to the CEHRT use requirements for the CJR model is included in § 510.120(b). We seek comments on the proposal for submission of this information. We are especially interested in comments about approaches to information submission, including the periodicity and method of submission to CMS that would minimize the reporting burden on participant hospitals while providing CMS with sufficient information about eligible clinicians in order to facilitate QP determinations to the extent the CJR model is considered to be an Advanced APM.

4. Documentation Requirements

For each participant hospital that chooses to meet and attest to CEHRT use, we propose that the participant hospital must maintain documentation of their attestation to CEHRT use and clinician financial arrangements lists submitted to CMS. These documents would be necessary to assess the completeness and accuracy of materials submitted by a participant hospital in Track 1 of CJR and to facilitate monitoring and audits. For the same reason, we further propose that the participant hospital must retain and provide access to the required documentation in accordance with § 510.110.

The proposal for documentation of attestation to CEHRT use and clinician financial arrangements lists submitted to CMS is included in § 510.120(c). We seek comment on this proposal for required documentation.

VI. Cardiac Rehabilitation Incentive Payment Model

A. Background

For patients with coronary and other atherosclerotic vascular disease, the American Heart Association and the American College of Cardiology Foundation's 2011 practice guideline for secondary prevention and risk reduction therapy specifically highlights health care treatment strategies following AMI or CABG.[108] These strategies include smoking cessation, close monitoring of blood pressure and cholesterol, and the use of certain medications.

The medical literature further indicates that cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) services, which incorporate the strategies discussed previously, are capable of achieving significant improvements in long-term patient outcomes. A January 2016 Cochrane Database of Systematic Reviews article reviewed 63 trials randomizing almost 15,000 patients and found that in long-term follow up (median 12 months), exercise-based CR services reduced cardiovascular mortality (but not total mortality), improved health-related quality of life, and reduced the risk of hospital admission.[109]

Despite the evidence from multiple studies that CR services improve health outcomes, the literature also indicates that these services are underutilized, estimating that only about 35 percent of AMI patients receive this indicated treatment.[110] Recent analysis confirms a similar pattern of underutilization for Medicare beneficiaries who are eligible for and could benefit from CR. This pattern is virtually unchanged over the past 2 decades, despite clinical practice guidelines for CR that were published in 1995 and subsequently endorsed by a number of professional associations and CMS.[111] [112] [113] Among beneficiaries

[108] Smith SC et al. AHA/ACCF secondary prevention and risk reduction therapy for patients with coronary and other atherosclerotic vascular disease: 2011 update: A guideline from the American Heart Association and American College of Cardiology Foundation endorsed by the World Heart Federation and the Preventive Cardiovascular Nurses Association. J Am Coll Cardiol. 2011;58(23):2432–2446.

[109] Anderson L et al. Exercise-based cardiac rehabilitation for coronary heart disease. Cochrane Database Syst Rev. 2016 Jan 5;1:CD001800.

[110] Receipt of outpatient cardiac rehabilitation among heart attack survivors—United States, 2005. MMWR Morbidity and mortality weekly report. 2008 Feb 1;57(4):89–94.

[111] Suaya JA, Shepard DS, Normand SL, Ades PA, Prottas J, Stason WB. Use of cardiac rehabilitation by Medicare beneficiaries after myocardial

Continued

hospitalized with a diagnosis of AMI in 2013, only about 15 percent had at least one claim for CR services, and of those who received CR services, slightly more than half received 25 or more CR sessions. Among beneficiaries hospitalized with an ICD–9–CM procedure code for percutaneous transluminal coronary angioplasty or coronary stenting in 2013, the findings on CR use were similar to those for AMI beneficiaries, with only about 23 percent having at least one claim for CR services, and of those who received CR services, slightly more than half received 25 or more CR sessions. Finally, among beneficiaries hospitalized in 2013 with ICD–9–CM procedure codes for coronary artery bypass surgery, about 45 percent had at least one claim for CR services, and slightly over 60 percent of those beneficiaries received 25 CR sessions or more, indicating slightly higher rates for utilization for these beneficiaries.[114] Barriers to CR utilization include low beneficiary referral rates (particularly of women, older adults, and ethnic minorities); lack of strong physician endorsement of CR to their patients; lack of awareness of CR; the financial burden on beneficiaries due to coinsurance and lost work; lack of accessibility of CR program sites; the Medicare CR requirement for physician supervision; and inadequate insurance reimbursement.[115] [116] [117] [118]

Moreover, beneficiaries with CAD often receive care in many different settings from multiple providers and suppliers over the long-term and subsequently commonly experience care that is fragmented and uncoordinated. For example, inpatient hospitals, physicians, and CR programs currently are paid separately for the services they provide, with limited financial incentives for providing care management and preventive services, limiting overuse of tests and procedures, and coordinating across care settings. Lack of coordination, of both care and financial incentives, across the continuum of CAD care, results in higher than necessary rates of adverse drug events, hospital readmissions, diagnostic errors, and other adverse outcomes, as well as lower than appropriate utilization of evidence-based treatments.

Medicare Part B generally covers CR/ICR services for all Medicare beneficiaries who are referred by their physician after having an AMI or CABG.[119] As specified in section 1861(eee) of the Act, CR/ICR programs must include all of the following: (1) Physician-prescribed exercise; (2) cardiac risk factor modification, including education, counseling, and behavioral intervention, tailored to the patient's individual needs; (3) psychosocial assessment; (4) outcomes assessment; and (5) an individualized treatment plan established, reviewed, and signed by a physician every 30 days that details how components are utilized for each patient. The CR/ICR services must be provided in a physician's office or a hospital outpatient setting, and a physician must be immediately available and accessible to furnish assistance and direction at all times when cardiac rehabilitation services are being furnished under the program.[120]

The number of CR program sessions are limited to a maximum of 2 one-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the Medicare Administrative Contractor under section 1862(a)(1)(A) of the Act.[121] ICR program sessions are limited to 72 one-hour sessions, up to 6 sessions per day, over a period of up to 18 weeks.[122] To be approved as an ICR program, a program must demonstrate through peer-reviewed published research that it has accomplished at least one of the following: (1) Positively affecting the progression of coronary heart disease; (2) reducing the need for coronary bypass surgery; or (3) reducing the need for PCI.[123]

B. Overview of the CR Incentive Payment Model

1. Rationale for the CR Incentive Payment Model

Considering the evidence demonstrating that CR/ICR services improve long-term patient outcomes, the room for improvement in CR/ICR service utilization for beneficiaries eligible for this benefit, and the need for ongoing, chronic treatment for underlying CAD among beneficiaries that have had an AMI or a CABG, we believe that there is a need for improved long-term care management and care coordination for beneficiaries that have had an AMI or a CABG and that incentivizing the use of CR/ICR services is an important component of meeting this need. We want to reduce barriers to high-value care by testing a financial incentive for hospitals that encourages the management of beneficiaries that have had an AMI or a CABG in ways that may contribute to long-term improvements in quality and reductions in Medicare spending.

We believe that there are important advantages to proposing such an incentive in conjunction with the EPMs that are also proposed in this rule. First, we wish to understand whether and how the effects of a financial incentive for the use of CR/ICR services differ depending upon whether a beneficiary's care is covered under an EPM or the Medicare FFS program. The proposed AMI and CABG models could be effective launching pads for beneficiaries to receive improved coordination, care management, and secondary risk reduction during the model episodes through greater use of medically necessary CR/ICR services, even if accountability for beneficiary care ultimately transitions to other entities, such as ACOs or PCMHs, after the AMI or CABG model episode ends. Therefore, the AMI and CABG models could make the proposed CR incentive payment more effective (if it is amplified by the broader care coordination infrastructure encouraged

infarction or coronary bypass surgery. Circulation. 2007;116:1653–1662

[112] Wenger N, Froelicher E, Smith L, Wenger N, Froelicher E, Smith L, Ades P, Berra K, Blumenthal J, Certo C, Dattilo A, Davis D, DeBusk R, Drozda J, Fletcher B, Franklin B, Gaston H, Greenland P, McBride P, McGregor C, Oldridge N, Piscatella J, Rogers F. Cardiac Rehabilitation as Secondary Prevention: Clinical Practice Guideline, No. 17. Rockville, Md: U.S. Dept of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research and National Heart, Lung, and Blood Institute; 1995. Publication AHCPR 96–0673.

[113] Centers for Medicare and Medicaid Services (CMS). Cardiac rehabilitation programs. In: Medicare National Coverage Determinations Manual, chapter 1, part 1, section 20.10.

[114] Medicare Part A and B claims from 2013 through 12 month follow-up, Chronic Conditions Warehouse.

[115] Balady GJ, Ades PA, Bittner VA et al. Referral, enrollment, and delivery of cardiac rehabilitation/secondary prevention programs at clinical centers and beyond: a presidential advisory from the American Heart Association. Circulation. 2011;124:2951–2960.

[116] Suaya JA, Shepard DS, Normand SL, Ades PA, Prottas J, Stason WB. Use of cardiac rehabilitation by Medicare beneficiaries after myocardial infarction or coronary bypass surgery. Circulation. 2007;116:1653–1662

[117] Wenger, NK. Current State of Cardiac Rehabilitation. J Am Coll Cardiol 2008;51:1619–31

[118] Arena, R et al. Increasing Referral and Participation Rates to Outpatient Cardiac Rehabilitation: The Valuable Role of Healthcare Professionals in the Inpatient and Home Health Settings. AHA Scientific Advisory. 2012;125:1321–1329

[119] *https://www.medicare.gov/coverage/cardiac-rehab-programs.html.*

[120] Section 1861(eee)(1) of the Act.

[121] 42 CFR 410.49(b)(1)(vii)

[122] Section 1861(eee)(1) of the Act

[123] A list of ICR programs, approved through the national coverage determination process, is posted to the CMS Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/ICR.html* and listed in the **Federal Register** at 42 CFR 410.49(c)(3).

by the EPM in comparison with its effect in the Medicare FFS payment methodology) or less effective (if the care coordination infrastructure encouraged by the EPM is itself sufficient to ensure appropriate use of CR/ICR services such that the CR incentive payment itself has less effect than in the Medicare FFS payment methodology). Second, we wish to be able to examine each intervention's separate effects on the quality and efficiency of the care beneficiaries receive. We believe that coordinating the design, implementation, and evaluation of the EPMs and the CR incentive payment model is the best way to ensure that we accomplish both of these goals.

2. General Design of the CR Incentive Payment Model

We propose the CR incentive payment model to test the effects on quality of care and Medicare expenditures of providing explicit financial incentives to hospitals (hereinafter CR participants) for beneficiaries hospitalized for treatment of AMI or CABG to encourage care coordination and greater utilization of medically necessary CR/ICR services for 90 days post-hospital discharge where the beneficiary's overall care is paid under either an EPM or the Medicare FFS program. Under the EPM, we propose in general that the hospital where the anchor hospitalization for AMI or CABG treatment occurs that begins the AMI or CABG model episode as discussed in section III.C.4.a. of this proposed rule would be financially accountable for the AMI or CABG model episode. Thus, we expect that EPM participants would be highly engaged in care management of beneficiaries for the 90-day post-discharge duration included in the episode and may be able to capitalize on that engagement to encourage greater use of medically appropriate CR/ICR services if they are also selected for participation in the CR incentive payment model. Therefore, under the CR incentive payment model, we propose to provide a CR incentive payment specifically to selected hospitals with financial responsibility for AMI or CABG model episodes (hereinafter EPM–CR participants) because they are already engaged in managing the AMI or CABG model beneficiary's overall care for a period of time following hospital discharge.

Similarly, we believe there are opportunities to test the same financial incentives for hospitals where the beneficiary's overall care is paid under the Medicare FFS program. Thus, we also propose to provide a CR incentive payment specifically to selected hospitals that are not AMI or CABG model participants (hereinafter FFS–CR participants). This design of the CR incentive payment model would enable us to test and improve our understanding of the effects of the CR incentive payment within the context of an EPM and the Medicare FFS program, as well as identify potential interactions between the proposed CR incentive payment and the underlying EPM and FFS payment methodologies. We understand that there may be providers and suppliers other than hospitals caring for beneficiaries with AMI or CABG whose care is paid under the Medicare FFS program and that could assume responsibility for encouraging greater utilization of CR/ICR services under the CR incentive payment model. However, for comparability to the roles and responsibilities of the hospitals that are the EPM participants selected for CR incentive payment model participation, we propose to identify hospitals as the participants in the CR incentive payment model for beneficiaries whose care is paid under the Medicare FFS program. Hospitals provide over 95 percent of CR/ICR services to Medicare beneficiaries and the beneficiaries in the CR incentive payment model are identified based on a hospitalization for AMI or CABG.[124] Thus, we believe that hospitals are an appropriate entity to take on care coordination responsibility for increasing the utilization of medically necessary CR/ICR services for those beneficiaries following AMI or CABG who are in the CR incentive payment model but that are not in an EPM.

To test strategies to encourage CR participants to prioritize referring beneficiaries following an AMI or CABG for important CR/ICR services, monitoring for beneficiary adherence to the treatment plan, and coordinating care, we propose to establish a per-service CR incentive amount for beneficiary CR use at two levels that would initially incentivize the use of any CR/ICR services and that would increase once a beneficiary meets or exceeds the proposed CR/ICR service utilization benchmark. We believe that encouraging timely referral of beneficiaries that have had an AMI or a CABG to CR/ICR programs would promote better adherence to CR/ICR service protocols, an expectation that is supported by data showing that patients who are referred early to CR were more likely to enroll.[125]

Historical claims data show that more than half of beneficiaries who receive one CR session go on to complete at least 25 sessions.[126] Thus, providing a CR incentive payment to reward increased referrals to CR/ICR programs, as well as monitoring for beneficiary adherence with the referral and participation in the sessions, may encourage better CAD-specific care management and care coordination for beneficiaries that have had an AMI or a CABG and, ultimately, improve quality and reduce spending long-term for these beneficiaries with CAD. CR participants that would be eligible for these CR incentive payments could further reduce potential beneficiary barriers to CR/ICR services by utilizing other flexibilities we propose for the AMI and CABG models and the CR incentive payment model, such as beneficiary engagement incentives as discussed in sections III.I.9. and VI.F.6. of this proposed rule for EPM–CR participants and FFS–CR participants, respectively. Furthermore, we refer to section III.J.8. of this proposed rule for our proposal to provide greater CR/ICR program flexibility that may increase the availability of CR/ICR services for AMI and CABG model beneficiaries by providing a waiver of the definition of a physician to include a physician or nonphysician practitioner (defined for the purposes of this waiver as a physician assistant, nurse practitioner, or clinical nurse specialist) in performing specific physician functions. We also refer to section VI.F.7. of this proposed rule for discussion of our proposal for a similar waiver of the physician definition to provide greater CR/ICR program flexibility to increase the availability of these services for beneficiaries in a FFS–CR participant, as defined later in this section.

While we recognize there are other services focused on secondary prevention for beneficiaries with CAD such as diabetes self-management training, as well as treatments including drugs for blood pressure and cholesterol control, we believe that CR/ICR services are unique as an underutilized Medicare benefit with a strong evidence-base of improved health outcomes for beneficiaries who have had an AMI or a CABG. Therefore, we believe that CR/ICR services are uniquely worthy of CR incentive payments to selected AMI and

[124] Analysis of cardiac rehabilitation utilization in care periods for AMI and CABG beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, that began in CYs 2012–2014.

[125] Grace SL et al. Effectiveness of inpatient and outpatient strategies in increasing referral and utilization of cardiac rehabilitation: a prospective, multi-site study. Implement Sci. 2012: 7:120.

[126] Analysis of CR/ICR services utilization in 2013 Medicare FFS Parts A and B claims.

CABG model participants as well as selected hospitals that would not be participating in these models in order to reward their efforts where we observe increased CR/ICR service utilization for CR incentive payment model beneficiaries. By proposing to provide CR incentive payments to encourage CR/ICR service utilization, we maximize our opportunity to positively affect the quality of care and reduce the cost-of-care for beneficiaries that have had an AMI or a CABG both within the short- and long-term. Like under other Innovation Center models, beneficiaries in the CR incentive payment model would retain freedom of choice to choose providers and services, although the proposed model provides financial incentives to CR participants to specifically encourage and support beneficiaries in adhering to a prescribed CR treatment plan following AMI or CABG.

By making CR incentive payments available to selected EPM–CR and FFS–CR participants and comparing them to EPM participants and hospitals paid under the Medicare FFS program for AMI and CABG care who are not CR participants, we would be able to observe the effects of these proposed CR incentive payments on utilization of CR/ICR services and short-term (within the episode or care period) and longer-term outcomes, including mortality, hospitalizations, complications, and other clinically relevant events, as well as on Medicare expenditures. In testing the effects of a CR incentive payment, we want to account for a range of factors and interactions that could potentially affect the outcomes we observe. We believe our proposed methodology would enable us to test and improve our understanding of the effects of the CR incentive payment within the context of an EPM and the Medicare FFS program, as well as examine potential interactions between the proposed CR incentive payment and the underlying EPM and FFS payment methodologies.

C. CR Incentive Payment Model Participants

The selection of MSAs for participation in the CABG and AMI EPMs is described in section III.B.5. of this proposed rule. This selection process would identify the 98 EPM MSAs from the 294 MSAs eligible for selection for the AMI and CABG models under the proposed rules. We propose that 45 MSAs be selected from within the pool of the 98 EPM MSAs for the CR incentive payment model (hereinafter EPM–CR MSAs). An additional 45 MSAs would be selected for the CR incentive payment model from the pool of MSAs who were eligible but not selected for EPM (hereinafter FFS–CR MSAs). The approach for both selections in the following paragraphs.

We are interested in identifying control group MSAs that are similar to the treatment MSAs in ways that might impact the nature of their response to the CR incentive payment model. Having well-matched MSAs in the four types of MSAs (FFS–CR, FFS-non CR, EPM–CR and EPM-non CR) is important to our ability to assess the specific impact of the CR incentive payment while holding other considerations constant. We are concerned that a simple random selection of FFS–CR and EPM–CR areas would have a large probability of selecting MSAs that are insufficiently similar to the EPM-non CR areas due to the small number of MSAs from which to choose. As such, CMS proposes the selection of the EPM–CR MSAs to balance the incidence of key characteristics between the EPM–CR and EPM-non CR MSAs and the selection of FFS–CR MSAs to be based on similarity to the randomly selected EPM MSAs.

The 294 MSAs originally eligible for selection would be classified into groups based on combinations of several key dimensions related to CR or ICR service provision within the MSA in the reference year including—

- Percent Starting CR/ICR services: Percent of eligible cases in the MSA who received one or more CR or ICR services in the reference year. CMS is considering dividing MSAs through alternative cut points of this metric including 20 percent and 30 percent;
- Percent Completing CR/ICR services: Percent of eligible cases in the MSA who completed 25 or more CR or ICR services in the reference year. CMS is considering dividing MSAs through alternative cut points including 50 percent, 60 percent and 70 percent of this metric; and.
- Number of CR/ICR providers: The number of providers who billed for CR/ICR services in the MSA during the reference year. CMS is considering dividing MSAs according to whether they had one hospital who billed for CR services or more than one hospital.

MSAs would be assigned into a group based on combinations of these measures. An example of a possible group would be a group of MSAs that are ''low starters, high users.'' Such a group might be defined as MSAs in which—(1) less than 20 percent of eligible patients start CR/ICR services; (2) more than 60 percent of individuals who start CR/ICR complete 25 or more sessions; and (3) more than one hospital bills for CR services.

We propose the selection of CR MSAs via a modified stratified random selection algorithm in which these groups serve as the selection strata. Specifically, we propose that the number of EPM–CR and FFS–CR MSAs selected from each group equals the number of EPM MSAs in the group multiplied by 0.46. This rate was chosen with the goal of selecting 45 EPM–CR MSAs out of 98 EPM MSAs (45/98 is approximately equal to 0.46). As an example of this approach to selection, consider a hypothetical group with 16 EPM MSAs and 28 FFS MSAs. We would randomly select 7 EPM–CR MSAs from the 16 EPM MSAs (7 is equal to 0.46×16 with rounding). The remaining 9 would be EPM-non CR. We would also randomly select 7 FFS–CR MSAs from the 28 FFS MSAs. The remaining 21 MSAs would be FFS-non CR MSAs. This approach would ensure balance with respect to group membership between EPM–CR MSAs and EPM-non-CR MSAs, as well as between EPM–CR MSAs and FFS–CR MSAs; it would not necessarily achieve balance with respect to group membership for other comparisons among model arms.

We also considered other approaches to selection. Under one alternative approach, we would select a number of EPM–CR MSAs from each group equal to the number of EPM MSAs in the group multiplied by 0.46 and a number of FFS–CR MSAs from each group equal to the number of FFS MSAs in the group multiplied by 0.23. As previously discussed, the rate 0.46 was chosen with the goal of selecting 45 EPM–CR MSAs out of 98 EPM MSAs. The rate 0.23 is based on the goal of selecting 45 FFS–CR MSAs out of 196 FFS MSAs (45/196 is approximately equal to 0.23). As in our proposed approach, the calculated number of MSAs to be selected from each group would be rounded to the nearest integer as necessary. This approach would ensure balance with respect to group membership between EPM–CR MSAs and EPM-non-CR MSAs, as well as between FFS–CR MSAs and FFS-non-CR MSAs; it would not necessarily achieve balance with respect to group membership for other comparisons among model arms.

Under another alternative approach, we would use a stratified random assignment approach to determine both EPM participation and CR participation. Specifically, under this approach, the number of EPM–CRs and FFS–CR MSAs selected from each group would each be equal to the total number of MSAs in that group multiplied by 0.15, the number of EPM-non-CR MSAs selected from each group would be equal to the

total number of MSAs in the group multiplied by 0.18, and the remaining MSAs in each group would be assigned to be FFS-non-CR MSAs. The rate 0.15 was chosen with the goal of selecting 45 EPM–CR MSAs and 45 FFS–CR MSAs out of 294 total MSAs (45/294 is approximately equal to 0.15), and the rate 0.18 was chosen with the goal of selecting 53 EPM-non-CR MSAs out of 294 total MSAs (53/294 is approximately equal to 0.18). As in our proposed approach, the calculated number of MSAs to be selected into each arm would be rounded to the nearest integer as necessary. This approach would ensure balance with respect to group membership for all comparisons across the four arms—EPM–CR, FFS–CR, EPM-non-CR, and FFS-non-CR—but would forgo the simplicity of simple random assignment for the selection of EPM MSAs.

For the purposes of being able to evaluate the CR incentive payment model as a whole, we propose to implement it in a consistent manner between the EPM–CR areas and the FFS–CR areas. As such, we propose to use similar approaches to identifying CR participants in each while also coordinating with the specifications and requirements of the AMI and CABG models. We propose that EPM–CR participants are hospitals that are AMI or CABG model participants located in the MSAs selected for the EPM–CR participation based on the methodology previously described in this section VI.C. of this proposed rule. We similarly propose that FFS–CR participants are hospitals located in the MSAs selected for FFS–CR participation based on the methodology previously described in section VI.C of this proposed rule and that meet all provisions in sections III.B.2. through III.B.4. of this proposed rule to be an EPM participant if the hospital were located in an MSA selected for the AMI or CABG model. We believe that requiring FFS–CR participants to meet all provisions in sections III.B.2. through III.B.4. of this proposed rule would ensure that FFS–CR participants resemble EPM–CR participants as closely as possible, which would contribute to our ability to test and evaluate the effect of the CR incentive payment and specifically whether there are differential effects of the CR incentive payment in the underlying EPM and FFS payment methodologies.

The proposal to select MSAs for the CR incentive payment model and to identify CR participants is included in § 512.703. We seek comments on our proposed approach to selecting MSAs and identifying CR participants.

D. CR/ICR Services That Count Towards CR Incentive Payments

We propose to identify CR/ICR services that count towards CR incentive payments on the basis of the presence of the HCPCS codes on PFS and OPPS claims that report CR/ICR services as displayed in Table 37. These HCPCS codes have been active since prior to 2013 through the present. We note that CMS specifies the CR/ICR service HCPCS codes in implementing the statutory coverage provisions for CR and ICR programs, and we would update this list of HCPCS codes for CR/ICR services for the CR incentive payment model in future CR performance years should CMS adopt different or additional HCPCS codes for reporting these services.[127] [128]

TABLE 37—HCPCS CODES FOR CARDIAC REHABILITATION AND INTENSIVE CARDIAC REHABILITATION SERVICES

HCPCS Code	Descriptor
93797	Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session).
93798	Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session).
G0422	Intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session.
G0423	Intensive cardiac rehabilitation; with or without continuous ECG monitoring; without exercise, per session.

We propose that within the AMI and CABG models, CR/ICR services paid by Medicare to any provider or supplier for AMI and CABG model beneficiaries during AMI and CABG model episodes would result in EPM–CR participant eligibility for CR incentive payments. For FFS–CR participants, we propose to use the terms ''AMI care period'' and ''CABG care period'' to refer to a period of AMI or CABG care, respectively, that would meet the requirements to be an AMI or CABG model episode in accordance with all provisions in subpart B if the FFS–CR participant were an AMI or CABG model participant. CR/ICR services paid by Medicare to any provider or supplier for beneficiaries during AMI care periods and CABG care periods would result in FFS–CR participant eligibility for CR incentive payments. Defining AMI care periods and CABG care periods using the AMI and CABG model episode definitions ensures that the care covered under AMI care periods and CABG care periods is comparable to AMI and CABG model episodes in terms of the criteria that must be met to start an AMI care period or CABG care period or an AMI or CABG model episode, as well as the duration of AMI care periods and CABG care periods and AMI and CABG model episodes. This comparability would contribute to our ability to test and evaluate the effects of the CR incentive payment and specifically to assess whether there are differential effects of the CR incentive payment in the underlying EPM and FFS payment methodologies.

We also propose that AMI and CABG model episodes take precedence over AMI care periods and CABG care periods. That is, an AMI care period or CABG care period would not begin if the beneficiary is in an AMI or CABG model episode when the AMI care period or CABG care period would otherwise begin. Similarly, an AMI care period or CABG care period would be canceled if at any time during the AMI care period or CABG care period the beneficiary initiates an AMI or CABG model episode. We believe that this is appropriate because AMI and CABG model participants would have ultimate responsibility for care coordination and the quality and cost of a beneficiary's

[127] 42 CFR 410.49

[128] MLN Matters® Number: MM6850 Revised. Related Change Request #: 6850; Related CR Release Date: May 21, 2010. Effective Date: January 1, 2010. Related CR Transmittal #: R1974CP, R126BP, R339PI, and R170FM. Implementation Date: October 4, 2010.

care during an AMI or CABG model episode. Giving precedence to AMI and CABG model episodes would also ensure that Medicare does not make duplicative CR incentive payments for a beneficiary and that a single beneficiary is not in an AMI or CABG model episode and an AMI care period or CABG care period at the same time.

We propose that for the purposes of the CR incentive payment, all AMI and CABG model episodes and all AMI care periods and CABG care periods must begin on or after July 1, 2017 and end on or before December 31, 2021. Thus, the CR performance years would be the same as the performance years proposed for the EPMs in section III.D.2.a. of this proposed rule. Given that the CR incentive payment model seeks to determine whether there are differential effects of the CR incentive payment in the underlying EPM and FFS payment methodologies, it is important the EPM and CR performance years be aligned for EPM–CR participants.

The proposal to establish which CR/ICR services count towards CR incentive payments is included in § 512.705. We seek comments on our proposal to establish which CR/ICR services count towards CR incentive payments.

E. Determination of CR Incentive Payments

1. Determination of CR Amounts That Sum to Determine a CR Incentive Payment

Given the potential benefits of CR/ICR services, in conjunction with the low adoption of these services, we seek to propose an incentive for CR participants that is sufficient to encourage them to increase clinically appropriate CR/ICR service referrals for beneficiaries; reduce barriers to beneficiary adherence a CR/ICR service treatment plan by making additional resources available for transportation to and from CR/ICR services; and incentivize CR participant monitoring and support of beneficiary adherence to all prescribed sessions of the CR/ICR program. As such, in addition to the usual payments that Medicare makes to providers and suppliers that furnish CR/ICR services, we propose to establish a two-level per-service CR incentive amount that would initially incentivize the use of any CR/ICR services and that would increase once a beneficiary meets or exceeds the proposed CR/ICR service utilization benchmark. The CR amount would be the dollar amount determined by the two-level per-service CR incentive amounts that apply to the number of CR/ICR services paid by Medicare to any provider or supplier for a beneficiary in an AMI or CABG model episode or AMI care period or CABG care period. CR amounts across all of a CR participant's beneficiaries that received CR/ICR services would be summed for the CR performance year to determine the CR incentive payment for a CR participant. CMS would pay the CR incentive payment from the Part B Trust Fund to the CR participant after the end of each CR performance year, and the beneficiary-specific CR amounts would be submitted to the CMS Master Database Management (MDM) System.

For the purpose of determining the CR incentive payment, we propose to count the number of CR/ICR services for the relevant time periods under the OPPS and PFS on the basis of the presence on paid claims of the HCPCS codes that report CR/ICR services as displayed in Table 37 and the units of service billed.

The initial level of the per-service CR incentive amount that would count toward the CR amount would be $25 per CR/ICR service for each of the first 11 CR/ICR services paid for by Medicare during an AMI or CABG model episode or AMI care period or CABG care period. We believe that $25 is an appropriate amount to account for the additional resources that CR participants would expend to reduce beneficiary barriers to utilizing any CR/ICR services and to support beneficiary adherence to all prescribed services in the CR/ICR program.

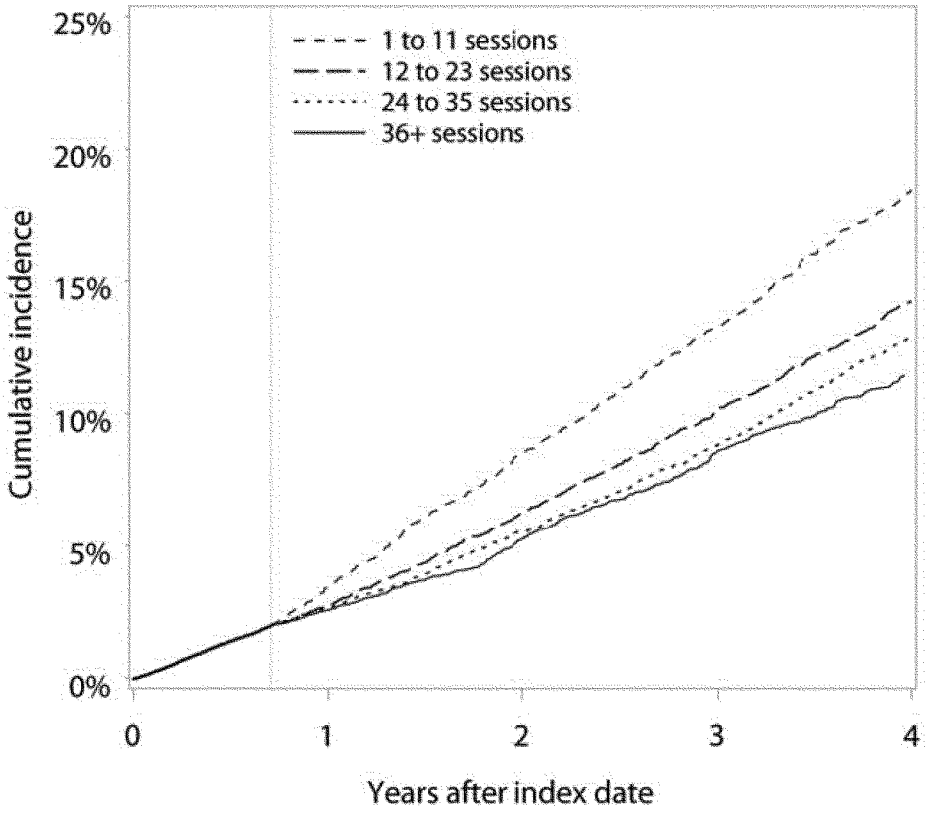
After 11 CR/ICR services are paid for by Medicare for a beneficiary, the level of the per-service CR incentive amount would increase to $175 per CR/ICR service for each additional CR/ICR service paid for by Medicare during the AMI or CABG model episode or AMI care period or CABG care period. This higher payment would account for the additional resources that CR participants expend to reduce beneficiary barriers to CR/ICR service utilization and also would reward CR participants for AMI or CABG model episodes or AMI care periods or CABG care periods in which beneficiaries meet or exceed the service utilization benchmark of 12 CR/ICR services.

We set the proposed service utilization benchmark based on evidence from the literature that shows reduced mortality for Medicare beneficiaries that complete at least 12 CR sessions relative to Medicare beneficiaries who complete 1–11 CR sessions. A study by Hammill et al found that over a 4-year follow-up period beneficiaries who completed 12–23 CR sessions had lower mortality compared to beneficiaries who completed 1–11 CR sessions and that beneficiaries who completed 24 or more CR sessions had lower mortality compared to beneficiaries that completed 12–23 sessions.[129] Figure 4 replicates Figure 2 from that study.

[129] Hammill BG, Curtis LH, Schulman KA, Whellan DJ. Relationship between cardiac rehabilitation and long-term risks of mortality and myocardial infarction among elderly Medicare beneficiaries. Circulation. 2010; 121:63–70.

[130] Figure 2 of Hammill BG, Curtis LH, Schulman KA, Whellan DJ. Relationship between cardiac rehabilitation and long-term risks of mortality and myocardial infarction among elderly Medicare beneficiaries. Circulation. 2010; 121:63–70. Note that the 30,161 overall beneficiaries in the table contained in the figure refers to the number of Medicare beneficiaries that initiated cardiac rehabilitation services between January 1, 2000 and December 31, 2005 in the national 5 percent sample used by Hammill et al.

FIGURE 4: CUMULATIVE INCIDENCE OF MORTALITY BY NUMBER OF CARDIAC REHABILITATION SESSIONS ATTENDED[130]

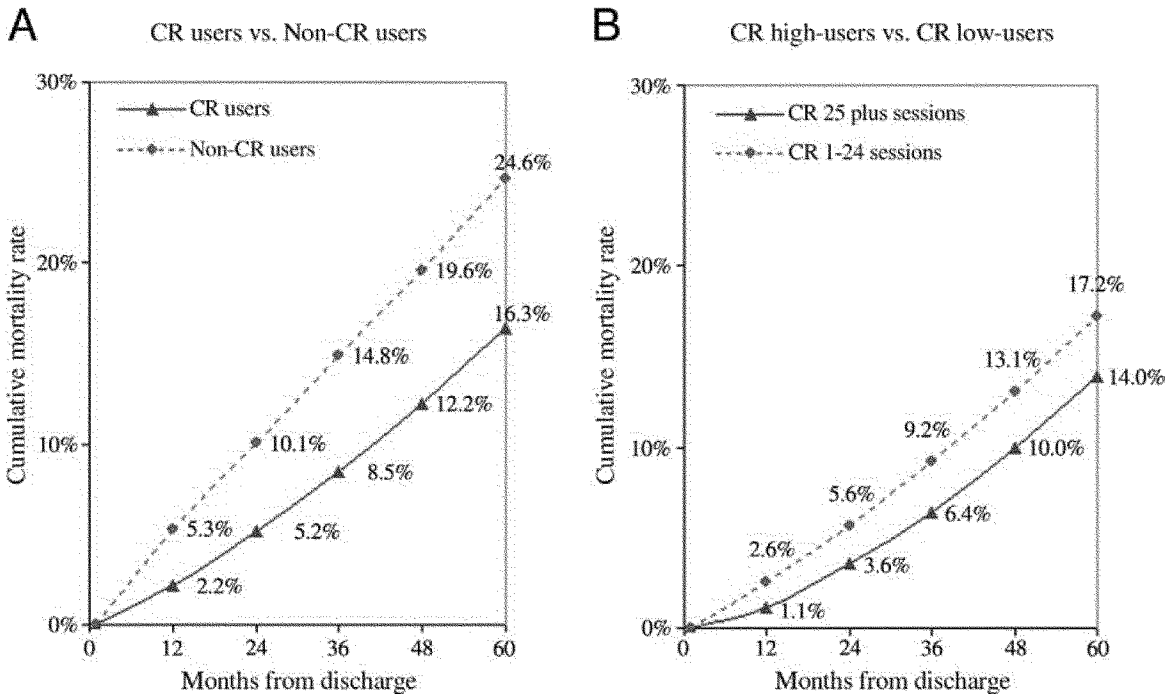


No. at risk					
Overall	30,161				
1 to 11 sessions		5937	4883	3865	2859
12 to 23 sessions		6933	5716	4427	3223
24 to 35 sessions		10,978	8955	6905	4885
36 sessions		5465	4513	3523	2481

Another study by Suaya et al showed that over a 5-year period beneficiaries who were hospitalized for coronary conditions or cardiac revascularization procedures and completed 1–24 CR sessions had lower mortality compared to beneficiaries who were probable candidates for CR but completed 0 CR sessions and that beneficiaries who completed 25 or more CR sessions had lower mortality compared to beneficiaries who completed 1–24 CR sessions.[131] Figure 5 replicates Figure 1 from that study.

[131] Suaya JA, Stason WB, Ades PA, Normand ST, Shephard DS. Cardiac rehabilitation and survival in older coronary patients. Journal of the American College of Cardiology 2009; 54:25–33.

FIGURE 5: ESTIMATES OF CUMULATIVE MORTALITY RATES FOR PROPENSITY-BASED MATCHED GROUPS OF CR USE[132]



We do not propose to set a cap on the number of CR/ICR services that would count toward the CR amount during an AMI or CABG model episode or AMI care period or CABG care period because the literature shows incremental improvements in outcomes associated with more CR/ICR services through 36 or more sessions. The duration of AMI and CABG model episodes and AMI care periods and CABG care periods is only 90 days post-discharge from the hospitalization that begins the episode or care period, or roughly 13 weeks, and Medicare already limits the number of covered CR/ICR services for a beneficiary. The number of CR program sessions are limited to a maximum of 2 one-hour sessions per day for up to 36 sessions over up to 36 weeks, with the option for an additional 36 sessions over an extended period of time if approved by the Medicare Administrative Contractor under section 1862(a)(1)(A) of the Act.[133] ICR program sessions are limited to 72 one-hour sessions, up to 6 sessions per day, over a period of up to 18 weeks.[134]

We believe that the higher per-service CR incentive amount that would count toward the CR amount when CR/ICR services paid by Medicare to any provider or supplier for a beneficiary in an AMI or CABG model episode or AMI care period or CABG care period meet or exceed the evidence-based service utilization benchmark would strengthen the financial incentive for CR participants to ensure beneficiary adherence to all prescribed CR/ICR services beyond the initial $25 per-service CR incentive amount for the first 11 CR/ICR services. Moreover, the higher level of the per-service CR incentive amount when a beneficiary completes at least 12 CR/ICR services provides a strong incentive for CR participants to expand CR referrals and to increase the likelihood that beneficiaries complete a clinically meaningful number of CR services. The proposal creates a continuous, significant incentive for increased CR/ICR service utilization that provides value beyond the service utilization benchmark of 12 CR/ICR services, consistent with the literature that shows a decrease in mortality for beneficiaries that complete more CR sessions relative to beneficiaries that complete fewer CR sessions.

The CR amount for a beneficiary in a CR participant's AMI and CABG model episodes or AMI care periods and CABG care periods in a CR performance year would be the sum of the $25 per-service CR incentive amount for each of the first 11 CR/ICR services and the $175 per-service CR incentive amount for each additional CR/ICR service paid by Medicare beyond the first 11. The CR participant's CR incentive payment for a CR performance year would be determined based on the sum of the CR amounts across all of its beneficiaries for that CR performance year.

We believe that this comprehensive CR incentive payment methodology would be appropriate because it would create an explicit, strong incentive for CR participants to expand the utilization of CR/ICR services to achieve at least the evidence-based service utilization benchmark of 12 ICR/CR services and then significantly and continuously incentivize the provision of additional CR/ICR services that provide additional value, even if the full benefit of CR/ICR services for beneficiaries that have had an AMI or a CABG is not realized until after an episode or care period ends. Moreover, the CR incentive payment could offset resource costs incurred by CR participants that successfully increase utilization of CR/ICR services, such as FFS–CR participants providing transportation or EPM–CR participants providing beneficiary engagement incentives as discussed in sections III.I.9. and VI.F.6. of this proposed rule for EPM–CR and FFS–CR participants, respectively.

Because the CR incentive payment would be made to the CR participant

[132] Figure 1 of Suaya JA, Stason WB, Ades PA, Normand ST, Shephard DS. Cardiac rehabilitation and survival in older coronary patients. Journal of the American College of Cardiology 2009; 54:25–33.

[133] 42 CFR 410.49(b)(1)(vii).

[134] Section 1861(eee)(1) of the Act.

retrospectively after the end of a CR performance year as discussed in section VI.E.4. of this proposed rule, the CR incentive payment would represent the totality of financial reward to the CR participant based on the proposed methodology for determining the payment based on CR/ICR service utilization during the CR performance year. The CR participant's resources required to support the increased utilization of CR/ICR services are likely to vary among beneficiaries. For example, it is possible that greater CR participant resources may be required to encourage and support the utilization of a beneficiary's first CR/ICR services during an AMI or CABG model episode or AMI care period or CABG care period, in comparison with promoting adherence to additional prescribed CR/ICR services once the care pattern is well-established for that beneficiary. The proposed retrospective payment approach means CR participants would have the flexibility to redesign care to meet the needs of their beneficiaries regarding increased utilization of CR/ICR services, even though the CR incentive payment methodology only provides the higher level per-service CR incentive amount when CR/ICR service utilization achieves levels associated with improved outcomes. This approach is consistent with the model payment methodology that is designed to reward the value and not the volume of services by providing a higher total financial reward for utilization of services that has been shown to result in improved outcomes.

The proposals for determining the amount of the CR incentive payments are included in § 512.710(a) and (b). We would also note that we expect to revisit the levels of the CR incentive payment and the service utilization benchmark over the CR performance years as we observe the effects of the model policies on CR/ICR service utilization and the long-term outcomes and Medicare expenditures for CR incentive payment model beneficiaries under the EPM and Medicare FFS program payment methodologies for overall care. For example, it is possible that the proposed CR incentive payment methodology could lead to substantial increases in CR/ICR service utilization such that the proposed CR incentive payment model policies may no longer be necessary or appropriate once new care patterns are well-established.

2. Relation of CR Incentive Payments to EPM Pricing and Payment Policies and Sharing Arrangements for EPM–CR Participants

We view the proposed CR incentive payments as separate and distinct from reconciliation payments and Medicare repayments for EPM–CR participants determined under § 512.305(d). The determination of these latter payments is based on an assessment of actual episode payments and quality of the totality of episode services and coordination of those services during AMI and CABG model episodes within a performance year, consistent with the goals of improving quality and reducing costs within the model episode itself. In contrast, the proposed CR incentive payment under the CR incentive payment model is a more circumscribed and specific payment designed to financially incentivize increased utilization of CR/ICR services which may improve quality and reduce costs for AMI and CABG model beneficiaries in the long-term, after the episodes end. Thus, we propose to determine and apply the CR incentive payment separately from the determination and application of reconciliation payments and Medicare repayments for EPM–CR participants. Moreover, would also note that we propose to make CR incentive payments to EPM–CR participants without application of the limitation on gains as specified in § 512.305(c)(2)(iii)(B). This is because the limitation on gains is designed to mitigate potential excessive reductions in utilization under the proposed EPMs, and by construction, the CR incentive payment would only be made when an EPM–CR participant increases utilization of CR/ICR services. Therefore, the CR incentive payment is unrelated to the comparison of actual EPM episode payment to the quality-adjusted target price in calculating the NPRA, to which the limitation on gains applies and that may ultimately result in a reconciliation payment to an EPM–CR participant.

Consistent with the aforementioned proposal and for the aforementioned reasons, in contrast to reconciliation payments, we propose to not permit the inclusion of CR incentive payments in sharing arrangements for EPM–CR participants specified in § 512.500. As discussed in section III.I.1. of this proposed rule, we believe that EPM participants may wish to enter into financial arrangements with providers and suppliers caring for EPM beneficiaries to share financial risks and rewards under the EPM, in order to align the financial incentives of those providers, suppliers, and Medicare ACOs with the EPM goals of improving quality and efficiency for EPM episodes. In contrast, the CR incentive payment for EPM–CR participants is specifically tied to increased utilization of CR/ICR services within AMI and CABG model episodes and, therefore, is designed to reward increased EPM–CR participant referral of AMI and CABG model beneficiaries to CR/ICR programs, as well as supporting beneficiary adherence to the referral and participation in CR/ICR services, rather than the quality and efficiency of EPM episodes themselves. Thus, we do not propose to allow CR incentive payments to be included in sharing arrangements, and the CR incentive payments may be shared with other individual and entities only under circumstances which comply with all existing laws and regulations, including fraud and abuse laws. Similarly, we do not propose that CR incentive payment be allowed to be shared by FFS–CR participants with other individuals and entities other than under circumstances which comply with all existing laws and regulations, including fraud and abuse laws. We refer to section VI.G. of this proposed rule for further discussion of considerations regarding financial arrangements under the CR incentive payment model.

Likewise, we propose to exclude CR incentive payments when updating quality-adjusted target prices for EPM–CR participants for performance years 3–5 of the EPM because payments for CR/ICR services already would be captured in the claims used to update those quality-adjusted target prices. Therefore, we believe that including the CR incentive payments would result in double counting expenditures for CR/ICR services when updating quality-adjusted target prices. We note that while the CR incentive payments would not be included in the calculation of actual EPM episode spending or when updating quality-adjusted target prices for EPM–CR participants, the claims for those CR/ICR services upon which the CR incentive payment was determined would be included in both calculations.

The proposals for keeping CR incentive payments, if any, separate from reconciliation payments and Medicare repayments as well as excluding them from sharing arrangements and updating quality adjusted target prices for EPM–CR participants are included in § 512.710(c) through (e). We seek comments on our proposals to keep CR incentive payments separate and exclusive.

3. CR Incentive Payment Report

For CR participants to receive timely and meaningful feedback on their performance with respect to the proposed CR incentive payments, we propose to annually issue to CR participants a report containing at a minimum—

- 1—The number of AMI and CABG model episodes or AMI care periods and CABG care periods attributed to the CR participant in which Medicare paid for 11 or fewer CR/ICR services for a beneficiary during the CR performance year, if any;
- 2—The total number of CR/ICR services Medicare paid for during AMI and CABG model episodes or AMI care periods and CABG care periods identified in (1);
- 3—The amount of the CR incentive payment attributable to the AMI and CABG model episodes or AMI care periods and CABG care periods identified in (1);
- 4—The number of AMI and CABG model episodes or AMI care periods and CABG care periods attributed to the CR participant in which Medicare paid for 12 or more CR/ICR services for a beneficiary during the CR performance year, if any;
- 5—The total number of CR/ICR services Medicare paid for during AMI and CABG model episodes or AMI care periods and CABG care periods identified in (4);
- 6—The amount of the CR incentive payment attributable to the AMI and CABG model episodes or AMI care periods and CABG care periods identified in (4); and
- 7—The total amount of the CR incentive payment.

We also considered including additional information in the CR incentive payment report, including information on the number of CR/ICR services paid for by Medicare during each AMI or CABG model episode or AMI care period or CABG care period attributed to the CR participant during the CR performance year. However, because EPM–CR participants and FFS–CR participants can request more specific beneficiary-level data that would contain information on CR/ICR services paid for by Medicare for each AMI or CABG model episode or AMI care period or CABG care period attributed to the CR participant during the CR performance year, as discussed in sections III.K.2. and VI.F.3. of this proposed rule, we do not propose to include such additional information in the CR incentive payment report.

For EPM–CR participants, we propose to issue this annual report at the same time we issue the reconciliation report specified in § 512.305(f). For FFS–CR participants, we propose to issue this report at the same time proposed for EPM–CR participants.

The proposal to issue a CR incentive payment report is included in § 512.710(f). We seek comments on our proposal to issue a CR incentive payment report to CR participants and what other information, if any, would be helpful to include in the CR incentive payment report.

4. Proposed Timing for Making CR Incentive Payments

We propose to make CR incentive payments on a retrospective basis. In the case of an EPM–CR participant, these payments would occur concurrently with EPM reconciliation payments or repayment amounts assessed for a specific CR performance year which is the same as the performance year for the EPM, subject to the relation of the CR incentive payment described in section VI.E.2. of this proposed rule and the appeals process for EPM participants described in section III.D.8. of this proposed rule. In the case of a FFS–CR participant, these payments would occur at the same time as is proposed for EPM–CR participants, subject to the appeals process described in section VI.F.2. of this proposed rule.

The proposed timing for making CR incentive payments is included in § 512.710(g). We seek comments on our proposed timing for making CR incentive payments.

F. Provisions for FFS–CR Participants

1. Access to Records and Retention for FFS–CR Participants

In section III.H. of this proposed rule, we discuss our proposals for record access and retention under the EPM. The proposals describe the access to records and retention requirements for all EPM participants, including EPM–CR participants and other individuals and entities with respect to the EPM and CR incentive payment model, if the latter is applicable to the EPM participant. Two of the six categories of information subject to the requirements, specifically compliance with the requirements of the CR incentive payment model and the obligation to repay any CR incentive payments owed to CMS, are relevant only to the CR incentive payment model. Thus, we propose to establish CR incentive payment model access to records and retention requirements for FFS–CR participants and any other individuals or entities providing items or services to a FFS–CR beneficiary that are the same as we propose for EPM–CR participants and other individuals and entities but only for the two categories of information that are applicable to the CR incentive payment model. The other four categories of information proposed for records access and retention under the EPM, specifically the calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments; the quality of the services furnished; the sufficiency of beneficiary notifications; and the accuracy of the EPM participant's submissions under CEHRT use requirements, are not relevant to the CR incentive payment model for FFS–CR participants and other individuals and entities providing items and services to FFS–CR beneficiaries because the CR incentive payment model includes no policies that relate directly to these categories of information.

The proposals for access to records and record retention for FFS–CR participants and other individuals and entities providing items and services to FFS–CR beneficiaries are included in § 512.715. We seek comment on our proposals, including whether it is necessary, reasonable and appropriate to impose these access and retention obligations on the FFS–CR participant and other individuals and entities providing items and services to FFS–CR beneficiaries for the proposed categories of information to be retained and made accessible. In addition, we seek comment on whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the CR incentive payment model are met.

2. Appeals Process for FFS–CR Participants

a. Overview

In section III.D.8. of this proposed rule, we discuss our proposals for the appeals process under the EPMs. The proposal outlines the appeals process requirements for all EPM participants, including EPM–CR participants, with respect to the EPM and CR incentive payment model, if the latter is applicable to the EPM participant. CR incentive payments as well as non-payment related issues, such as enforcement matters, are relevant only to the CR incentive payment model. Thus, we propose to establish CR incentive payment model appeals process for FFS–CR participants that have the same requirements as we propose for the EPM but based on only the CR incentive payment and non-

payment related issues, such as enforcement matters. All other appealable items under the EPM, specifically related to payment, reconciliation amounts, repayment amounts, determinations associated with quality measures affecting payment are not relevant to the CR incentive payment model for any FFS–CR participants because the CR incentive payment model includes no policies that relate directly to these categories of information.

b. Notice of Calculation Error (First Level Appeal)

We propose the following calculation error process for the CR incentive payment model to contest matters related to the calculation of the FFS–CR participant's CR incentive payment as reflected in the CR incentive payment report. FFS–CR participants would review their CR incentive payment report and be required to provide written notice of any error in a calculation error form that must be submitted in a form and manner specified by CMS. Unless the FFS–CR participant provides such notice, the CR incentive payment report would be deemed final within 45 calendar days after it is issued, and CMS would proceed with payment. 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. We propose that if a FFS–CR participant does not submit timely notice of a calculation error, which is notice within 45 calendar days of the issuance of the CR incentive payment report, the FFS–CR participant would be precluded from later contesting the CR incentive payment report for that CR performance year.

In summary, we propose the following requirements in § 512.720(a) for notice of calculation error:

- Subject to the limitations on review in subpart H of this part, if a FFS–CR participant wishes to dispute calculations involving a matter related to a CR incentive payment, the FFS–CR participant is required to provide written notice of the error, in a form and manner specified by CMS.
- Unless the FFS–CR participant provides such notice, CMS deems final the applicable CR incentive payment report 45 calendar days after the applicable CR incentive payment report is issued and proceeds with the payment as applicable.
- If CMS receives a notice of a calculation error within 45 calendar days of the issuance of the applicable CR incentive payment report, 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 FFS–CR participant.
- Only FFS–CR participants may use the notice of calculation error process described in this subpart.

We seek comment on the proposed notice of calculation error requirements.

c. Dispute Resolution Process (Second Level of Appeal)

We propose the following dispute resolution process. First, we propose that only a FFS–CR participant may utilize this dispute resolution process. Second, in order to access the dispute resolution process a FFS–CR participant must have timely submitted a calculation error form, as previously discussed, regarding the CR incentive payment. We propose these matters would include any amount or calculation indicated on a CR incentive payment report, including calculations not specifically reflected on a CR incentive payment report but which generated figures or amounts reflected on a CR incentive payment report. We propose calculation of CR incentive payment amounts would need to be first adjudicated by the calculation error process as previously detailed. If a FFS–CR participant wants to engage in the dispute resolution process with regard to the calculation of a CR incentive payment amount, we propose it would first need to submit a calculation error form. Where the FFS–CR participant does not timely submit a calculation error form, we propose the dispute resolution process would not be available to the FFS–CR participant with regard to the CR incentive payment report for that CR performance year.

If the FFS–CR participant did timely submit a calculation error form and the FFS–CR participant is dissatisfied with CMS's response to the FFS–CR participant's notice of calculation error, the FFS–CR participant 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 FFS–CR participant's assertion that CMS or its representatives did not accurately calculate CR incentive payment in accordance with CR incentive payment model rules.

Where the matter is unrelated to payment, such as termination from the CR incentive payment model, the FFS–CR participant need not submit a calculation error form. We propose to require the FFS–CR participant 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 propose CMS would process the request as discussed later in this section.

We propose 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 FFS–CR participant in writing within 15 calendar days of receiving the FFS–CR participant'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 view to occur no later than 30 days after the date of the Scheduling Notice. The provisions at § 425.804(b), (c), and (e) (as in effect on the publication date of this proposed rule) would apply to reviews conducted pursuant to the reconsideration review process for the CR incentive payment model. 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.

In summary, we propose the following requirements in § 512.720(b) for the reconsideration process:

- If the FFS–CR participant is dissatisfied with CMS's response to the notice of a calculation error, the FFS–CR participant may request a reconsideration review in a form and manner as specified by CMS.
- The reconsideration request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the FFS–CR participant's assertion that CMS or its representatives did not accurately calculate the CR incentive payment in accordance with subpart H of this part.
- If CMS does not receive a request for reconsideration from the FFS–CR participant within 10 calendar days of the issue date of CMS's response to the FFS–CR participant's notice of calculation error, then CMS's response

to the calculation error is deemed final and CMS proceeds with the applicable processes, as described in subpart H of this part.

• The CMS reconsideration official notifies the FFS–CR participant in writing within 15 calendar days of receiving the FFS–CR participant's review request of the following:

++ The date, time, and location of the review.

++ The issues in dispute.

++ The review procedures.

++ The procedures (including format and deadlines) for submission of evidence. 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 notification.

• 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 the FFS–CR participant.

• The CMS reconsideration official issues a written determination within 30 days of the review. The determination is final and binding.

• Only a FFS–CR participant may utilize the dispute resolution process described in this subpart. We seek comment on the proposed reconsideration process for the CR incentive payment model.

d. Exception to the Notice of Calculation Error Process and Notice of Termination

If the FFS–CR participant contests a matter that does not involve an issue contained in, or a calculation which contributes to a CR incentive payment report, a notice of calculation error is not required. In instances where a notice of calculation error is not required, for example a FFS–CR participant's termination from the CR incentive payment model, we propose the FFS–CR participant provide a written notice to CMS requesting review within 10 calendar days of the notice. CMS has 30 days to respond to the FFS–CR participant's request for review. If the FFS–CR participant fails to notify CMS, the decision is deemed final.

In summary, we propose the following requirements in § 512.720(c) for an exception to the notice of calculation error process:

• If the FFS–CR participant contests a matter that does not involvean issue contained in, or a calculation which contributes to a CR incentive payment report a notice of calculation error is not required. In these instances, if CMS does not receive a request for reconsideration from the FFS–CR participant within 10 calendar days of the notice of the initial determination, the initial determination is deemed final and CMS proceeds with the action indicated in the initial determination.

In summary, we propose the following requirements in § 512.720(d) for notice of termination:

• If an FFS–CR participant receives notification that it has been terminated from the CR incentive payment model, it must provide a written request for reconsideration to CMS requesting review of the termination within 10 calendar days of the notice. CMS has 30 days to respond to the FFS–CR participant's request for review. If the FFS–CR participant fails to notify CMS, the termination is deemed final.

We seek comment on the proposed exception to the process and notice of termination.

e. Limitations on Review

In summary, we propose the following requirements in § 512.720(e) for 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:

++ 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 section 1115A(b)(3) of Act.

++ The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of Act.

++ Decisions to expand 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 (e)(1) or (2) of this section.

We seek comment on the proposed limitations on review.

The proposals for the appeals process for FFS–CR participants are included in § 512.720. We seek comment on our proposals for the appeals process as it related to FFS–CR participants. The two-step appeal process for payment matters—(1) calculation error form, and (2) reconsideration review—is used broadly in other CMS models. We seek comment on whether we should develop an alternative appeal process. In addition, we seek comment on whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the CR incentive payment model are met.

3. Data Sharing for FFS–CR Participants

a. Overview

Section III.K. of this proposed rule discusses our proposed policies for the types and formats of financial data that we would make available to EPM participants, frequency with which we would make these data available, and authority for making these data available to EPM participants. Specifically, in section III.K.2. of this proposed rule, we propose to provide certain financial data in two formats. First, we propose to make summary beneficiary claims data reports on beneficiaries' use of health care services during the baseline and performance periods upon request and in accordance with applicable privacy and security laws and established privacy and security protections. These data would consist of summary claims data reports that would contain payment information such as episode counts, total average spending for each episode, based upon categories, including, inpatient services, outpatient services, skilled nursing facility services, and carrier/Part B services. Alternatively, for EPM participants with the capacity to analyze raw claims data, we propose to make more detailed beneficiary-level information available upon request and in accordance with applicable privacy and security laws and established privacy and security protections. In addition to these more detailed data, we would include episode summaries, indicators for excluded episodes, diagnosis and procedure codes, and enrollment and dual eligibility information for beneficiaries that initiate EPM episodes. In section III.K.2. of this proposed rule, we also noted our view that making this information available to EPM participants would provide tools to monitor, understand, and manage utilization and expenditure patterns as well as to develop, target, and implement quality improvement programs and initiatives.

In addition to the aforementioned data, we propose in section III.K.3. of this proposed rule to provide comparable aggregate regional data to EPM participants. Our proposal to make these regional data available is because regional pricing data would be used to determine benchmark and quality-adjusted target prices for EPM participants, and these aggregate regional data would assist participant in better understanding the basis of these prices. In section III.K.4. of this proposed rule, we propose to make 3

years of baseline data available to EPM participants prior to the models' start date, which we believe would help the participant assess its practice patterns, identify cost drivers, and ultimately redesign its care practices to improve efficiency and quality. In section III.K.5 of this proposed rule, we propose to provide to EPM participants, upon request and in accordance with the HIPAA Privacy Rule, up to 6 quarters of claims data as frequently as on a quarterly basis throughout the EPM participant's participation or until they notify CMS that they no longer wish to receive these data.

As stated in section III.K.6 of this proposed rule, we believe our proposals are consistent with and authorized under 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 would 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). As we stated in section III.K.6. of this proposed rule, EPM participants would be using the data on their patients to evaluate the performance of the participant 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, we noted our view that this provision covers the uses we would expect under the proposed EPMs. We also noted our view that, in proposing to make available the ''minimum necessary'' data to accomplish the intended purpose of the use, our proposal was consistent with (45 CFR 164.502(b)). Last, we stated our belief that our 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 exception to the Privacy Act, which would otherwise prohibit 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)). For a more detailed discussion of our proposals and authority for sharing data with EPM participants, please see section III.K. of this proposed rule.

b. Data Sharing With CR Participants

As is the case with the proposed EPMs, we believe that making certain beneficiary-identifiable claims information available, upon request and in accordance with applicable privacy and security laws and established privacy and security protections, is necessary for CR participants to best improve their performance with respect to increasing utilization of CR/ICR services, which we believe should result in improved healthcare outcomes and reduced healthcare costs. However, we believe that a more limited set of data would be needed for purposes of testing the CR incentive payment model than would be made available under the proposed EPMs. This is because the purposes and processes related to the proposed CR incentive payment model are narrower in focus than under the proposed EPMs where hospitals must coordinate care across a broader array of providers and services to improve health care quality across a broader range of dimensions. Also, unlike the EPMs where a participant's performance each performance year is compared against historical spending, the CR incentive payments are based only on a CR participant's CR/ICR service utilization performance within a given CR performance year. Further, CR incentive payments are tied only to the CR participant's performance and are unrelated to performance within a region.

Thus, upon request and in accordance with applicable privacy and security laws and established privacy and security protections, we propose to make the following data available to FFS–CR participants:

- Inpatient claims—containing potential admissions for CABG and AMI MS–DRGs (and PCI DRGs with an AMI ICD–CM diagnosis code in the principal or any secondary diagnosis code position).
- Carrier and Outpatient claims—containing CR/ICR services that occurred in the 90-day period after discharge (called the AMI care period or CABG care period).

We would note that our proposal pertains only to FFS–CR participants and not to EPM–CR participants. This is because an EPM–CR participant that has requested data under the EPM would already have had the data previously described made available to them under their broader data sharing request. As such, we believe that also making these data separately available to EPM–CR participants would be duplicative and could create confusion for participants. We would also note that we do not propose to make historical payment or aggregate regional payment data available to FFS–CR participants. This is because, as previously discussed, neither historical nor regional CR/ICR service utilization performance would be factors considered when determining their eligibility for or the amount of a CR incentive payment.

As is the case for our proposed data sharing with EPM participants, we propose to make these data available in either summary or claims-level format, depending on the FFS–CR participant's request. Also, we propose to make these data available consistent with the same schedule we propose to use for making data available to EPM participants and to make available up to 6 quarters of claims data as frequently as on a quarterly basis throughout the FFS–CR participant's participation or until they notify CMS that they no longer wish to receive these data. As is the case with the EPMs, we propose that the data files would be packaged and sent to a data portal (to which the FFS–CR participants must request and be granted access) in a ''flat'' or binary format for the FFS–CR participant to retrieve.

The proposal to share data with FFS–CR participants is included in § 512.725. We seek comments on our data sharing proposals.

4. Compliance Enforcement for FFS–CR Participants and Termination of the CR Incentive Payment Model

In section III.F. of this proposed rule, we discuss our proposals for compliance enforcement under the EPM. The proposal outlines the non-compliance by EPM participants, including EPM–CR participants with respect to the EPM and CR incentive payment model, if the latter is applicable to the EPM participant that may trigger compliance enforcement by CMS and the enforcement mechanisms available to CMS. Four out of the seven

remedial actions, specifically issuing a warning letter to the EPM participant, requiring the EPM participant to develop a corrective action plan, commonly referred to as a CAP, reducing or eliminating the EPM participant's CR incentive payment, and terminating the EPM participant from the CR incentive payment model, are relevant to the CR incentive payment model. Thus, we propose to establish compliance enforcement for the CR incentive payment model for FFS–CR participants that is substantively similar to the requirements as we propose for the EPM but that the CMS enforcement mechanisms may use with FFS–CR participants be the four remedial actions previously listed in this section. All other types of enforcement mechanisms under the EPM, specifically, reducing or eliminating the EPM participant's reconciliation payment, requiring the EPM participant to terminate a sharing arrangement with an EPM collaborator and prohibiting the EPM collaborator from further engagement in sharing arrangements with the EPM participant, and allowing CMS to add 25 percent to a repayment amount on an EPM participant's reconciliation report under certain circumstances, are not relevant to the CR incentive payment model for any FFS–CR participants because the CR incentive payment model includes no policies that relate directly to these categories of activity.

Another distinction between the policies proposed under the EPMs and the CR incentive payment model is regarding prevention of EPM–CR participants from avoiding the high cost and high severity patients and targeting low cost and low severity patients. Under the EPMs, we prohibit EPM participants from avoiding both potentially high cost or high severity patients and targeting both potentially low cost or low severity patients. Under the CR incentive payment model we are only concerned with FFS–CR participants avoiding high severity patients and targeting low severity patients. The goal of EPM is to maintain or improve quality and coordination of care while reducing program expenditures. In contrast, the goals of the CR incentive payment model are to reduce cardiovascular mortality, improve health-related quality of life, and reduce the risk of hospital admission. The EPM explicit prohibition of avoiding high cost and targeting low cost patients is not included for the FFS–CR participants as cost savings are not a goal for participants under the CR incentive payment model.

We propose that CMS would have the remedial actions detailed in this section available for use against FFS–CR participants where such FFS–CR participant furnishing CR services to a beneficiary during the CR incentive payment model is not compliant in a matter listed in § 512.730(b)(1). These mechanisms would support CMS's goal for the CR incentive payment model to prevent overutilization of CR services that are not medically necessary, prevent FFS–CR participants from avoiding high severity patients and seeking out low severity patients, safeguard program integrity, protect against fraud and abuse, and deter noncompliance with CR incentive payment model requirements.

Upon discovering an instance of noncompliance by a FFS–CR participant with the requirements of the CR incentive payment model, CMS, HHS, or a designee of such Agencies may take remedial action against such FFS–CR participant. Any information collected by CMS in relation to termination of a participant from the model would be shared with our program-integrity colleagues at HHS, the Department of Justice, and their respective designees. Should such participant, or one of its EPM collaborators, collaboration agents, or downstream collaboration agents, be noncompliant with the requirements of the EPMS or engage in unlawful behavior related to participation in the EPMS, we note that such information could be used in proceedings unrelated to the enforcement mechanisms in this section. FFS–CR participants also would be subject to all applicable requirements and conditions for Medicare participation not otherwise waived under section 1115A(d)(1) of the Act.

In summary, we propose in § 512.730 that FFS–CR participants must comply with all requirements outlined in subpart H. Except as specifically noted subpart H, 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.

Further, we propose in § 512.730 that CMS may take the remedial actions later discussed in this section, if a FFS–CR participant—

- Fails to comply with any requirements of this subpart or is identified as noncompliant through monitoring by HHS (including CMS and OIG) of the CR incentive payment model, including but not limited to—

++ Avoiding potentially high severity patients;

++ Targeting potentially low severity patients;

++ Failing to provide medically appropriate services or systematically engaging in the over or under delivery of appropriate care;

++ Failing to provide beneficiaries with complete and accurate information; or

- Takes any action that threatens the health or safety of patients;
- Avoids at risk Medicare beneficiaries, as this term is defined in § 425.20;
- 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 of this subpart;
- Takes any action that CMS determines for program integrity reasons is not in the best interests of the CR incentive payment 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 CR incentive payment 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; or
- 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 CR incentive payment model.

We propose the remedial actions to include the following:

- Issuing a warning letter to the FFS–CR participant.
- Requiring the FFS–CR participant to develop a corrective action plan, commonly referred to as a CAP.
- Reducing or eliminating the FFS–CR participant's CR incentive payment.
- Terminating the FFS–CR participant from the CR incentive payment model.

The proposals for compliance enforcement for FFS–CR participants are included in § 512.730. We seek comment on our proposals for compliance enforcement as it is related to FFS–CR participants. In addition, we seek comment on whether additional or different safeguards would be needed to ensure program integrity, protect against

abuse, and ensure that the goals of the CR incentive payment model are met.

We further propose under § 512.905, CMS may terminate the CR incentive payment model for reasons including but not limited to—

- CMS no longer has the funds to support the CR incentive payment model; or
- CMS terminates the applicable 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.

5. Enforcement Authority for FFS–CR Participants

OIG authority is not limited or restricted by the provisions of the CR incentive payment model, including the authority to audit, evaluate, investigate, or inspect the FFS–CR participants. Additionally, no CR incentive payment model provisions limit or restrict the authority of any other Government Agency to do the same.

The proposals for enforcement authority for FFS–CR participants in the CR incentive payment model are included in § 512.735. We seek comment 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 CR incentive payment model are met.

6. Beneficiary Engagement Incentives for FFS–CR Participants

We propose to allow EPM participants to provide beneficiary engagement incentives under certain conditions as discussed in section III.I.9. of this proposed rule based on the goals of the EPM to improve EPM episode quality and efficiency. The goals of the CR incentive payment model in which some EPM participants also participate are to increase CR/ICR service care coordination and the medically necessary utilization of CR/ICR services in AMI and CABG model episodes for EPM–CR participants and in AMI care periods and CABG care periods for FFS–CR participants. We believe that one mechanism that may be useful to CR participants in achieving this goal is the provision of transportation to CR/ICR services as in-kind patient engagement incentives to AMI and CABG model beneficiaries and beneficiaries in AMI care periods and CABG care periods (hereinafter FFS–CR beneficiaries). As discussed earlier in this section, lack of accessibility of CR program sites can be a significant barrier to beneficiary adherence to a CR treatment plan. We do not believe there are beneficiary engagement incentives other than transportation that would be important for achieving the CR incentive payment model goals of increasing CR/ICR service care coordination and the medically necessary utilization of CR/ICR services. However, we believe that EPM–CR and FFS–CR participants should generally have the same regulatory flexibilities that are directly relevant to advancing the CR incentive payment model goals so that we can evaluate the CR incentive payment model under the two different underlying payment methodologies for AMI and CABG care (episode or FFS) and draw conclusions about the relationship between the CR incentive payment model and the underlying payment methodology for care.

Under the proposed beneficiary engagement incentive policies for the EPM, EPM–CR participants would be able to provide beneficiary transportation to CR/ICR services in order to achieve the clinical goal of the EPM of beneficiary adherence to a care plan, subject to certain conditions on these incentives that are necessary to ensure that their provision is solely for the purpose of achieving the EPM goals of improvements in episode quality and efficiency. When transportation is provided by an EPM–CR participant as a beneficiary engagement incentive for CR/ICR services, its use would also be aligned with the CR incentive payment model goals of increasing CR/ICR service care coordination and the medically necessary utilization of CR/ICR services. Thus, our proposal for beneficiary engagement incentives under the EPM meets the potential need for transportation to CR/ICR services for AMI and CABG model beneficiaries under an EPM–CR participant.

We propose to allow FFS–CR participants to provide transportation to CR/ICR services as a beneficiary engagement incentive for FFS–CR beneficiaries during AMI care periods and CABG care periods to allow these participants similar use of beneficiary engagement incentives to achieve the CR incentive payment model goals as would be available to EPM–CR participants for that purpose. We propose the same conditions on beneficiary engagement incentives provided by FFS–CR participants as would be applicable to EPM beneficiary engagement incentives when those beneficiary incentives are transportation.

The proposed conditions for transportation when provided as a beneficiary engagement incentive by FFS–CR participants are—

- The incentive must be provided directly by the FFS–CR participant or by an agent of the FFS–CR participant under the FFS–CR participant's direction and control to the FFS–CR beneficiary during an AMI care period or CABG care period;
- Transportation must not be tied to the receipt of items or services other than CR/ICR services during AMI care periods or CABG care periods;.
- Transportation must not be tied to the receipt of items or services from a particular provider or supplier;
- The availability of transportation must not be advertised or promoted except that a beneficiary may be made aware of the availability of transportation at the time the beneficiary could reasonably benefit from it;
- The cost of transportation must not be shifted to another federal health care program, as defined at section 1128B(f) of the Act;.

In addition, as we would apply to transportation as a beneficiary engagement incentive under the EPM, we propose the same documentation requirements for beneficiary engagement incentives provided by FFS–CR participants;.

- FFS–CR participants must maintain documentation of transportation furnished as a beneficiary engagement incentive that exceeds $25 in retail value;
- The documentation established contemporaneously with the provision of transportation must include at least the following:

++ The date the transportation is provided.

++ The identity of the beneficiary to whom the transportation was provided.

- The FFS–CR participant must retain and provide access to the required documentation in accordance with § 512.715.

Our proposals for beneficiary engagement incentives provided by FFS–CR participants are included in § 512.740. We seek comment on our proposed provisions for beneficiary engagement incentives for FFS–CR participants and welcome comment on additional or alternative program integrity safeguards. We also seek comment about beneficiary engagement incentives other than transportation that could advance the CR incentive payment model goals of increased CR/ICR service care coordination and the medically necessary utilization of CR/ICR services in AMI care periods and CABG care periods.

7. Waiver of Physician Definition for Providers and Suppliers of CR/ICR Services Furnished to FFS–CR Beneficiaries During an AMI Care Period or CABG Care Period

a. Overview of Program Rule Waivers

In section III.J. of this proposed rule we discuss the proposed waivers of certain program rules that we believe offers providers and suppliers more flexibility so that they may increase coordination of care and management of beneficiaries in EPM episodes. These additional flexibilities are being proposed through our waiver authority under section 1115A of the Act, which affords broad authority for the Secretary to waive statutory Medicare program requirements as necessary to carry out the provisions of section 1115A. As discussed later in this section, we are using this authority to propose a waiver of the physician definition for providers and suppliers of CR/ICR services furnished to FFS–CR beneficiaries during an AMI care period or CABG care period. This proposed waiver is similar to the CR/ICR wavier for beneficiaries in the EPM episodes discussed in section III.J.8 of this proposed rule.

b. General Physician Requirements for Furnishing CR/ICR Services

A CR program, as defined in § 410.49(a) of regulations, means a physician-supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, psychosocial assessment, and outcomes assessment. An ICR program, as defined in § 410.49(a) of the regulations, means a physician-supervised program that furnishes cardiac rehabilitation and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in § 410.49(c). A physician is defined under § 410.49(a), and under § 1861(r)(1) of the Act as a doctor of medicine or osteopathy.

In general, the following physician functions are required under § 410.49 in furnishing CR/ICR services;

- Medical director—defined at § 410.49(a) as a physician that oversees or supervises the cardiac rehabilitation or intensive rehabilitation program at a particular site;
- Supervising physician—defined at § 410.49(a) as a physician that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under cardiac rehabilitation and intensive cardiac rehabilitation programs;
- Physician-prescribed exercise—defined at § 410.49(a) as aerobic exercise combined with other types of exercise (that is, strengthening, stretching) as determined to be appropriate for individual patients by a physician; and
- Individualized treatment plan—defined at § 410.49(a) as a written plan tailored to each individual patient that, under § 410.49(b)(2)(v), must be established, reviewed, and signed by a physician every 30 days.

c. Proposed Waiver of Physician Definition for Providers and Suppliers of CR/ICR Services Furnished to EPM Beneficiaries During AMI or CABG Model Episodes

In section III.J.8. of this proposed rule, for providers or suppliers of CR/ICR services furnished to EPM beneficiaries during the proposed AMI or CABG model episodes, we propose to waive the physician definition, under § 410.49, to allow a physician or a qualified nonphysician practitioner to perform the functions of supervising physician, prescribing exercise, and establishing, reviewing, and signing an individualized treatment plan every 30 days. A nonphysician practitioner, for the purposes of this proposed waiver is defined as a physician assistant, nurse practitioner, or clinical nurse specialist as authorized under sections 1861(s)(2)(K)(i) and (ii) of the Act and defined in section 1861(aa)(5) of the Act, or in §§ 410.74, 410.75, and 410.76 of the regulations. We do not believe a nonphysician practitioner is qualified to act in the capacity of a medical director. Thus, we are specifically excluding the medical director function from this proposed waiver. We propose this waiver to provide greater program flexibility that might increase the availability of CR/ICR services furnished to EPM beneficiaries during AMI or CABG model episodes. This proposed waiver is codified at proposed § 512.630.

d. Proposed Waiver of Physician Definition for Providers or Suppliers of CR/ICR Services Furnished to FFS–CR Beneficiaries During AMI Care Periods or CABG Care Periods

Providers and suppliers may furnish CR/ICR services to FFS–CR beneficiaries during AMI care periods or CABG care periods, as described in this section of this proposed rule. To provide greater program flexibility that might increase the availability of CR/ICR services to FFS–CR beneficiaries, we propose to provide a waiver to the definition of a physician to include a nonphysician practitioner (defined for the purposes of this waiver as a physician assistant, nurse practitioner, or clinical nurse specialist as authorized under sections 1861(s)(2)(K)(i) and (ii) of the Act and defined in section 1861(aa)(5) of the Act, or in §§ 410.74, 410.75, and 410.76 of the regulations). Thus, this proposed waiver would allow, in addition to a physician, a nonphysician practitioner to perform the functions of supervisory physician, prescribing exercise, and establishing, reviewing, and signing an individualized treatment plan for providers or suppliers of CR/ICR services furnished to a FFS–CR beneficiary during an AMI care period or CABG care period. This proposed waiver for FFS–CR beneficiaries is similar to the proposed physician definition waiver for EPM beneficiaries during the proposed AMI or CABG model episodes as discussed in section III.J.8. of this proposed rule. All other definitions and requirements related to a physician or supervising physician under § 410.49 continue to apply. We solicit comments on this proposed waiver to allow nonphysician practitioners to perform the physician functions previously specified for the provision of CR/ICR services furnished to FFS–CR beneficiaries. This proposed waiver is codified at proposed § 512.745.

For a FFS–CR beneficiary, this waiver would apply to any provider or supplier that furnishes CR/ICR services to that beneficiary during an AMI care period or CABG care period. We anticipate monitoring the outcomes of care for beneficiaries that receive CR/ICR services under this waiver during an AMI care period or CABG care period. The monitoring may involve an analysis of all or a sample of claims, medical records, or other clinical data for beneficiaries and providers or suppliers of CR/ICR services. We solicit comments on approaches we may take to monitor this waiver to ensure this program flexibility does not have a negative effect on how beneficiaries receive CR/ICR services which then may affect the outcome of the beneficiary's care.

G. Considerations Regarding Financial Arrangements Under the CR Incentive Payment Model

As discussed in section VI.E.2. of this proposed rule, we propose to not permit the inclusion of CR incentive payments in sharing arrangements for EPM participants specified in § 512.500. Similarly, we do not propose to allow specific financial arrangements for FFS–CR participants. Thus, financial arrangements regarding CR incentive payments paid by CMS to CR

participants would be subject to all existing laws and regulations, including all fraud and abuse laws and applicable CR payment and coverage requirements. Given that more than 95 percent of CR/ICR services were historically furnished by hospital outpatient departments (HOPDs) to beneficiaries in the 90 days following discharge from a hospitalization for AMI or CABG, we expect that in many cases the CR participant that is accountable under the CR incentive payment model would itself carry out the model implementation activities, including coordination of CR/ICR services to CR beneficiaries, through the hospital's own CR program.[135] However, in other cases, depending on beneficiary choices and the availability of CR/ICR services and expertise in a CR participant's local community, CR participants may wish to engage other individuals and entities, including individuals and entities that are not providers and suppliers, in order to advance the CR incentive payment model goals of increased CR/ICR service care coordination and the medically necessary utilization of CR/ICR services in AMI and CABG model episodes and AMI care periods and CABG care periods. Thus, we expect that all financial relationships with other individuals and entities under the CR incentive payment model would be narrowly focused on certain activities related to the CR participant's specific plan to advance the goals of model.

For example, we expect that CR participants may choose to engage with providers, suppliers, and other organizations that are neither providers nor suppliers to assist with matters such as CR/ICR service utilization data analysis; beneficiary outreach; CR beneficiary care coordination and management for CR/ICR service referral and adherence to a treatment plan; CR participant compliance with the terms and conditions of the CR incentive payment model; or other model activities. These individuals and entities may play important roles in a CR participant's plans to implement the CR incentive payment model based on their direct clinical care for beneficiaries in AMI or CABG model episodes or AMI care periods or CABG care periods; their prior experience with cardiovascular risk-factor reduction and management initiatives; their care coordination expertise; or their familiarity with the local community and access to resources that may reduce barriers to beneficiary utilization of CR/ICR services. We expect that all relationships established between CR participants and other individuals and entities for such purposes of the CR incentive payment model would only be those permitted under existing law and regulation. We would also expect that all of these relationships would solely be based on the level of engagement of the individual's or entity's resources to directly support the CR participant's CR incentive payment model implementation.

We recognize, however, that we do not have precedent with other CMS models and programs that have a similar design to the CR incentive payment model. Thus, we seek comment on whether there are other types of financial arrangements that CR participants would wish to pursue in advancing the model goals of increased CR/ICR service care coordination and the medically necessary utilization of CR/ICR services in AMI and CABG model episodes and AMI care periods and CABG care periods. We specifically request comments on which individuals and entities would be parties to the financial arrangements; what specific CR incentive payment model implementation activities would be included in the financial arrangements; and what methodologies would be used for sharing the CR incentive payment under such financial arrangements. In addition, we seek comment on what safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the CR incentive payment model would be met. Based on comments and our early implementation experience with the CR incentive payment model, we may make specific proposals around CR incentive payment model financial arrangements in future rulemaking.

VII. 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. We have, however, summarized the anticipated information collection requirements in the Regulatory Impact Analysis.

VIII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''DATES'' section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IX. 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 proposed rules.

A. Statement of Need

1. Need for EPM Proposed Rule

This proposed rule is necessary in order to implement and test three new EPMs 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 of enhancing the quality of care furnished to individuals.'' Under the FFS program, 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. The goal for the proposed EPMs is to improve the quality of care provided to beneficiaries in an applicable episode while reducing episode spending through financial accountability.

Payment approaches that reward providers for assuming financial and performance accountability for a particular episode of care can create incentives for the implementation and coordination of care redesign between participants and other providers and suppliers such as physicians and post-acute care providers. Under the proposed EPMs, CMS will test whether an EPM for AMI, CABG, and SHFFT episodes of care will reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We believe the proposed models have the potential to benefit Medicare beneficiaries by improving the coordination and transition of care, improving the coordination of items and services paid for through FFS Medicare, encouraging more provider investment in infrastructure and redesigned care processes for higher-quality and more

[135] Analysis of cardiac rehabilitation utilization in care periods for AMI and CABG beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CYs 2012 through 2014.

efficient service delivery, and incentivizing higher-value care across the inpatient and post-acute care spectrum. The goal for the proposed EPMs is to improve the quality of care provided to beneficiaries in an applicable episode while reducing episode spending.

The proposals for the AMI, CABG, and SHFFT models would require the participation of hospitals in multiple geographic areas that might not otherwise participate in testing episode payment for the proposed episodes of care. CMS is testing other episode payment models with the BPCI initiative and the CJR model. The BPCI initiative is voluntary; risk-bearing organizations applied to participate and chose from 48 clinical episodes. In the CJR model, acute care hospitals in selected geographic areas are required to participate in the CJR model for all eligible LEJR episodes that initiate at a CJR model participant hospital. Realizing the full potential of new EPMs will require the engagement of an even broader set of providers than have participated to date in our episode payment models such as the BPCI initiative and the CJR model. As such, we are interested in testing and evaluating the impact of episode payment for the three proposed EPMs in a variety of circumstances, including those hospitals that may not otherwise participate in such a test.

2. Need for CJR Modifications

This proposed rule also includes proposed modifications to the CJR model. Acute care hospitals in selected geographic areas are required to participate in the CJR model for LEJR episodes that initiate at a CJR model participant hospital. The modifications proposed here clarify and update provisions of the CJR model and create alignment between CJR and the proposed AMI, CABG, and SHFFT models. The primary impact of these changes will be related to: (1) Incorporation of BPCI and EPM reconciliation payments and Medicare repayments in setting quality-adjusted target prices in performance years 3–5; and (2) updates to the calculation of composite quality scores.

3. Need for CR Incentive Payment Model

CR and intensive CR services are capable of achieving significant improvements in patient outcomes beyond the proposed AMI and CABG model 90-day post-discharge care period. Despite evidence from multiple studies that CR services improve health outcomes, these services remain underutilized. Beneficiaries with CAD often receive care in many different settings from multiple providers over the long-term and subsequently commonly experience care that is fragmented and uncoordinated. Lack of coordination, of both care and financial incentives, across the continuum of CAD care, results in higher than necessary rates of adverse drug events, hospital readmissions, diagnostic errors, and other adverse outcomes, as well as lower than appropriate utilization of evidence-based treatments. The CR incentive payment model will test whether a financial incentive for hospitals that encourages the management of beneficiaries that have had an AMI or a CABG in ways that may contribute to long-term improvements in quality and reductions in Medicare spending.

4. Aggregate Impact of EPMs, CJR, and CR Incentive Payment Model

As detailed in Table 38, we estimate a total aggregate impact of $170 million in net Medicare savings over the proposed duration of the AMI, CABG, and SHFFT models, July 2017–December 2021. As detailed in Table 39, we estimate the proposed changes in the CJR model, along with the revised assumption that participating hospitals will report quality data, will increase estimated costs to the Medicare program by $35 million over the duration of the CJR model (April 2016–December 2020) relative to the financial estimate published in the CJR final rule (80 FR 73288). These estimated impacts represent the net effect of federal transfers that incent hospitals for improving care while making it more efficient. Furthermore, the proposed models may benefit beneficiaries since the models require participants to be accountable for episodes extending 90 days post-hospital discharge, which may potentially improve the coordination of FFS items and services, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery that demonstrate a dedication and focus toward patient-centered care. Although it is possible that participating hospitals may respond to the demonstration through improvements in the efficiency of care that reduce FFS Medicare spending during these episodes, such reductions in Medicare spending will be largely offset through greater reconciliation payments paid by CMS to the participating hospital. As long as reductions in Medicare FFS spending for participating hospitals are equally offset through greater reconciliation payments from CMS to those participating hospitals, the financial impact to the Medicare program should not be significantly different from what we have currently estimated.

As detailed in Table 40, we estimate a total aggregate impact between $27 million in net Medicare costs and $32 million in net Medicare savings from July 2017–December 2024 through the cardiac rehabilitation incentive payment model. These estimated impacts represent the net effect of federal transfers to CR–EPM and CR–FFS participants and savings related to decreased future utilization in beneficiaries who receive CR/ICR services. A range of potential impacts is provided due to uncertainty in the likely increase in CR/ICR utilization based on the CR incentive provided.

We solicit comment on the assumptions and analysis presented throughout this regulatory impact section.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) 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. This proposed 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 proposed rule that either explicitly or implicitly pre-empts any state law, and furthermore we do not believe that this proposed 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

a. EPMs

Nationally, the total number of historical episodes ending in CY 2014 that began with IPPS hospitalizations and extended 90 days post-hospital discharge were approximately 168,000 for AMI; 48,000 for CABG; and 109,000 for SHFFT. The total Medicare spending for these historical episodes was approximately $4.1 billion, $2.3 billion, and $4.7 billion, respectively. Based on analysis of Medicare claims for historical episodes in 2012–2014, the mean estimated total payment for AMI episodes (defined based on ICD–CM diagnosis code and DRGs as described in section III.C of this proposed rule) is about $24,000, where approximately 61 percent of the spending is attributable to hospital inpatient services, 18 percent is attributable to post-acute care services and 21 percent to physician, outpatient hospital and other spending. For CABG episodes (defined based on DRGs as described in section III.C. of this proposed rule) the mean estimated total payment is about $47,000, where approximately 68 percent of the spending is attributable to hospital inpatient services, 12 percent is attributable to post-acute care services and 20 percent to physician, outpatient hospital and other spending. For SHFFT episodes (defined based on DRGs as described in section III.C. of this proposed rule) the mean estimated total payment is about $43,000, where approximately 33 percent of the spending is attributable to hospital inpatient services, 50 percent is attributable to post-acute care services and 17 percent to physician, outpatient hospital and other spending.

We propose to test the AMI and CABG models in 98 MSAs out of 294 MSAs eligible for selection, as described in section III.B.5. of this proposed rule; we propose to test the SHFFT model in 67 MSAs in which CJR is currently operating as discussed in section III.B.4. of this proposed rule. In the 2014 calendar year there were 136,000 episodes for AMI, and 42,000 for CABG in the 294 MSAs eligible for selection, and 33,000 episodes for SHFFT in the 67 MSAs eligible for participation.

b. CJR

The overall magnitude of the CJR model is described in the CJR final rule (80 FR 73288). The modifications proposed in this rule are not related to episode definition or hospital selection and therefore do not affect the number of episodes included in the model or the mean episode payment. The primary impact of the changes proposed will be related to the calculation of quality-adjusted target prices, which will now incorporate reconciliation payments and Medicare repayments in years 3–5 of the model and include modifications to the calculation of composite quality scores. For the CJR final rule we assumed that hospitals will not report voluntarily submitted patient reported outcome measures data to CMS. Given prior experience in the Medicare program with voluntary reporting, we are revising our assumption to assume that all hospitals in CJR report this quality data. These modifications along with the revised assumptions regarding quality reporting will raise the costs estimated to the Medicare program by $35 million from the estimate of $343 million in savings as published in the CJR final rule (80 FR 73288).

c. CR Incentive Payment Model

We propose to test the CR incentive payment model in 45 of the 98 MSAs selected for the AMI and CABG EPMs, as well as 45 FFS MSAs selected through stratified random sampling, as described in section VI of this proposed rule. As discussed subsequently in this analysis and displayed in Table 40, this is likely to result in an impact between $27 million in net Medicare costs and $32 million in net Medicare savings from July 2017 through December 2024.

d. Aggregate Effects on the Market

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 models. Changes in Medicare payment policy often have substantial implications for non-Medicare payers. As an example, non-Medicare patients may benefit if participating EPM hospitals introduce system wide changes that improve the coordination and quality of health care. Other payers may also be developing episode payment models and may align their payment structures with CMS or may be waiting to utilize results from CMS evaluations of episode payment models. 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 welcome comments on our assumptions and calculations.

2. Effects on the Medicare Program

a. EPMs

Under the proposed EPMs, the CMS will test whether an EPM for AMI, CABG, and SHFFT episodes of care will reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. Payment approaches that reward providers for assuming financial and performance accountability for a particular episode of care can potentially create incentives for the implementation and coordination of care redesign between participants and other providers and suppliers such as physicians and post-acute care providers. The proposed EPMs could enable hospitals to consider the most appropriate strategies for care redesign, including—(1) increasing post-hospitalization follow-up and medical management for patients; (2) coordinating across the inpatient and post-acute care spectrum; (3) conducting appropriate discharge planning; (4) improving adherence to treatment or drug regimens; (5) reducing readmissions and complications during the post-discharge period; (6) managing chronic diseases and conditions that may be related to the proposed EPM episodes; (7) choosing the most appropriate post-acute care setting; and (8) coordinating between providers and suppliers such as hospitals, physicians, and post-acute care providers.

We are interested in testing and evaluating the impact of episode payment for the AMI, CABG, and SHFFT models in a variety of circumstances, including those hospitals that may not otherwise participate in such a test. The clinical circumstances of the episodes we are proposing differ in important ways from the LEJR episodes included in the CJR

model. We expect the patient population included in these episodes would be substantially different from the patient population in CJR episodes, due to the clinical nature of the cardiac and SHFFT episodes. Beneficiaries in these episodes commonly have chronic conditions that contribute to the initiation of the episodes, and need both planned and unplanned care throughout the EPM episode following discharge from the initial hospitalization that begins the episode. Both AMI and CABG model episodes primarily include beneficiaries with cardiovascular disease, a chronic condition which likely contributed to the acute events or procedures that initiate the episodes. About half the average AMI model historical episode spending was for the initial hospitalization, with the majority of spending following discharge from the initial hospitalization due to hospital readmissions, while there was relatively less spending on SNF services, Part B professional services, and hospital outpatient services. In CABG model historical episodes, about three-quarters of episode spending was for the initial hospitalization, with the remaining episode spending relatively evenly divided between Part B professional services and hospital readmissions, and a lesser percentage on SNF services. Similar to AMI episodes, post-acute care provider use was relatively uncommon in CABG model historical episodes, while hospital readmissions during CABG model historical episodes were relatively common. SHFFT model historical episodes also were accompanied by substantial spending for hospital readmissions, and post-acute care provider use in these episodes also was high.[136]

We believe that by requiring participation by a large number of hospitals with diverse characteristics, the proposed EPMs would result in a robust data set for evaluating this payment approach, and would stimulate the rapid development of new evidence-based knowledge. Testing the proposed EPMs in this manner would also allow us to learn more about patterns of inefficient utilization of health care services and how to possibly incentivize quality improvement for beneficiaries receiving services in AMI, CABG, and SHFFT episodes.

Under the proposed EPMs, as described further in section III.B.2. of this proposed rule, an AMI, CABG, or SHFFT model episode would begin with an inpatient admission assigned to one of the following MS–DRGs upon beneficiary discharge: For AMI episodes, AMI MS–DRGs (280–282) and those PCI MS–DRGs (246–251) representing IPPS admissions for AMI that are treated with PCIs; CABG MS–DRGs (231–236); and SHFFT MS–DRGs (480–482). Episodes would end 90 days after the date of discharge from the anchor or chained anchor hospitalization. The proposed EPM episodes would include the inpatient stays and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, post-acute care, and physician services. Furthermore, we have proposed to designate EPM participant hospitals as the episode initiators and to be financially responsible for episode cost under the proposed EPMs. We propose to require all hospitals paid under the IPPS and physically located in selected geographic areas to participate, with limited exceptions. Eligible beneficiaries who receive care at these hospitals will automatically be included in the models. Geographic areas, based on MSAs, are proposed to be selected through a random sampling methodology. We believe the proposed EPMs may have financial and quality of care effects on non-hospital providers that are involved in the care of Medicare beneficiaries during model episodes, 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 across the inpatient and post-acute care spectrum spanning the episode of care.

As described in section III.D.2. of this proposed rule, we propose to continue paying hospitals and other providers and suppliers according to the usual Medicare FFS payment systems. After the completion of a performance year, the Medicare claims payments for services furnished to the beneficiary during the EPM episode, based on claims data, would be combined to calculate an actual EPM episode payment. The actual EPM episode payment would then be reconciled against an established EPM quality-adjusted target price. The amount of this calculation, if positive, would be paid to the participant in a reconciliation payment. If negative, we would require repayment from the participant beginning in performance year 2 of the EPMs. EPM participants' quality performance also would be assessed at reconciliation; each participant would receive a composite quality score and a corresponding quality category. EPM participants achieving a quality category of ''acceptable'' or higher would be eligible for a reconciliation payment.

We also propose to phase in the requirement that participants whose actual EPM episode payments exceed the quality-adjusted target price pay the difference back to Medicare beginning for performance year 2. Under this proposal, Medicare would not require repayment from participants for performance year 1 for actual EPM episode payments that exceed their quality-adjusted target price in performance year 1, and an applicable discount factor would be used for calculating repayment amounts for performance years 2 and 3, consistent with our final policies for the CJR model.

Due to the clinical characteristics and common patterns of care in AMI model episodes, we propose payment adjustments in the cases of certain transfers and readmissions of beneficiaries to inpatient hospitals for these episodes. These payment adjustments are discussed in detail in section III.D.4.b.(1). of this proposed rule. We also propose to limit how much a participant can gain or lose based on its actual EPM episode payments relative to quality-adjusted target prices; we propose additional policies to further limit the risk of high payment cases for all EPM participants and for special categories of EPM participants as described in section III.D. of this proposed rule.

Based on the mix of financial and quality incentives, the proposed EPMs could result in a range of possible outcomes for participants. The effects on hospitals of potential savings and liabilities will have varying degrees.

(1) Assumptions

We used standardized Medicare claims data from July 2012 through September 2015 to simulate the impact that the proposed EPMs would have on Medicare spending for AMI, CABG, and SHFFT model episodes. Specifically, we applied the methodology provided in this proposed rule for calculating quality-adjusted target prices. For the SHFFT model, we applied this methodology to hospitals in the MSAs in which CJR is currently operating. For the AMI and CABG models, we applied this methodology to a hypothetic cohort including all eligible hospitals in a randomly selected group of 115 MSAs among 294 MSAs eligible for selection. The results for the AMI and CABG models were then multiplied by 98/115

[136] Episodes for AMI, CABG, and SHFFT beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that end in CY 2014.

to adjust for only 98 MSAs being selected. Quality-adjusted target prices were calculated based on hospital performance from 90-day episodes starting between July 2012 and June 2015. Specifically, all IPPS hospitals in the selected MSAs were included in this analysis; model-specific hospital exclusions were applied based on participation in BPCI Models 2 or 4 for the AMI, PCI, CABG, or SHFFT models as appropriate.

We identified the anchor hospitalization based on episode definition criteria in section III.C. of this proposed rule and included the related spending that occurred 90 days after discharge. We removed payments excluded from the episode as unrelated to the EPM episode diagnosis and procedures based on clinical rationale, as defined in section III.C.3.b. of this proposed rule. Payments during the 90-day episodes were calculated using CMS standardized payment amounts.

We trended utilization and prices in the prior years to match national performance for episodes starting from July 2014 through June 2015. BPCI reconciliation payments were then credited to BPCI episodes during this time frame. We then incorporated the proposed outlier policy to cap spending for high cost outlier episodes such that payments are capped at the price MS–DRG anchor value that is 2 standard deviations above the regional mean as described in section III.C of this proposed rule.

After we pooled episodes for each price MS–DRG, we calculated average episode prices for each hospital and region, as well as a hospital-specific weight representing a case mix value for each hospital that is dependent only on episode volume for a given price MS–DRG 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 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 episode volume across the 3 historical years, with low volume as defined in section III.C.4.b.(6) of this proposed rule, by setting their episode benchmark price as the region's experience. These average prices were then disaggregated based on the national severity factor of average episode spending as described in section III.C.4.b.(9) of this proposed rule, the computed hospital-specific weight, the hospital's wage index was then applied back to the price, and a discount specific to the hospital's quality category was applied.

After calculating quality-adjusted target prices for price MS–DRGs for each hospital appropriate for the first 2 performance years, we compared these quality-adjusted target prices against actual performance between July 2014 and June 2015. We capped actual spending for individual episodes based on the methodology in this proposed rule for high cost outlier spending episodes. After incorporating the proposed outlier policy, total Medicare FFS spending was reconciled against the quality-adjusted target price and total number of episodes for the hospital. The aggregate impacts were then determined by multiplying by the total episodes for each price MS–DRG.

We propose that the difference between each episode's actual payment and the relevant quality-adjusted target price (calculated as quality-adjusted target price subtracted by actual episode payment) would be aggregated for all episodes for a participant within the performance year, creating the NPRA. 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. 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 proposed rule, with 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. For rural hospitals, MDHS, SCHs and RRCs, we are proposing a 3 percent repayment limit in performance year 2 and a 5 percent repayment limit in performance year 3 and subsequent years. As described in section III.C.7.e. of this proposed rule, if average 30-day post-episode spending for an EPM participant in any given EPM performance year is greater than 3 standard deviations above the regional average 30-day post-episode spending, based on the 30-day post-episode spending for episodes attributed to all regional hospitals in the same region as the EPM participant hospital, the EPM participant hospital would repay Medicare for the difference. This is not modelled as we would expect the repayments from EPM hospitals to CMS under this post-episode spending calculation to be minimal.

As described in section III.E. of this proposed rule, we propose the use of a composite quality score for each EPM, where the composite quality score reflects a combination of outcome and patient experience measures. Points for quality performance and improvement (as applicable) will be awarded for each episode measure and then summed to develop a composite quality score that will determine the EPM participant's quality category for the episode. Quality performance will make up the majority of available points in the composite quality score, with improvement points available as ''bonus'' points for the measure. Additionally, participants may voluntarily submit outcome measures data in the SHFFT and AMI models, resulting in an extra 2 points in their overall quality scores, up to a maximum score of 20. The composite quality score will be used as part of a pay-for-performance methodology to assign respective EPM participants to four quality categories.

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.

In general, we used quality data as publicly reported on Hospital Compare in 2015 and 2016 to model the impact of this policy, with 2016 measures used to calculate performance and the difference between 2015 and 2016 measures used to calculate improvement. We proposed to calculate the HLMR by using 10 of the 11 publicly reported measures, taking the average of all publicly reported measures except how well hospital staff help patients manage pain, consistent with revisions under consideration for this HCAHPS measure.

Specifically, we used the following data to model the impact of this policy:

- To calculate performance for the AMI model, we utilized: Hospital 30-day, all-cause, risk-standardized mortality rate following acute myocardial infarction hospitalization (NQF #0230) measure results based on the performance period of April 1, 2012 through March 31, 2015; excess days in acute care after hospitalization for acute

myocardial infarction measure results based on the performance period of April 1, 2012 through March 31, 2015; and HCAHPS survey data (NQF #0166) 2015 based on the performance period of January 1, 2015 through December 31, 2015.

- To calculate improvement for the AMI model, we utilized: Hospital 30-day, all-cause, risk-standardized mortality rate following acute myocardial infarction hospitalization (NQF #0230) measure results based on the performance period of April 1, 2011 through March 31, 2014; excess days in acute care after hospitalization for acute myocardial infarction measure results based on the performance period of April 1, 2011 through March 31, 2014; and HCAHPS survey data (NQF #0166) 2015 based on the performance period of January 1, 2014 through December 31, 2014.
- To calculate performance for the CABG model, we utilized hospital 30-day, all-cause, risk-standardized mortality rate following coronary artery bypass graft surgery (NQF #2558) measure results based on the performance period of April 1, 2012 through March 31, 2015 and HCAHPS survey data (NQF #0166) 2015 based on the performance period of January 1, 2015 through December 31, 2015.
- To calculate improvement for the CABG model, we utilized hospital 30-day, all-cause, risk-standardized mortality rate following coronary artery bypass graft surgery (NQF #2558) measure results based on the performance period of April 1, 2011 through March 31, 2014 and HCAHPS survey data (NQF #0166) 2015 based on the performance period of January 1, 2014 through December 31, 2014.
- To calculate performance for the SHFFT model, we utilized hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results based on the performance period of April 1, 2012 through March 31, 2015 and HCAHPS survey data (NQF #0166) 2015 based on the performance period of January 1, 2015 through December 31, 2015.
- To calculate improvement for SHFFT, we utilized hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results based on the performance periods of April 1, 2011 through March 31, 2015 and HCAHPS survey data (NQF #0166) 2015 based on the performance period of January 1, 2014 through December 31, 2014.

Consistent with prior experience in the Medicare program, which indicates that when payment is tied to voluntary reporting of quality measures most hospitals report such measures, we assume that most hospitals in the AMI and SHFFT models will submit voluntary measures to qualify for the reduced discount. For the AMI and CABG models, we developed composite quality scores for all eligible hospitals among the 294 MSAs eligible for selection. Selected hospitals were assigned to a performance percentile and assigned the corresponding quality performance score points listed in Tables 15 and 17 of this proposed 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 were in the top 10 percent of the improvement distribution received quality improvement points. Because 2015 data were not available for the AMI excess days measure, we randomly assigned improvement points for this measure (0.5 points) to 10 percent of hospitals. For SHFFT, hospitals in selected MSAs were assigned to a performance percentile and assigned the corresponding quality performance score points listed in Table 19 of this proposed 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 2 deciles from the prior year received quality improvement points.

Based on these composite quality scores, 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 proposed rule, composite quality scores will affect hospitals' eligibility for reconciliation payments and determine hospitals' effective discount percentages at reconciliation.

To simulate the impact for performance year 1, or July 1, 2017 through December 31, 2017, we calculated the NPRA assuming no downside risk to participants, and using the quality-adjusted 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 sum of quality-adjusted target prices for all episodes) for performance year 1, Medicare will not require repayment of the NPRA because we are not requiring participant responsibility for repayment for the first performance year. Additionally, as part of this estimate, we accounted for whether a participant met the minimum composite quality score to be eligible for a reconciliation payment. Lastly, we have applied the 5 percent stop-gain limit on the estimated reconciliation payments made to participants, and a 3 percent cap for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers.

For the simulation in performance year 2, we used the quality-adjusted target price calculated for performance year 2 that is two-thirds hospital experience and one-third regional experience. A 5 percent stop-loss and stop-gain limit was applied to reconciliation payments and repayments, and 3 percent stop-loss and stop-gain limit was applied for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers.

For the simulation in year 3, we rebased episode prices to incorporate the reconciliation payments simulated from the first performance year. To simulate reconciliation in year 3 we used the quality-adjusted 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 and stop-gain limit on reconciliation payments and repayments from acute care hospitals included in this analysis, but used a 5 percent stop-loss and stop-gain limit on reconciliation payments and repayments from rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers. For performance year 4 we simulated the reconciliation process using the episode quality-adjusted target price based on 100 percent of the regional experience, and a stop-loss and stop-gain limit set to 20 percent for acute care hospitals, and a stop-loss and stop-gain limit of 10 percent for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers.

For performance year 5 we rebased prices to include the simulated EPM reconciliation payments and repayments from performance years 1, 2, and 3. We simulated reconciliation in the fifth performance year using quality-adjusted target prices that are based on 100 percent of the regional experience,

and applied the stop-loss and stop-gain limits of 20 percent.

(2) Analyses

TABLE 38—ESTIMATES OF IMPACT ON THE MEDICARE PROGRAM BY PROPOSED EPM *

	Year(s)					Across all 5 years of proposed models
	2017	2018	2019	2020	2021	
AMI & CABG net financial impact	7	(3)	(6)	(17)	(21)	(40)
SHFFT net financial impact	6	(10)	(24)	(45)	(57)	(130)
Total: Net financial impact of all EPM proposals	12	(13)	(30)	(61)	(79)	(170)

* Note: In millions. Totals do not necessarily equal the sums of rounded components.

Table 38 summarizes the estimated impact for the AMI, CABG, and SHFFT models. Our model estimates that the Medicare program will save $170 million over the 5 performance years (2017 through 2021).

The first performance year of the EPMs is expected to cost the Medicare program $12 million in reconciliation payments made by CMS to participants. We have proposed that no repayments will be assessed because hospitals are not subject to downside risk in performance year 1. Participants that would receive reconciliation payments are the hospitals that provide lower cost care relative to their regional average.

In the second performance year of the EPMs, participants on net are expected to pay $13 million to CMS. Downside risk is waived for all participants in the first quarter of the second performance year. For the final 3 quarters in the second performance year, we have proposed a 5 percent stop-loss and stop-gain limit for acute care hospitals in the second performance year, with exception for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral center hospitals which would be subject to a 3 percent stop-loss and stop-gain limit. These limits would cap the total amount of repayments paid by hospitals to CMS.

In the third performance year of the models, net reconciliation payments are expected to be $30 million in savings to the Medicare program. For performance years 4 and 5 of the models, the episode quality-adjusted target price will be based on full regional pricing. This creates greater variation between the quality-adjusted target price and hospitals own experience. The stop-gain and stop-loss limits of 20 percent are applied, with a stop-gain and stop-loss limit of 5 percent for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers hospitals. As a result, net payments are expected to be $61 million from participants to the Medicare program in the fourth year and $79 million in the fifth year. These estimated savings in years 4 and 5 represent 2.0 percent of total episode spending in those years. The total savings to the Medicare program after the 5 performance years are expected to be $170 million out of $13.8 billion or 1.2 percent in total episode spending. Costs to the Medicare program may increase if providers are able to use waivers provided to increase episode volume among beneficiaries that would be expected to be less costly than the hospital's quality-adjusted target price without the need for improving the coordination of car.

(3) Uncertainties

These estimates are somewhat uncertain. As a result, the proposed models could produce more Medicare savings or could result in additional costs to the Medicare program. This analysis assumes that the demonstration incentives drive no change in utilization for the use of services within the bundled episode, as this would not materially affect the financial impact. The prospective prices for the proposed episodes 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 episode that is not driven by the demonstration incentives, 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 episode that is not driven by the demonstration incentives, then costs to the Medicare program may increase due to greater reconciliation payments paid by Medicare to participants.

We are also assuming that most hospitals will submit voluntary measures to qualify for the reduced discount. As a sensitivity test, if no hospitals report this data, the AMI model and SHFFT models together are estimated to save the Medicare program an additional $36 million over the 5 performance years.

Additionally, we were unable to fully estimate the impact of the proposal in section III.D. which addresses beneficiaries in EPMs who are also aligned or attributed to a Medicare Shared Savings Program participant or a participant in an ACO model initiated by the CMS Innovation Center. Savings achieved during an EPM episode are proposed to be attributed to the EPM participant, with EPM reconciliation payments for ACO-aligned beneficiaries treated as ACO expenditures, which should serve to minimize the financial impact of ACO overlap on overall savings. As described in section III.D.6, beginning in July 2017 we are proposing to exclude from AMI, CABG, and SHFFT episodes beneficiaries aligned to ACOs in the Next Generation ACO model and ESRD ESCOs in the Comprehensive ESRD Care Initiative in tracks with downside risk for financial losses. Excluding these beneficiaries from the proposed EPMs will have the effect of reducing the number of eligible episodes and therefore the expected savings generated by implementation of the EPMs. Due to the uncertainty associated with projecting future beneficiary alignment to ACOs, ACO participation, and beneficiaries experiencing EPM episodes across the performance years of the models, we are unable to quantify the impact of this proposed exclusion.

Due to the uncertainty of estimating this model, actual results could be higher or lower than this estimate. Our analysis to the best of our ability presents the cost and transfer payment effects of this proposed rule to the best of our ability. We solicit comments on the assumptions and analysis presented. Additionally, we note that for these estimates, we did not make assumptions for changes in efficiency or utilization over the course of the performance period.

b. CJR

We propose to modify the CJR model to include reconciliation payments and Medicare repayments in our

calculations when updating CJR episode quality-adjusted target prices for performance years 3 through 5. We also propose to create consistency between the CJR composite quality scores and SHFFT composite quality scores by—(1) awarding quality improvement points based on an improvement of 2 deciles (rather than 3 deciles as in the final CJR rule); (2) capping the total composite quality score at 20; and(3) utilizing an updated HCAHPS algorithm.

(1) Assumptions and Uncertainties

We used final action Medicare claims data from January 1, 2012 through December 31, 2014 to update the impact originally outlined in the CJR final rule (80 FR 73288) to reflect the changes proposed here for the CJR model. Specifically, we estimated the effect of including BPCI and CJR reconciliation payments and Medicare repayments in setting quality-adjusted target prices in performance years 3–5 to include the new quality adjusted discounts that begin in the first performance year, and by updating our prior assumption regarding CJR participation with voluntary reporting of quality metrics to be more consistent with prior experience in the Medicare program.

Due to proposed changes in the calculation of the CJR composite scores, we used quality data as publicly reported on Hospital Compare in 2015 and 2016 to model the impact of this policy, with 2016 measures used to calculate performance and the difference between 2015 and 2016 measures used to calculate improvement. We proposed to calculate the HLMR by using 10 of the 11 publicly reported measures, taking the average of all publicly reported measures except how well hospital staff help patients manage pain, consistent with revisions under consideration for this HCAHPS measure. Calculations are as follows:

- To calculate performance for the CJR model, we utilized hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results based on the performance period of April 1, 2012 through March 31, 2015 and HCAHPS survey data (NQF #0166) 2015 based on the performance period of January 1, 2015 through December 31, 2015.
- To calculate improvement for CJR, we utilized hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results based on the performance periods of April 1, 2011 through March 31, 2015 and HCAHPS survey data (NQF #0166) 2015 based on the performance period of January 1, 2014 through December 31, 2014.

For the purpose of this analysis, we assumed that hospitals participating in the CJR model will voluntarily submitted patient-reported outcome measures to qualify for the lower discount, consistent with prior experience in the Medicare program.

CJR participants were assigned to a performance percentile and assigned the corresponding quality performance score as described in the CJR final rule (80 FR 73288). 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 2 deciles from the prior year received quality improvement points, with the total composite quality score capped at 20. These composite quality scores, updated to be consistent with the methodology proposed in the CJR modifications, were then applied to the development of quality-adjusted target prices as described in the CJR final rule (80 FR 73288).

We note that we are proposing a modification to the application of the stop-loss and stop-gain limits to exclude hospital responsibility for post-episode spending from the application of these limits. We assume that the number of hospitals affected by this change would be small and have not modelled the impact of this change.

(2) Analyses

TABLE 39—ESTIMATES OF IMPACT ON THE MEDICARE PROGRAM FOR CJR MODEL *

	Year(s)					Across all 5 years of the proposed model
	2016	2017	2018	2019	2020	
Original CJR net financial impact from final rule	11	(36)	(71)	(120)	(127)	(343)
CJR modifications net financial impact	3	6	13	11	2	35

* In millions. Totals do not necessarily equal the sums of rounded components.

Modifications to the CJR model proposed in section V. of this proposed rule would begin at the time of reconciliation for performance year 1 and therefore affect estimates of the impact of the model from April 2016–December 2020. The change in the estimated net financial impact to the Medicare program from the modifications in this proposed rule is $22 million, and the updated assumptions regarding the number of hospitals that report quality data is modelled to be $14 million dollars. The total estimated net financial impact to the Medicare program from both the modifications in the proposed rule and revised assumptions are $35 million. Due to the uncertainty of estimating this model, actual results could be higher or lower than this estimate. Additionally, we note that due to the uncertainty associated with projecting future beneficiary alignment to ACOs, ACO participation, and beneficiaries experiencing CJR episodes across the performance years of the models, we are unable to quantify the impact of proposed exclusions related to ACOs. We are also unable at this time to estimate the impacts of considering certain CJR and EPM providers and Affiliated Practitioners to be participating in Advanced APMs. Eligible clinicians that qualify as QPs for a year through participation in EPMs and CJR will receive a bonus equal to 5 percent of their prior year Medicare payments, thereby increasing Medicare expenditures.

c. CR Incentive Payment Model

As detailed in section VI of this proposed rule, the CR incentive payment model will test whether a financial incentive for hospitals that encourages the management of beneficiaries that have had an AMI or a CABG in ways that may contribute to long-term improvements in quality and reductions in Medicare spending. We proposed the CR incentive payment model to test the effects on quality of care and Medicare expenditures of

providing explicit financial incentives to CR participants for beneficiaries hospitalized for treatment of AMI or CABG to encourage care coordination and greater utilization of medically necessary CR/ICR services for 90 days post-hospital discharge where the beneficiary's overall care is paid under either an EPM or the Medicare FFS program.

Under the CR incentive payment model, we proposed to provide a CR incentive payment to selected hospitals with financial responsibility for AMI or CABG model episodes (hereinafter EPM–CR participants) because they are already engaged in managing the AMI or CABG model beneficiary's overall care for a period of time following hospital discharge. We also proposed to provide a CR incentive payment to selected hospitals that are not AMI or CABG model participants (hereinafter FFS–CR participants), enabling us to test and improve our understanding of the effects of the CR incentive payment within the context of an EPM and the Medicare FFS program, as well as to identify potential interactions between the proposed CR incentive payment and the underlying EPM and FFS payment methodologies. We have therefore proposed to test the CR incentive payment model in 45 of the 98 MSAs selected for the AMI and CABG EPMs, as well as 45 FFS MSAs selected through stratified random sampling.

(1) Assumptions and Uncertainties

We used final action Medicare claims data from January 1, 2012 through December 31, 2015 to identify CR and ICR services that count towards CR incentive payments on the basis of the presence of the HCPCS codes on PFS and OPPS claims and APC codes on OPPS claims that report CR/ICR services. We then compared total Medicare spending over 3 years post hospital discharge for AMI and CABG for patients that received cardiac rehabilitation services within 90 days of discharge, to patients that did not receive cardiac rehabilitation services within 90 days of discharge. We found that among patients continuously enrolled over 3 years in FFS Medicare Part A and B those receiving cardiac rehabilitation services within 90 days of discharge from an AMI and or CABG hospitalization had lower Medicare spending relative to patients whom did not receive cardiac rehabilitation services post discharge from an AMI and or CABG hospitalization, even after adjusting for differences in age, sex, and case-mix between the two populations. The difference in average spending between the group that received cardiac rehabilitation services and the group that did not receive cardiac rehabilitation services within 90 days of discharge represents the reduction in Medicare spending we would anticipate from an additional beneficiary receiving cardiac rehabilitation services due to the cardiac rehabilitation incentive payment model.

CR incentive payments apply to CR/ICR sessions during the 90-day episode (for EPM participants) or 90-day care period (for FFS participants) from date of discharge. CR and ICR services paid by Medicare to any provider or supplier for model beneficiaries during AMI or CABG model episodes/care periods would result in participant eligibility for CR incentive payments.

To model the impact of the cardiac rehabilitation incentive payment model we calculated the costs of the incentive payments for patients receiving cardiac rehabilitation services, as well as any reduction in Medicare spending due to more patients receiving cardiac rehabilitation services. For the 294 MSAs eligible for the AMI and CABG EPM, we used Medicare claims data for the 2015 calendar year to calculate what the cardiac rehabilitation incentive payments would be for all patients receiving cardiac rehabilitation services within 90 days of an AMI and CABG hospitalization. For a given increase in the proportion of patients observed in the 2015 calendar year that receive cardiac rehabilitation services, we calculated both the cost of the cardiac rehabilitation incentive payments for these additional patients, as well as the estimated reduction in Medicare spending over a 3 year period due to these new patients receiving cardiac rehabilitation services. We calculated pricing based on the structure described in section VI.E. For a given rate of patients receiving cardiac rehabilitation services we summed the costs of CR incentive payments. We then subtracted the estimated reduction in Medicare spending due to any increase in the rate of patients receiving cardiac rehabilitation services relative to the rate receiving such services in the 2015 calendar year to arrive at the net financial impact. To adjust the results to account for only 90 MSAs being selected for the cardiac rehabilitation incentive payment model we multiplied the final results by 90/294. The final results were then multiplied by 90/294 as only 90 MSAs are to be selected for the cardiac rehabilitation incentive payment model.

We recognize that utilization of CR/ICR services is driven by many factors, and we lack sufficient data to reliably estimate the effect of a CR incentive payment on beneficiary utilization of CR/ICR services, particularly during the 90-day episode/care period. Therefore, we calculated a range of potential impacts based on alternatives in the increase in cardiac rehabilitation utilization, ranging from no change to an increase in utilization of 4 percentage points.

(2) Analyses

TABLE 40—RANGE OF POTENTIAL LONG-TERM IMPACT OF CARDIAC REHABILITATION INCENTIVE PAYMENT MODEL ON THE MEDICARE PROGRAM *

Year	Increase in cardiac rehabilitation utilization:		
	No increase	2 percentage points	4 percentage points
2017	1	1	1
2018	6	5	5
2019	6	4	1
2020	6	2	(3)
2021	7	.....	(7)
2022	.....	(7)	(15)
2023	.....	(5)	(10)
2024	.....	(2)	(5)
Total: 2017–2024	27	(2)	(32)

* In millions of dollars. Totals do not necessarily equal the sums of rounded components.

Table 40 summarizes the estimated impact for the CR incentive payment model. Our model estimates that the impact on the Medicare program may range from up to $27 million of spending to $32 million of savings between 2017 and 2024, depending on the change in utilization of CR/ICR services based on the proposed incentive structure. The model only estimates the financial effects of additional patients receiving CR/ICR services, and does not take into account potential changes in the volume of CR/ICR services that patients may receive within 90 days of hospital discharge. Increasing CR/ICR services within 90 days of hospital discharge will increase CR/ICR incentive payments, and may influence Medicare spending after the 90 day episode. Due to the uncertainty of estimating this model, actual results could be higher or lower than this estimate. Our analysis to the best of our ability presents the cost and transfer payment effects of this proposed rule. We solicit comments on the assumptions and analysis presented.

d. 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, as well as the CJR model. 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 MSDRGs. 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. 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. We believe that our experiences with BPCI support the design of the EPMs.

Although there is some evidence from BPCI and ACE suggesting that providers may improve their performance, the participants that volunteered to participate may be in a better position to reduce episode spending relative to the average provider. The CJR model is testing the first bundled payment model under the Innovation Center authority in which providers are required to participate. The CJR model test began in April 2016. The design of the EPMs proposed here incorporates early learnings from the CJR model, and we propose additional refinements to the CJR rule in this proposed rule to support successful implementation.

Finally, although we project savings to Medicare under the proposed EPMs and CJR, 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 it is determined that termination or modification is necessary, such actions would be undertaken through rulemaking.

3. Effects on Beneficiaries

We believe that episode payment models may have the potential to benefit beneficiaries because the intent of the models is to test whether providers under episode payment models 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 post-acute care spectrum spanning the episode of care. We believe that episode payment models have a patient-centered focus such that they incentivize improved healthcare delivery and communication delivered around the needs of the beneficiary, thus potentially benefitting the beneficiary community. However, the demonstration does not affect beneficiary cost sharing with each provider or premiums paid by beneficiaries. If there is a shift in provider usage within each bundle, then beneficiary cost sharing could be higher or lower than would otherwise be experienced.

We propose several patient outcomes and patient experience measures to tie payment to quality performance with the intent that this approach would encourage the provider community to focus on and deliver improved quality care for Medicare beneficiaries. Additionally, participants must meet an acceptable level of quality performance in order to qualify to receive a reconciliation payment. The accountability of participants for both quality and cost of care provided for Medicare beneficiaries within an episode provides participants with new incentives to improve the health and well-being of the Medicare beneficiaries they treat.

Additionally, the proposed EPMs and CJR do not affect the beneficiary's freedom of choice to obtain health services from any individual or organization qualified to participate in the Medicare program guaranteed under section 1802 of the Act. Eligible beneficiaries who choose to receive services from a participant would not have the option to opt out of inclusion in the models. Although the proposed EPMs and CJR allow participants to enter into risk-sharing arrangements with certain other providers, and participants may recommended those providers to the beneficiary, participants 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 have proposed to use our existing authority, if necessary, to audit participants if claims analysis indicates an inappropriate change in delivered services. As described in section III.G. of this proposed rule, given that participants would receive a reconciliation payment when they are able to reduce average costs per case and achieve acceptable or greater quality performance, 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 participants—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 proposed to require providers to supply beneficiaries with written information regarding the design and implications of these EPMs as well as their rights under Medicare, including their right to use their provider of choice.

We have proposed to implement 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 post-hospital discharge episode duration is sufficiently long to minimize the risk that any episode-related care will be delayed beyond the end of the episode. Moreover, we propose that as part of the payment definition (see section III.D of this proposed rule) that certain outlier costs 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.

Lastly, we note that Medicare payments for services will continue to be made for each Medicare FFS payment system under CJR and these EPMs. Because we propose to waive beneficiary coinsurance for reconciliation payments and repayments, beneficiaries will be subject to copayments, deductibles, and coinsurance consistent with Medicare FFS payments, rather than as determined by quality-adjusted target prices. We assume that beneficiary payments will not be affected, as only the hospital will be subject to the reconciliation process. If EPM participants are successful in improving quality or care while reducing costs, beneficiaries may benefit through reduced out-of-pocket expenditures. Alternatively, if participating providers respond to the demonstration by shifting medical care outside of the 90 day bundle, than this may negatively impact the quality of care that beneficiaries receive. We welcome public comments on our estimates of the impact of our proposals on Medicare beneficiaries.

4. 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 models proposed here would not include any rural hospitals, given that the models would only include hospitals located in MSAs, as proposed in section III.A. However, we also note that for purposes of our proposal to include a more protective stop-loss policy for certain hospitals, 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. The proposed models will affect some rural hospitals based on this definition.

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 have proposed additional financial protections for certain categories of hospitals, including rural hospitals. In performance year 2, an EPM participant could owe Medicare no more than 10 percent of the sum of quality-adjusted target prices for the hospital's episodes in an EPM as we phase in repayment responsibility under the models. In performance year 3 and beyond when full repayment responsibility is in place, no more than 20 percent of the sum of quality-adjusted target prices for the hospital's episodes in an EPM could be owed by a hospital to Medicare. However, for rural hospitals, Medicare Dependent Hospitals, Rural Referral Centers and Sole Community, we proposed a stop loss limit policy of 3 percent of episode payments for these categories of hospitals. More specifically, in performance year 2, a hospital could owe Medicare no more than 3 percent of the sum of quality-adjusted target prices for the hospital's episodes in an EPM. In performance years 3 through 5, a hospital could owe Medicare no more than 5 percent of the sum of quality-adjusted target prices for the hospital's episodes. Although we propose these additional protections, we believe that few rural hospitals will be included in the models, and therefore that few will need those protections.

AMI, CABG, and SHFFT episodes account for less than 5 percent of all discharges, and because relatively few of these procedures are performed at small rural hospitals, and because the EPMs are 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 proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

We are soliciting public comments on our estimates and analysis of the impact of our proposals on those small rural hospitals.

5. 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/smallbusiness-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 proposed rule relating to acute care hospitals would have some effects on a substantial number of other providers involved in these episodes of care including surgeons and other physicians, skilled nursing facilities, physical therapists, and other providers.

Although we acknowledge that many of the affected entities are small entities, and the analysis discussed throughout this proposed rule discusses aspects of episode payment models that may or will affect them, we have no reason to assume that these effects will reach the threshold level of 3 percent of revenues used by HHS to identify what are likely to be ''significant'' impacts. 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. Hospitals currently experience frequent changes to payment (for example, as both hospital affiliations and preferred provider networks change) that may impact revenue, and we have no reason to assume that this will change significantly under the proposed models.

Accordingly, we have determined that this proposed rule will not have a significant impact on a substantial number of small entities. We solicit public comments on our estimates and analysis of the impact of our proposals on those small entities.

6. Effects of Information Collection

There are three primary sets of information collection activities that EPM participants may be engaged in: Activities related to quality reporting, activities related to Advanced APM participation, and ad hoc reporting of beneficiary notification upon request by

CMS. Here, we briefly describe the anticipated scope and effects of information collection in each of these three areas for EPM participants.

Quality reporting associated with the EPMs includes EPM-specific quality measures, HCAHPS, and voluntarily reported quality measures (AMI and SHFFT models only), described in more detail in section III.E. of this proposed rule. IPPS hospitals are subject to incentives under quality reporting incentives such as the HVBP program and Medicare Electronic Health Record (EHR) Incentive Program, among others. Most IPPS hospitals already report information for the EPM-specific quality measures and HCAHPS for other CMS programs, and those hospitals that do not otherwise report this information to CMS would not be required to report under the EPMs. Thus, EPM participants would have no additional information collection activities for the required quality measures under the EPMs.

For the AMI model, participants have the option of reporting data for the Hybrid AMI Mortality measure. This measure includes a combination of claims and EHR data for a total of five EHR-based clinical data elements and six claims-based elements. AMI voluntary data submission must occur within 60 days of most recent data collection period. Successful submission of optional Hybrid AMI Mortality measure data will be based upon inclusion of five key clinical data elements.

We anticipate that participants who choose to engage in voluntary reporting of the Hybrid AMI Mortality measure will engage in the following process:

- Hospitals receive the measure authoring tool (MAT) output, a template layout for the data reporting file, and other artifacts that describe what they are supposed to do and how. The only data elements required are simple labs and vital signs that are collected consistently in structured fields. All hospitals with EHRs should be able to extract these from structured fields. Many will have some experience based on work with eCQMs.
- Hospitals review the MAT output and submit questions or request clarification via ongoing Q&A.
- Hospitals create a query for their EHR database using the MAT output and populate the reporting file with the core clinical data elements (CCDE). The hospital IT staff will typically run some queries on a small set of admissions and look at the corresponding charts to make sure they are getting the right data and may modify the query if needed.
- Hospitals submit the CCDE to CMS on the prescribed template (QRDA, consolidated clinical document architecture (CCDA), or simple excel file are all options).
- Hospitals do not need to do any measure calculation. Once data elements are submitted, CMS will link with claims data to calculate measure scores.

Given this process, the initial effort of establishing operability will create the majority of burden. Once the initial effort of establishing the query is complete, the burden will be minimal, as the same query can be run against the EHR for ongoing reporting. We assume that the primary cost for a hospital will be the IT support to set up the initial query and ensure the correct data is being pulled from the EHR. The data elements should be less burdensome than a typical eCQM because participants do not need to create new fields, all data is feasibly accessed in current EHRs without creating new clinical workflows, and hospitals do not need to do any measure calculation.

AMI model participants must meet the following requirements for each performance year in order to fulfill the successful Hybrid AMI Mortality data collection criterion. In performance year 1, participants will be required to submit this data for 50 percent of eligible AMI episodes occurring during the 2-month period between July 1, 2017 and August 31, 2017. In performance year 2, AMI voluntary data submission will be for 10 months of eligible discharges. In performance years 3 through 5, participants will need to submit data for the entire performance year. Furthermore, in performance years 2 through 5, participants will be required to submit the five key clinical data elements for at least 90 percent of eligible AMI discharges.

We are unable to provide a direct cost estimate for hospitals at this time, but hope to learn through commenters and expect to learn more as part of model testing. The voluntary data submission initiative will allow AMI model participants to build processes to extract and report the EHR data elements, as well as support CMS testing of systems required for Hybrid AMI Mortality measure (NQF #2473) production including data receiving and auditing, the merging EHR and claims data, calculation and production of measure results.

For the SHFFT model, the optional quality measure is based on a patient reported outcomes measure, which draws upon patient interviews to gain insights into patient experience and related outcomes.

We anticipate that participants who choose to engage in voluntary reporting of the THA/TKA PRO and limited risk variable data submission will engage in the following process:

- Participating hospitals will need to establish a means to collect patient-reported outcome data from patients pre-operatively and, again, post-operatively. In addition, they would need to collect select additional risk variables from patient charts.
- The specific instruments (and risk variables) have been vetted by a Technical Expert Panel and public comment: Veterans RAND 12 Item Health Survey (VR–12) or Patient-Reported Outcomes Measurement Information System (PROMIS) Global-10 generic PRO survey; Hip disability and Osteoarthritis Outcome Score (HOOS)/ Knee injury and Osteoarthritis Outcome Score (KOOS) Jr. or HOOS/KOOS subscales PRO survey; additional risk variables that can be physician-reported or chart-abstracted.
- If hospitals select the least burdensome instruments, data collection requires patients to answer 16 through 17 outcome questions and 3 risk factor questions. Estimates from instrument developers, input from the patient members of a Technical Expert Panel, and empirical results from a survey of physicians collecting similar data on THA/TKA patients support minimal patient burden (under 5 minutes) to collect the required data.
- Pre-operative survey completion could be arranged to be completed online, by phone, or at pre-operative clinic or hospital admission intake visits. Post-operative survey completion must occur between 270 and 365 days after the eligible elective primary procedure, and may occur in a variety of ways, such as online or by phone.
- Hospitals will collect or extract 6 risk variables that are commonly available in the medical record.

Currently available data suggests costs associated with information collection for this measure can vary tremendously. We anticipate the SHFFT patient-reported outcomes reporting costs to a participant hospital would decrease over time as the collection process in streamlined and integrated into clinical care workflows. A number of hospitals are already collecting this data either as a part of an established registry or for participation in the existing CJR bundled payment. For these participants, the burden of developing data collection systems will be minimal. We also seek comment, in particular from hospitals already collecting this

data, on our assumptions and information on any costs associated with this work.

Participating hospitals must meet the following requirements for each performance year in order to fulfill the successful PRO data collection criterion. In performance year 1, participants must submit data for at least 50 percent of eligible procedures or at least 50 cases. In performance year 2, participants must submit data for at least 60 percent of eligible procures or at least 75 cases. In performance year 3, participants must submit data for at least 70 percent of eligible procures or at least 100 cases. In performance years 4 and 5, participants must submit data for at least 80 percent of eligible procures or at least 200 cases.

We are unable to provide a direct cost estimate for hospitals at this time, but expect to learn more as part of SHFFT and CJR model testing, but seek comment on our assumptions.

Overall, we anticipate the net burden of voluntary data submissions in the AMI and SHFFT models will be marginal, as we anticipate hospitals will only choose to proceed with optional data submission if they believe the net financial benefit will be positive.

Information collection related to the Track 1 EPMs and the Track 1 CJR model to meet the Advanced APM requirements included in the Quality Payment Program proposed rule and to operationalize the EPMs and CJR as Advanced APMs includes EPM and CJR participant attestation to CEHRT and clinician financial arrangements lists submission. We believe that the selection by EPM and CJR participants to meet and attest to the CEHRT use requirement would create no significant additional administrative burden on EPM and CJR model participants. With respect to the submission of clinician financial arrangements lists (no more frequently than quarterly), while the required submission of this information under the Track 1 EPMs and the Track 1 CJR model may create some additional administrative requirements for certain EPM and CJR participants, we expect that Track 1 EPM participants could modify their contractual relationships with their EPM collaborators with which the EPM participant directly contracts to require the EPM collaborators to submit this information to the EPM participants. We also expect that EPM participants could modify their contracts with EPM collaborators to include similar requirements in their contracts with collaboration agents and in the contracts of collaboration agents with downstream collaboration agents.

Finally, we expect that participants are able to produce lists of beneficiaries who have received compliant notification of participation in model. We provided flexible guidelines for this requirement as specific record keeping methods can be chosen by individual participants so long as the necessary information is maintained readily available to report upon request. We seek comment on any burden derived from this requirement. In total, we anticipate marginal additional reporting burden resulting from this proposed rule. We are interested in comments from stakeholders regarding methodology for data submission which minimizes duplication and optimizes information collection for participants.

7. 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 2016, that is approximately $146 million. This proposed 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 $146 million in any 1 year.

D. Alternatives Considered

Throughout this proposed rule, we have identified our proposed policies and alternatives that we have considered, and provided information as to the effects of these alternatives and the rationale for each of the proposed policies. We solicit and welcome comments on our proposals, on the alternatives we have 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 hospitals in the CJR model, hospitals proposed for inclusion in the SHFFT model, and to hospitals that could be selected to participate in the proposed AMI and CABG models. This proposed rule will not impinge directly on hospitals that are not participating in CJR or the EPMs. However, it may encourage innovations in health care delivery in other areas or in care paid through other payers. For example, a hospital and affiliated providers may choose to extend their arrangements for an EPM to other payers, not just those beneficiaries paid under Medicare FFS. 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 EPMs. We welcome comments that address these or other possibilities.

We present the implications of alternatives considered in the development of the EPMs here. As discussed in section III.C., we propose to define beneficiary inclusion in the AMI model by discharge under an AMI MS–DRG (280–282), representing those individuals admitted with AMI who receive medical therapy but no revascularization, and discharge under a PCI MS–DRG (246–251) with an ICD–10–CM diagnosis code of AMI on the IPPS claim for the anchor hospitalization in the principal or secondary diagnosis code position. Alternately, we could define beneficiary inclusion based only on the principal diagnosis code. Doing so would result in a 2.4 percent fewer episodes included in the AMI model annually.

As discussed in section III.E., we proposed to allow participants to qualify for a higher composite quality score in the AMI and SHFFT models based on submission of voluntary measures. If we had not provided the option for participants to achieve an increased composite quality score for voluntary reporting (or if we assume no hospitals report this data), the AMI model and SHFFT models are estimated to save the Medicare program an additional 36 million over the 5 performance years.

As discussed in section VI. of this proposed rule, we have proposed the selection of CR MSAs via a modified stratified random selection based on several key dimensions related to CR/ICR service provision, including percent of eligible cases in the MSA who receive CR/ICR services, percent who complete CR or ICR services, and the number of CR/ICR providers. We also outlined alternative MSA selection strategies and solicited comments on the MSA selection approach. We anticipate that, because these approaches draw from the same pool of eligible MSAs without regard to MSA size or total cost of care during the episode or care period, the overall financial impact of different selection methodologies will be minimal, and the primary impact of varied MSA selection approaches will be on balance among model arms for evaluation.

E. Accounting Statement and Table

As required by OMB Circular A–4 under Executive Order 12866 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*) in Table 41, we have prepared an accounting statement showing the classification of transfers, benefits, and costs associated with the

provisions in this proposed rule. The accounting statement is based on estimates provided in this regulatory impact analysis.

TABLE 41—ACCOUNTING STATEMENT ESTIMATED IMPACTS FOR NEW EPISODE PAYMENT MODELS AND PROPOSED CHANGES TO COMPREHENSIVE CARE FOR JOINT REPLACEMENT

Category	Primary estimate	Source citation (RIA, preamble, etc.)
BENEFITS		
Annualized monetized transfers: Discount rate 7%	$19 million	Change from baseline to proposed changes (Tables 38 and 39).
Annualized monetized transfers: Discount rate 3%	21 million	
From whom to whom?	From Participant IPPS Hospitals to Federal Government.	

TABLE 42—ACCOUNTING STATEMENT ESTIMATED IMPACTS FOR CARDIAC REHABILITATION INCENTIVE PAYMENT MODEL

Category	Assuming no change in the rate of patients receiving cardiac rehabilitation services	Source citation (RIA, preamble, etc.)
BENEFITS		
Annualized monetized transfers: Discount rate 7%	$5 million	Change from baseline to proposed changes (Table 40).
Annualized monetized transfers: Discount rate 3%	5 million	
From whom to whom?	From Federal Government to Participant IPPS Hospitals.	
Category	Assuming a 2 percentage point increase in the rate of patients receiving cardiac rehabilitation services	Source citation (RIA, preamble, etc.)
BENEFITS		
Annualized monetized transfers: Discount rate 7%	$0 million	Change from baseline to proposed changes (Table 40).
Annualized monetized transfers: Discount rate 3%	−0 million	
From whom to whom?	From Federal Government to Health Care Providers.	
Category	Assuming a 4 percentage point increase in the rate of patients receiving cardiac rehabilitation services	Source citation (RIA, preamble, etc.)
BENEFITS		
Annualized monetized transfers: Discount rate 7%	−$3 million	Change from baseline to proposed changes (Table 40).
Annualized monetized transfers: Discount rate 3%	−4 million	
From whom to whom?	From Federal Government to Health Care Providers.	

F. Conclusion

This 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 proposed rule, we estimate that the financial impact of the AMI, CABG, and SHFFT EPM models proposed here would be net federal savings of $170 million over a 5-year performance period (2017 through 2021), the financial impact of the CJR model as modified here with the revised assumptions on hospital reporting of quality data would be an estimated net federal cost of $35 million over a 5-year period (2016 through 2020) relative to the estimates published in the CJR final rule. The financial impact of the CR incentive payment model would be net change in federal spending between $27 million in additional costs and $32 million in savings to the Medicare program over an 8-year period (2017 through 2024).

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 510

Administrative Practice and Procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 512

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 proposes to amend 42 CFR Chapter IV as follows:

Subchapter H—Health Care Infrastructure and Model Programs

PART 510—COMPREHENSIVE CARE FOR JOINT REPLACEMENT MODEL

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

Authority: Secs. 1102, 1115A, and 1871 of the Social Security Act (42 U.S.C. 1302, 1315(a), and 1395hh).

■ 2. Section 510.2 is amended by—
■ a. Revising the definition of ''ACO'';
■ b. Adding in alphabetical order definitions for ''ACO participant'' and ''ACO provider/supplier'';
■ c. Revising the definition for ''Alignment payment'';
■ d. Adding in alphabetical order definitions for ''Applicable discount factor'', ''CEHRT'', and ''CJR activities'';
■ e. Revising the definition of ''CJR collaborator'';
■ f. Adding in alphabetical order a definition for ''Collaboration agent'';
■ g. Removing the definition of ''Collaborator agreement'';
■ h. Revising the definitions of ''Distribution arrangement'' and ''Distribution payment'';
■ i. Adding in alphabetical order definitions for ''Downstream collaboration agent'', ''Downstream distribution arrangement'', ''Downstream distribution payment'', and ''Episode benchmark price'';
■ j. Removing the definition of ''Episode target price'';
■ k. Revising the definitions of ''HHA'' and ''Historical episode payment'';
■ l. Adding in alphabetical order a definition for ''Hospital'';
■ m. Removing the definitions of ''IPPS hospital (or hospital)'' and ''practice collaboration agent'';
■ n. Adding in alphabetical order a definition for ''Quality-adjusted target price''; and
■ o. Revising the definition of ''Quality improvement points''.

The additions and revisions read as follows:

§ 510.2 Definitions.

* * * * *

ACO means an accountable care organization, as defined at § 425.20 of this chapter, that participates in the Medicare Shared Savings Program.

ACO participant has the meaning set forth in § 425.20 of this chapter.

ACO provider/supplier has the meaning set forth in § 425.20 of this chapter.

* * * * *

Alignment payment means a payment from a CJR collaborator to a participant hospital under a sharing arrangement, for the sole purpose of sharing the participant hospital's responsibility for making repayments to Medicare.

* * * * *

Applicable discount factor means the discount percentage established by the participant hospital's quality category as determined in § 510.315 and that is applied to the episode benchmark price for purposes of determining a participant hospital's Medicare repayment in performance years 2 and 3.

* * * * *

CEHRT means certified electronic health record technology that meet the requirements of 45 CFR 170.102.

CJR activities means activities related to promoting accountability for the quality, cost, and overall care for CJR beneficiaries, including managing and coordinating care; encouraging investment in infrastructure enabling technologies and redesigned care processes for high quality and efficient service delivery; the provision of items and services during a CJR episode in a manner that reduces costs and improves quality; or carrying out any other obligation or duty under CJR.

CJR collaborator means an ACO or one of the following Medicare-enrolled individuals or entities that enters into a sharing arrangement:

(1) SNF.
(2) HHA.
(3) LTCH.
(4) IRF.
(5) Physician.
(6) Nonphysician practitioner.
(7) Provider or supplier of outpatient therapy services.
(8) Physician group practice (PGP).
(9) Hospital.
(10) CAH.

* * * * *

Collaboration agent means an individual or entity that is not a CJR collaborator and that is either of the following:

(1) A PGP member that has entered into a distribution arrangement with the same PGP in which he or she is an owner or employee;

(2) An ACO participant or ACO provider/supplier that has entered into a distribution arrangement with the same ACO in which it is participating.

* * * * *

Distribution arrangement means a financial arrangement between a CJR collaborator that is an ACO or PGP and a collaboration agent for the sole purpose of distributing some or all of a gainsharing payment received by the ACO or PGP.

Distribution payment means a payment from a CJR collaborator that is an ACO or PGP to a collaboration agent, under a distribution arrangement, composed only of gainsharing payments.

* * * * *

Downstream collaboration agent means an individual who is not a CJR collaborator or a collaboration agent and who is a PGP member that has entered into a downstream distribution arrangement with the same PGP in which he or she is an owner or employee, and where that PGP is a collaboration agent.

Downstream distribution arrangement means a financial arrangement between a collaboration agent that is both a PGP and an ACO participant and a downstream collaboration agent for the sole purpose of distributing some or all of a distribution payment received by the PGP.

Downstream distribution payment means a payment from a collaboration agent that is both a PGP and an ACO participant to a downstream collaboration agent, under a downstream distribution arrangement, composed only of distribution payments.

* * * * *

Episode benchmark price means a dollar amount assigned to CJR episodes based on historical episode payment data (3 years of historical Medicare payment data grouped into CJR episodes according to the episode definition as described in § 510.200(b)) prior to the application of the effective discount factor or applicable discount factor, as described in § 510.300(c).

* * * * *

HHA means a Medicare enrolled home health agency.

Historical episode payment means the expenditures for historical episodes that occurred during the historical period used to determine the episode benchmark price.

Hospital means a provider subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

* * * * *

Quality-adjusted target price means the dollar amount assigned to CJR episodes as the result of adjusting the episode benchmark price by the participant hospital's effective discount factor or applicable discount factor based on the participant hospital's quality category, as described in § 510.300(c) and § 510.315(f).

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 for performance years 2 through 5 increases from the previous performance year by at least 2 deciles on the performance percentile scale, as described in § 510.315(d). For performance year 1, CMS will add quality improvement points 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 corresponding time period in the previous year by at least 2 deciles on the performance percentile scale, as described in § 510.315(d).

* * * * *

■ 3. Section 510.110 is added to subpart B to read as follows:

§ 510.110 Access to records and retention.

Participant hospitals, CJR collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities performing CJR activities must do all of the following:

(a) Allow the Government, including CMS, OIG, HHS 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, distribution arrangements, downstream distribution arrangements and the documentation required under §§ 510.500(d) and 510.525(c)) sufficient to enable the audit, evaluation, inspection or investigation of any of the following:

(1) The individual's or entity's compliance with CJR model requirements.

(2) The calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments.

(3) The obligation to repay any reconciliation payments owed to CMS.

(4) The quality of the services furnished to a CJR beneficiary during a CJR episode.

(5) The sufficiency of CJR beneficiary notifications.

(6) The accuracy of the CJR participant hospital's submissions under CEHRT use requirements.

(b) 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—

(1) CMS determines a particular record or group of records should be retained for a longer period and notifies the participant hospital at least 30 calendar days before the disposition date; or

(2) There has been a dispute or allegation of fraud or similar fault against the participant hospital, CJR collaborator, collaboration agents, downstream collaboration agent, or any other individual or entity performing CJR activities in which case the records must be maintained for 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

■ 4. Section 510.120 is added to subpart B to read as follows:

§ 510.120 CJR participant hospital CEHRT track requirements.

(a) *CJR CEHRT use.* For performance years 2 through 5, CJR participant hospitals choose either of the following:

(1) *CEHRT use.* Participant hospitals attest in a form and manner required by CMS to their use of CEHRT as defined in § 414.1305 of this chapter to document and communicate clinical care with patients and other health professionals.

(2) *No CEHRT use.* Participant hospitals do not attest in a form and manner required by CMS to their use of CEHRT as defined in § 414.1305 to document and communicate clinical care with patients and other health professionals.

(b) *Clinician financial arrangements list.* Each participant hospital that chooses CEHRT use as provided in paragraph (a)(1) of this section must submit to CMS a clinician financial arrangements list in a form and manner specified by CMS on a no more than quarterly basis. The list must include the following information on individuals for the period of the CJR performance year specified by CMS:

(1) *CJR collaborators.* For each CJR collaborator who is a physician, nonphysician practitioner, or provider of outpatient therapy services during the period of the CJR performance year specified by CMS:

(i) The name, TIN, and NPI of the CJR collaborator.

(ii) The start date and, if applicable, end date, for the sharing arrangement between the CJR participant hospital and the CJR collaborator.

(2) *Collaboration agents.* For each collaboration agent who is a physician or nonphysician practitioner of a PGP that is a CJR collaborator during the period of the CJR performance year specified by CMS:

(i) The TIN of the PGP that is the CJR collaborator, and the name and NPI of the physician or nonphysician practitioner.

(ii) The start date and, if applicable, end date, for the distribution arrangement between the CJR collaborator that is a PGP and the physician or nonphysician practitioner who is a PGP member.

(3) *Downstream collaboration agents.* For each downstream collaboration agent who is a physician or nonphysician practitioner member of a PGP that is also an ACO participant in an ACO that is an CJR collaborator during the period of the CJR performance year specified by CMS:

(i) The TIN of the PGP that is the ACO participant, and the name and NPI of the physician or nonphysician practitioner.

(ii) The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent that is both PGP and an ACO participant and the physician or nonphysician practitioner who is a PGP member.

(4) *Attestation to no individuals.* If there are no individuals that meet the requirements to be reported, as specified in paragraphs (b)(1) through (3) of this section, the participant hospital must attest in a form and manner required by CMS that there are no individuals to report on the clinician financial arrangements list.

(c) *Documentation requirements.* (1) Each participant hospital that chooses CEHRT use as provided in paragraph (a)(1) of this section must maintain documentation of their attestation to CEHRT use and clinician financial arrangements lists.

(2) The participant hospital must retain and provide access to the required documentation in accordance with § 510.110.

■ 5. Section 510.205 is amended by adding paragraph (a)(6) to read as follows:

§ 510.205 Beneficiary inclusion criteria.

(a) * * *

(6) For episodes that begin on or after July 1, 2017, are not aligned to an ACO in the Next Generation ACO model or an ACO in a track of the Comprehensive ESRD Care Initiative incorporating downside risk for financial losses.

* * * * *

■ 6. Section 510.300 is amended by:

■ a. Revising the section heading;

■ b. Revising paragraphs (a) introductory text, (a)(1) through (3), and (a)(5);

■ d. Revising the heading for paragraph (b) and revising paragraphs (b)(1) introductory text, (b)(3), (5), and (7);

■ e. Adding paragraph (b)(8); and

■ f. Revising paragraph (c).

The revisions and additions read as follows:

§ 510.300 Determination of episode quality-adjusted target prices.

(a) *General.* CMS establishes episode quality-adjusted target prices for participant hospitals for each performance year of the model as

specified in this section. Episode quality-adjusted target prices are established according to the following:

(1) *MS–DRG and fracture status.* MS–DRG assigned at discharge for anchor hospitalization and present 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 quality-adjusted target prices.* Episode quality-adjusted target prices are updated to account for Medicare payment updates no less than 2 times per year, for updated quality-adjusted target prices effective October 1 and January 1, and at other intervals if necessary.

(3) *Episodes that straddle performance years or payment updates.* The quality-adjusted target price that applies to the type of episode as of the date of admission for the anchor hospitalization is the quality-adjusted target price that applies to the episode.

* * * * *

(5) *Quality performance.* Quality-adjusted target prices reflect effective discount factors or applicable discount factors based on a hospital's composite quality score, as specified in §§ 510.300(c) and 510.315(f).

* * * * *

(b) *Episode quality-adjusted target price.* (1) CMS calculates quality-adjusted 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 quality-adjusted target price and reconciliation calculations. The calendar years used for historical expenditure calculations are as follows:

* * * * *

(3) *Exception for low-volume hospitals.* Quality-adjusted target prices for participant hospitals with fewer than 20 CJR episodes in total across the 3 historical years of data used to calculate the quality-adjusted target price are based on 100 percent regional historical episode payments.

* * * * *

(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 quality-adjusted target price.

* * * * *

(7) *Communication of episode quality-adjusted target prices.* CMS communicates episode quality-adjusted target prices to participant hospitals before the performance period in which they apply.

(8) *Inclusion of reconciliation payments and repayments.* For performance years 3, 4, and 5 only, reconciliation payments and repayment amounts under §§ 510.305(f)(2) and 510.305(f)(3) and from LEJR episodes included in the BPCI initiative are included in historical episode payments.

(c) *Discount factor.* A participant hospital's episode quality-adjusted target prices incorporate discount factors to reflect Medicare's portion of reduced expenditures from the CJR model as described in this section.

(1) *Discount factors affected by the quality incentive payments and the composite quality score.* 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 the effective discount factor or applicable discount factor used for calculating reconciliation payments and repayment amounts. The quality-adjusted target prices incorporate the effective or applicable discount factor at reconciliation.

(2) *Discount factor for reconciliation payments.* The discount factor for reconciliation payments in all performance years is 3.0 percent.

(3) *Discount factors for repayment amounts.* The discount factor for repayment amounts is—

(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

(iii) In performance years 4 and 5, 3.0 percent.

* * * * *

■ 7. Section 510.305 is amended by revising paragraphs (e) introductory text, (e)(1)(ii) and (v), (f)(1)(i) and (ii), and (h)(6), adding paragraph (h)(7), revising paragraph (i), and adding paragraph (j) to read as follows:

§ 510.305 Determination of the NPRA and reconciliation process.

* * * * *

(e) *Calculation of the NPRA.* By comparing the quality-adjusted 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) * * *

(ii) Multiplies each episode quality-adjusted target price 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 quality-adjusted target price applies.

* * * * *

(v) Applies the following prior to determination of the reconciliation payment or repayment amount:

(A) *Limitation on loss.* Except as provided in paragraph (e)(1)(v)(C) of this section, the total amount of the NPRA and subsequent reconciliation calculation 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 (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.

(*5*) The post-episode spending and ACO overlap calculation amounts in paragraphs (j)(1) and (j)(2) of this section are not subject to the limitation on loss.

(B) *Limitation on gain.* The total amount of the NPRA and subsequent reconciliation calculation 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 (i) of this section, the subsequent

reconciliation calculation reassesses the limitation on gain for a given performance year by applying the limitations on gain limits to the aggregate of the 2 reconciliation calculations.

(*5*) The post-episode spending and ACO overlap calculation amounts in paragraphs (j)(1) and (j)(2) of this section are not subject to the limitation on gain.

(C) *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 due to the NPRA and subsequent reconciliation calculation cannot exceed 3 percent of the amount calculated in paragraph (e)(1)(iii) of this section. For performance years 3 through 5, the amount cannot exceed 5 percent of the amount calculated in paragraph (e)(1)(iii) of this section.

* * * * *

(f) * * *

(1) * * *

(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 (i) of this section and the post-episode spending and ACO overlap calculations as described in paragraph (j) of this section are added to the current year's NPRA in order to determine the reconciliation payment or repayment amount.

* * * * *

(h) * * *

(6) The post-episode spending amount and ACO overlap calculation for the previous performance year, as applicable.

(7) The reconciliation payment or repayment amount.

(i) *Subsequent reconciliation calculation.* (1) 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 episode cancelations due to overlap between the CJR model and other CMS models and programs, or for other reasons as specified in § 510.210(b).

(2) The subsequent calculation for performance years 1 through 4 occurs concurrently with the first reconciliation process for the following 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 aggregate calculation of the amounts described in paragraphs (e)(1)(iv) and (i)(1) of this section for that performance year (the initial reconciliation and the subsequent reconciliation calculation) to ensure such amount does not exceed the applicable stop-loss or stop-gain limits. Because there will be no additional performance year after performance year 5, the subsequent reconciliation calculation for performance year 5 will occur independently in 2022.

(j) *Additional adjustments to the reconciliation payment or repayment amount.* (1) In order to account for shared savings payments, CMS will reduce the reconciliation payment or increase the repayment amount for the subsequent performance year (for years 1 through 4) by the amount of the participant hospital's discount percentage that is paid to the ACO in the prior performance year as shared savings. (This amount will be assessed independently for performance year 5 in 2022.) This adjustment is made only 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 programs:

(i) The Pioneer ACO model.

(ii) The Medicare Shared Savings Program.

(iii) The Comprehensive ESRD Care Initiative (excluding a track with downside risk for episodes that initiate after July 1, 2017).

(iv) The Next Generation ACO model (for CJR episodes that initiate prior to July 1, 2017).

(2) *Increases in post-episode spending.* If the average post-episode Medicare Parts A and B payments for a participant hospital in the prior performance year is greater than 3 standard deviations above the regional average post-episode payments for the same performance year, then the spending amount exceeding three standard deviations above the regional average post-episode payments for the same performance year is subtracted from the net reconciliation or added to the repayment amount for the subsequent performance year for years 1 through 4, and assessed independently for year 5.

■ 8. Section 510.310 is amended by—

■ a. Revising paragraphs (a)(1) and (2).

■ b. Removing paragraph (a)(3)

■ c. Resdesignating paragraph (a)(4) as paragraph (a)(3).

■ d. Adding a new paragraph (a)(4).

■ e. Revising paragraph (c).

■ f. Redesignating paragraph (d) as paragraph (e).

■ g. Adding a new paragraph (d).

■ h. Revising newly designated paragraph (e)(6).

The revisions and addition read as follows:

§ 510.310 Appeals process.

* * * * *

(a) * * *

(1) Unless the participant hospital provides such notice, CMS deems final the CJR reconciliation report 45 calendar days after it is issued and proceeds with the payment or repayment processes as applicable.

(2) If CMS receives a notice of a calculation error within 45 calendar days of the issuance of the reconciliation report, 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.

* * * * *

(4) Only participant hospitals may use the notice of calculation error process described in this part.

* * * * *

(c) *Exception to the process.* If the participant hospital contests a matter that does not involve an issue contained in, or a calculation that contributes to, a CJR reconciliation report, a notice of calculation error is not required. In these 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) *Notice of a participant hospital's termination from the CJR model.* If a participant hospital receives notification that it has been terminated from the CJR model, it must provide a written notice to CMS requesting review of the termination within 10 calendar days of the notice. CMS has 30 days to respond to the participant hospital's request for review. If the participant hospital fails to notify CMS, the termination is deemed final.

(e) * * *

(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 section 1115A(c)(1) or (2) of the Act.

■ 9. Section 510.315 is amended by—

■ a. Revising paragraph (c) introductory text.

■ b. Redesignating paragraph (c)(1)(ix) as paragraph (c)(1)(viii).
■ c. Redesignating paragraph (c)(2)(ix) as paragraph (c)(2)(viii).
■ d. Revising paragraph (d) and (f).
The revisions read as follows:

§ 510.315 Composite quality scores for determining reconciliation payment eligibility and quality incentive payments.

* * * * *

(c) *Quality performance points.* CMS computes quality performance points for each quality measure based on the participant hospital's performance relative to the distribution of performance of all ''subsection (d)'' hospitals that are eligible for payment under IPPS and meet the minimum patient case or survey count for that measure.

* * * * *

(d) *Quality improvement points.* For performance year 1, if a participant hospital's quality performance percentile on an individual measure described in § 510.400(a) increases from the corresponding time period in the previous year by at least 2 deciles on the performance percentile scale, then the hospitals is eligible to receive quality improvement points equal to 10 percent of the total available point for that individual measure up to a maximum composite quality score of 20 points. For performance years 2 through 5, 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 2 deciles on the performance percentile scale, then the hospitals is eligible to receive quality improvement points equal to 10 percent of the total available point for that individual measure up to a maximum composite quality score of 20 points.

* * * * *

(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 effective discount factors or applicable discount factors described in § 510.300(c):

(1) A 1.0 percentage point reduction to the effective discount factor or 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 effective discount factor or applicable discount factor for participant hospitals with excellent quality performance, defined as composite quality scores that are greater than 13.2.

■ 10. Section 510.400 is amended by revising paragraph (c)(3) to read as follows:

§ 510.400 Quality measures and reporting.

* * * * *

(c) * * *

(3) Does not publicly report the voluntary patient-reported outcomes and limited risk variable data during this model, but indicates whether a hospital has successfully submitted such data in accordance with § 510.400(b).

■ 11. Section 510.405 is amended by revising paragraph (b) to read as follows:

§ 510.405 Beneficiary choice and beneficiary notification.

* * * * *

(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. In circumstances where, due to the patient's condition, it may not be feasible to provide notification at such times, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable but no later than discharge from the participant hospital accountable for the episode. 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 written agreement memorializing a sharing arrangement. This requirement may be fulfilled by the hospital including in the detailed notification provided to Medicare beneficiaries a web address where beneficiaries may access this list.

(2) *Physician, nonphysician practitioner, and PGP provision of notice.* A participant hospital must require any physician, nonphysician practitioner, or PGP 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 if known to the physician, nonphysician practitioner, and PGP collaborators or upon provision of the services during the episode.

(3) *Other CJR collaborators.* A participant hospital must require each CJR collaborator (other than physicians, nonphysician practitioners, or PGP collaborators) to provide written notice of the structure of the model and the existence of its sharing arrangement with the participant hospital to any Medicare beneficiary that meets the criteria specified in § 510.205. An ACO that is a CJR collaborator must require their ACO participants for which the ACO has an ACO distribution arrangement to provide written notice of the structure of the model and the existence of the ACO's 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 CJR collaborator during the CJR episode.

(4) *Discharge planning notice.* A participant hospital must provide the beneficiary with a written notice of any potential financial liability that may arise from non-covered services recommended or presented as an option as part of discharge planning. This notice must be provided to the beneficiary 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 participant 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 participant hospital must

notify the beneficiary that the service would not be covered by Medicare.

(ii) If the participant hospital is discharging a beneficiary to a SNF prior to the occurrence of a 3 day hospital stay, and the beneficiary is being admitted to or is considering a SNF that would not qualify under the SNF 3-day waiver in § 510.610, the participant hospital must 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 that would be covered by Medicare Part B during a non-covered inpatient SNF stay.

(5) Participant hospitals and CJR collaborators must be able to generate upon request a list of all beneficiaries who have received a notice required by this section, including the type of notice and the date the notice was delivered. Lists of beneficiaries that receive notifications must be retained and provided access to CMS, or its designees, in accordance with § 510.110.

■ 12. Section 510.410 is amended by revising paragraphs (b)(1) introductory text, (b)(1)(i) introductory text, (b)(1)(i)(F), (b)(1)(ii), (b)(1)(vi) through (x), (b)(2)(i) through (v), (vi), and (b)(3) to read as follows:

§ 510.410 Compliance enforcement.

* * * * *

(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 its related CJR collaborators, collaboration agents, or downstream collaboration agents—

(i) Fails to comply with any 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:

* * * * *

(F) Failing to follow the requirements related to sharing arrangements.

(ii) Has signed a sharing arrangement, distribution arrangement, or downstream distribution arrangement that is noncompliant with the requirements of this part.

* * * * *

(vi) Fails to provide an accurate clinician financial arrangements list as specified in § 510.120(b).

(vii) 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.

(viii) 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 CJR.

(ix) 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.

(x) 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 CJR.

(2) * * *

(i) Issuing a warning letter to the participant hospital.

(ii) Requiring the participant hospital to develop a corrective action plan, commonly referred to as a CAP.

(iii) Reducing or eliminating a participant hospital's reconciliation payment.

(iv) Requiring a participant hospital to terminate a sharing arrangement with a CJR collaborator and prohibiting further engagement in sharing arrangements with the participant hospital by that CJR collaborator.

(v) Prohibiting the participant hospital from participating in the CEHRT track.

(vi) Terminating the participant hospital's participation in the CJR model. Where a participant is terminated from the CJR model, the participant hospital will remain liable for all negative NPRA generated from episodes of care that occurred prior to termination.

(3) CMS may add 25 percent to a repayment amount on a participant hospital's reconciliation report if all of the following conditions are true:

(i) CMS has required a corrective action plan from a participant hospital;

(ii) The participant hospital owes a repayment amount to CMS; and

(iii) The participant hospital fails to timely comply with the corrective action plan or is noncompliant with the CJR model's requirements.

■ 13. Section 510.500 is revised to read as follows:

§ 510.500 Sharing arrangements under the CJR model.

(a) *General.* (1) A participant hospital may enter into a sharing arrangement with a CJR collaborator to make a gainsharing payment, or to receive an alignment payment, or both. A participant hospital must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement.

(2) A sharing arrangement must comply with the provisions of this section and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

(3) Participant hospitals must develop, maintain, and use a set of written policies for selecting individuals and entities to be CJR collaborators. These policies must contain criteria related to, and inclusive of, the quality of care delivered by the potential CJR collaborator. The selection criteria cannot be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.

(4) If a participant hospital enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the CJR model.

(b) *Requirements.* (1) A sharing arrangement must be in writing and signed by the parties, and entered into before care is furnished to CJR beneficiaries under the sharing arrangement.

(2) Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.

(3) The sharing arrangement must require the CJR collaborator and its employees, contractors (including collaboration agents), and subcontractors (including downstream collaboration agents) to comply with the following:

(i) 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);

(ii) All applicable Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the sharing arrangement; and

(iii) All other applicable laws and regulations.

(4) The sharing arrangement must require the CJR collaborator to have a

compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the CJR model.

(5) The sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(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, its receipt of alignment payments, and its use of beneficiary incentives in the CJR model.

(7) The written agreement memorializing a sharing arrangement must specify the following:

(i) The purpose and scope of the sharing arrangement;

(ii) The obligations of the parties, including specified CJR activities and other services to be performed by the parties under the sharing arrangement;

(iii) The date of the sharing arrangement;

(iv) Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out CJR activities; and

(v) The financial or economic terms for payment, including:

(A) Eligibility criteria for a gainsharing payment.

(B) Eligibility criteria for an alignment payment.

(C) Frequency of gainsharing or alignment payment.

(D) Methodology and accounting formula for determining the amount of a gainsharing payment or alignment payment.

(8) The sharing arrangement must not—

(i) Induce the participant hospital, CJR collaborator, or any employees, contractors, or subcontractors of the participant hospital or CJR collaborator to reduce or limit medically necessary services to any Medicare beneficiary; or

(ii) 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.

(c) *Gainsharing payment, alignment payment, and internal cost savings conditions and restrictions.* (1) Gainsharing payments, if any, must—

(i) Be derived solely from reconciliation payments, or internal cost savings, or both;

(ii) Be distributed on an annual basis (not more than once per calendar year);

(iii) Not be a loan, advance payment, or payment for referrals or other business; and

(iv) Be clearly identified as a gainsharing payment at the time it is paid.

(2)(i) To be eligible to receive a gainsharing payment, a CJR collaborator must meet quality of care criteria for the performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment. The quality of care criteria must be established by the participant hospital and directly related to the CJR episode.

(ii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator other than a PGP or an ACO must have directly furnished a billable item or service to a CJR beneficiary during a CJR episode that occurred in the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount.

(iii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator that is a PGP 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 same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount; and

(B) The PGP must have contributed to CJR activities and been clinically involved in the care of CJR beneficiaries during the same performance year for which the CJR participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. For example, a PGP might have been clinically involved in the care of CJR beneficiaries by:

(1) Providing care coordination services to beneficiaries during and/or after inpatient admission;

(2) Engaging with a participant hospital in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care for CJR episodes and reduce CJR episode spending; or

(3) In coordination with other providers and suppliers (such as members of the PGP, the participant hospital, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of CJR beneficiaries.

(iv) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator that is an ACO must meet the following criteria:

(A) The ACO must have had an ACO provider/supplier that directly furnished, or an ACO participant that billed for, an item or service that was rendered to a CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount; and

(B) The ACO must have contributed to CJR activities and been clinically involved in the care of CJR beneficiaries during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed the repayment amount. For example, an ACO might be have been clinically involved in the care of CJR beneficiaries by:

(1) Providing care coordination services to CJR beneficiaries during and/or after inpatient admission;

(2) Engaging with a participant hospital in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care and reduce spending for CJR episodes; or

(3) In coordination with providers and suppliers (such as ACO participants, ACO providers/suppliers, the participant hospital, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of CJR beneficiaries.

(3)(i) The methodology for accruing, calculating and verifying internal cost savings must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(ii) The methodology used to calculate internal cost savings must reflect the actual, internal cost savings achieved by the participant hospital through the documented implementation of CJR activities identified by the participant hospital and must exclude:

(A) Any savings realized by any individual or entity that is not the participant hospital; and

(B) ''Paper'' savings from accounting conventions or past investment in fixed costs.

(4) The total amount of a gainsharing payment for a performance year paid to a CJR collaborator must not exceed the following:

(i) In the case of a CJR collaborator who is a physician or nonphysician practitioner, 50 percent of the Medicare-approved amounts under the PFS for items and services furnished by that physician or nonphysician practitioner to the participant hospital's CJR beneficiaries during CJR episodes that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made.

(ii) In the case of a CJR collaborator that is a PGP, 50 percent of the Medicare-approved amounts under the PFS for items and services billed by the PGP and furnished to the participant hospital's CJR beneficiaries by members of the PGP during CJR episodes that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made.

(5) The amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities. The methodology may take into account the amount of such CJR activities provided by a CJR collaborator relative to other CJR collaborators.

(6) For a performance year, the aggregate amount of all gainsharing payments that are derived from a reconciliation payment must not exceed the amount of the reconciliation payment the participant hospital receives from CMS.

(7) No entity or individual, whether a party to a sharing arrangement 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 past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.

(8) 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.

(9) The sharing arrangement must require the participant hospital to recoup any gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation report or was based on the submission of false or fraudulent data.

(10) 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—

(i) Issued, distributed, or paid prior to the calculation by CMS of a repayment amount reflected in a reconciliation report;

(ii) Loans, advance payments, or payments for referrals or other business; or

(iii) Assessed by a participant hospital if it does not owe a repayment amount.

(11) The participant hospital must not receive any amounts under a sharing arrangement from a CJR collaborator that are not alignment payments.

(12) For a performance 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.

(13) The aggregate amount of all alignment payments from a CJR collaborator to the participant hospital may not be greater than:

(i) With respect to a CJR collaborator other than an ACO, 25 percent of the participant hospital's repayment amount.

(ii) With respect to a CJR collaborator that is an ACO, 50 percent of the participant hospital's repayment amount.

(14) The methodology for determining alignment payments must not directly account for the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.

(15) All gainsharing payments and any alignment payments must be administered by the participant hospital in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(16) All gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(d) *Documentation requirements.* (1) Participant hospitals must:

(i) Document the sharing arrangement contemporaneously with the establishment of the arrangement;

(ii) Maintain accurate current and historical lists of all CJR collaborators, including collaborator names and addresses; update such lists on at least a quarterly basis; and publicly report the current and historical lists of CJR collaborators on a Web page on the participant hospital's Web site; and

(iii) Maintain and require each CJR collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum the:

(A) Nature of the payment (gainsharing payment or alignment payment);

(B) Identity of the parties making and receiving the payment;

(C) Date of the payment;

(D) Amount of the payment; and

(E) Date and amount of any recoupment of all or a portion of a CJR collaborator's gainsharing payment.

(2) The participant hospital must keep records of:

(i) Its process for determining and verifying its potential and current CJR collaborators' eligibility to participate in Medicare;

(ii) Its plan to track internal cost savings;

(iii) Information on the accounting systems used to track internal cost savings;

(iv) A description of current health information technology, including systems to track reconciliation payments and internal cost savings; and

(v) Its plan to track gainsharing payments and alignment payments.

(3) The participant hospital must retain and provide access to, and must require each CJR collaborator to retain and provide access to, the required documentation in accordance with § 510.110.

■ 14. Section 510.505 is revised to read as follows:

§ 510.505 Distribution arrangements.

(a) *General.* (1) A PGP or ACO that has entered into a sharing arrangement with a participant hospital may distribute all or a portion of any gainsharing payment it receives from the participant hospital only in accordance with a distribution arrangement.

(2) All distribution arrangements must comply with the provisions of this section and all other applicable laws and regulations, including the fraud and abuse laws.

(b) *Requirements.* (1) All distribution arrangements must be in writing and

signed by the parties, contain the date of the agreement, and be entered into before care is furnished to EPM beneficiaries under the distribution arrangement.

(2) Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any distribution payments from an ACO must be determined in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities and that may take into account the amount of such CJR activities provided by a collaboration agent relative to other collaboration agents.

(6) The amount of any distribution payments from a PGP to a member must be determined either in a manner that complies with § 411.352(g) of this chapter or in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities and that may take into account the amount of such CJR activities provided by a collaboration agent relative to other collaboration agents.

(7) Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g), a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to a CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

(8) Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g), the total amount of distribution payments for a performance year paid to a collaboration agent must not exceed the following:

(i) In the case of a collaboration agent who is physician or nonphysician practitioner, 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the collaboration agent to the participant hospital's CJR beneficiaries during CJR episodes that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

(ii) In the case of a collaboration agent that is a PGP, 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by the PGP for items and services furnished to the participant hospital's CJR beneficiaries during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

(9) With respect to the distribution of any gainsharing payment received by a PGP or ACO, the total amount of all distribution payments must not exceed the amount of the gainsharing payment received by the CJR collaborator from the participant hospital.

(10) All distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(11) The collaboration agent must retain the 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 the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(13) The CJR collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 510.110, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any distribution payment(s).

(iii) The identity of each collaboration agent that received a distribution payment.

(iv) A description of the methodology and accounting formula for determining the amount of any distribution payment.

(14) The CJR collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same participant hospital.

(15) The CJR collaborator must retain and provide access to, and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 510.110.

■ 15. Section 510.506 is added to read as follows:

§ 510.506 Downstream distribution arrangements.

(a) *General.* (1) An ACO participant that is a PGP and that has entered into a distribution arrangement with a CJR collaborator that is an ACO may distribute all or a portion of any distribution payment it receives from the CJR collaborator only in accordance with downstream distribution arrangement.

(2) All downstream distribution arrangements must comply with the provisions of this section and all applicable laws and regulations, including the fraud and abuse laws.

(b) *Requirements.* (1) All downstream distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to CJR beneficiaries under the downstream distribution arrangement.

(2) Participation in a downstream distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a downstream distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any downstream distribution payment must be determined either in a manner that complies with § 411.352(g) of this chapter or in accordance with a methodology that is substantially based on the quality of care and the provision of CJR activities and that may take into account the amount of such CJR activities provided by a downstream collaboration agent relative to other downstream collaboration agents.

(6) Except for a downstream distribution payment that complies with

§ 411.352(g), a downstream collaboration agent is eligible to receive a downstream distribution payment only if the PGP billed for an item or service furnished by the downstream collaboration agent to a CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprise the gainsharing payment from which the ACO made the distribution payment to the PGP that is an ACO participant.

(7) Except for a downstream distribution payment that complies with § 411.352(g), the total amount of downstream distribution payments for a performance year paid to a downstream collaboration agent must not exceed 50 percent of the total Medicare-approved amounts under the PFS for services billed by the PGP and furnished by the downstream collaboration agent to the participant hospital's CJR beneficiaries during CJR episodes that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment from which the ACO made the distribution payment to the PGP that is an ACO participant.

(8) The total amount of all downstream distribution payments made to downstream collaboration agents must not exceed the amount of the distribution payment received by the PGP from the ACO.

(9) All downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(10) The downstream collaboration agent must retain his or her ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(11) The downstream distribution arrangement must not—

(i) Induce the downstream 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.

(12) The PGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 510.110, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any downstream distribution payment.

(iii) The identity of each downstream collaboration agent that received a downstream distribution payment.

(iv) A description of the methodology and accounting formula for determining the amount of any downstream distribution payment.

(13) The PGP may not enter into a downstream distribution arrangement with any PGP member who has either of the following:

(i) A sharing arrangement with a participant hospital.

(ii) A distribution arrangement with the ACO the PGP is a participant in.

(14) The PGP must retain and provide access to, and must require downstream collaboration agents to retain and provide access to, the required documentation in accordance with § 510.110.

■ 16. Section 510.515 is amended by revising paragraphs (a)(2) and (3) and (b) through (d) and removing paragraph (e).

The revisions read as follows:

§ 510.515 Beneficiary incentives under the CJR model.

* * * * *

(a) * * *

(2) The item or service provided must be reasonably connected to medical care provided to a beneficiary during a CJR episode of care.

(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 (c) of this section, for a beneficiary in a CJR episode by engaging the beneficiary in better managing his or her own health.

(b) *Technology provided to a CJR beneficiary.* Beneficiary engagement incentives involving technology are subject to the following additional conditions:

(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 (c) 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 CJR participant; 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.

(c) *Clinical goals of the CJR model.* The following are the 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 LEJR procedure.

(d) *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 established contemporaneously 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 documentation regarding items of technology exceeding $100 in retail value must also include contemporaneous documentation of any attempt to retrieve technology at the end of a CJR episode as described in paragraph (b)(3) of this section.

(4) The CJR participant hospital must retain and provide access to the required documentation in accordance with § 510.110.

■ 17. Section 510.610 is revised to read as follows:

§ 510.610 Waiver of SNF 3-day rule.

(a) *Waiver of the SNF 3-day rule.* For episodes being tested in the CJR model that begin on or after January 1, 2017, CMS waives the SNF 3-day rule for coverage of a SNF stay for a beneficiary who meets the eligibility criteria in 510.205 on the date of discharge from the anchor hospitalization, but only if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the CJR beneficiary's admission to the SNF.

(b) *Financial liability for non-covered SNF services.* (1) If CMS determines that the waiver requirements specified in paragraph (a) of this section were not met, the following apply:

(1) CMS makes no payment to a SNF for SNF services if the SNF admits a CJR beneficiary who has not had a qualifying inpatient stay.

(2) In the event that CMS makes no payment for SNF services furnished by a SNF as a result of paragraph (b)(1) of this section, the beneficiary protections specified in paragraph (b)(3) of this section apply, unless the participant hospital has provided the beneficiary with a discharge planning notice in accordance with 501.405(b)(4).

(3) If the participant hospital does not provide the beneficiary with a discharge planning notice in accordance with § 510.405(b)(4)—

(A) The SNF must not charge the beneficiary for the expenses incurred for such services;

(B) The SNF must return to the beneficiary any monies collected for such services; and

(C) The participant hospital is financially liable for the expenses incurred for such services.

(4) If the participant hospital provided a discharge planning notice to the beneficiary in accordance with § 510.405(b)(4), then normal SNF coverage requirements apply and the beneficiary may be financially liable for noncovered SNF services.

(c) *Other requirements.* All other Medicare rules for coverage and payment of Part A-covered services continue to apply except as otherwise waived in this part.

■ 18. Section 510.620 is amended by revising paragraph (a) to read as follows:

§ 510.620 Waiver of deductible and coinsurance that otherwise apply to reconciliation payments and repayments.

(a) *Waiver of deductible and coinsurance.* CMS waives the requirements of sections 1813 and 1833(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.

* * * * *

■ 19. Part 512 is added to subchapter H to read as follows:

PART 512—EPISODE PAYMENT MODEL

Sec.

Subpart A—General Provisions

512.1 Basis and scope.
512.2 Definitions.

Subpart B—Episode Payment Model Participants

512.100 EPM episodes being tested.
512.105 Geographic areas.
512.110 Access to records and retention.
512.120 EPM participant CEHRT track requirements.

Subpart C—Scope of Episodes

512.200 Time periods for EPM episodes.
512.210 Included and excluded services.
512.230 Beneficiary inclusion criteria.
512.240 Determination of the EPM episode.

Subpart D—Pricing and Payment

512.300 Determination of episode quality-adjusted target prices and actual episode payments.
512.305 Determination of the NPRA and reconciliation process.
512.307 Subsequent calculations.
512.310 Appeals process.
512.315 Composite quality scores for determining reconciliation payment eligibility and effective and applicable discount factors.
512.320 Treatment of incentive programs or add-on payments under existing Medicare payment systems.
512.350 Data sharing.

Subpart E—Quality Measures, Beneficiary Protections, and Compliance Enforcement

512.400 Quality measures and reporting—general.
512.411 Quality measures and reporting for AMI model.
512.412 Quality measures and reporting for CABG model.
512.413 Quality measures and reporting for SHFFT model.
512.450 Beneficiary choice and beneficiary notification.
512.460 Compliance enforcement.

Subpart F—Financial Arrangements and Beneficiary Incentives

512.500 Sharing arrangements under the EPM.
512.505 Distribution arrangements under the EPM.
512.510 Downstream distribution arrangements under the EPM.
512.520 Enforcement authority under the EPM.
512.525 Beneficiary engagement incentives under the EPM.

Subpart G—Waivers

512.600 Waiver of direct supervision requirement for certain post-discharge home visits.
512.605 Waiver of certain telehealth requirements.
512.610 Waiver of SNF 3-day rule.
512.615 Waiver of certain post-operative billing restrictions.
512.620 Waiver of deductible and coinsurance that otherwise apply to reconciliation payments or repayments.
512.630 Waiver of physician definition for furnishing cardiac rehabilitation and intensive cardiac rehabilitation services to an EPM beneficiary.

Subpart H—CR Incentive Payment Model for EPM and Medicare Fee-for-Service Participants

512.700 Basis and scope.
512.703 CR incentive payment model participants.
512.705 CR/ICR services that count towards CR incentive payments.
512.710 Determination of CR incentive payments.

Provisions for FFS–CR Participants

512.715 Access to records and retention for FFS–CR participants.
512.720 Appeals process for FFS–CR participants.
512.725 Data sharing for FFS–CR participants.
512.730 Compliance enforcement for FFS–CR participants.
512.735 Enforcement authority for FFS–CR participants.
512.740 Beneficiary engagement incentives for FFS–CR participant use.
512.745 Waiver of physician definition for furnishing CR and ICR services to a FFS–CR beneficiary.

Subparts I–J [Reserved]

Subpart K—Model Termination

512.900 Termination of an episode payment model.
512.905 Termination of the CR Incentive Payment Model.

Authority: Secs. 1102, 1115A, and 1871 of the Social Security Act (42 U.S.C. 1302, 1315(a), and 1395hh).

Subpart A—General Provisions

§ 512.1 Basis and scope.

(a) *Basis.* This part implements the test of episode payment models 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 each episode payment model.

(2) The episodes being tested in each episode payment model.

(3) The methodology for pricing and payment under each episode payment model.

(4) Quality performance standards and quality reporting requirements.

(5) Safeguards to ensure preservation of beneficiary choice and beneficiary notification.

§ 512.2 Definitions.

For the purposes of this part, the following definitions are applicable unless otherwise stated:

ACO means an accountable care organization, as defined at § 425.20 of this chapter, that participates in the Shared Savings Program.

ACO participant has the meaning set forth in § 425.20 of this chapter.

ACO provider/supplier has the meaning set forth in § 425.20 of this chapter.

Actual episode payment means the sum of Medicare claims payments for items and services that are included in the episode in accordance with § 512.210(a), excluding the items and services described in § 512.210(b).

Alignment payment means a payment from an EPM collaborator to an EPM participant under a sharing arrangement, for the sole purpose of sharing the EPM participant's responsibility for making repayments to Medicare.

AMI means acute myocardial infarction, an event caused by diminished blood supply to the heart leading to irreversible heart muscle cell damage or death.

AMI care period means a period of AMI care that would meet the requirements to be an AMI model episode in accordance with all provisions in subpart B if the FFS–CR participant were an AMI model participant.

AMI model means the EPM for AMI.

AMI model participant means an EPM participant that is an IPPS hospital (other than those hospitals specifically excepted under § 512.100(b)) with a CCN primary address in one of the geographic areas selected for participation in the AMI model in accordance with § 512.105(b), as of the date of selection or any time thereafter during any performance year.

Anchor hospitalization means a hospitalization that initiates an EPM episode and has no subsequent inpatient-to-inpatient transfer chained anchor hospitalization.

Anchor hospitalization portion means the part of an EPM episode that occurs during the anchor or chained anchor hospitalization.

Anchor MS–DRG means the MS–DRG assigned to the first hospitalization discharge, which initiates an EPM episode.

Applicable discount factor means the discount percentage established by the EPM participant's quality category as determined in § 512.315, that is applied to the episode benchmark price for purposes of determining an EPM participant's Medicare repayment in performance years 2 (DR) and 3.

BPCI stands for the Bundled Payment for Care Improvement initiative.

CABG means coronary artery bypass graft, a surgical procedure that diverts the flow of blood around a section of a blocked or partially blocked artery in the heart, creating a new pathway that improves blood flow to heart muscle.

CABG care period means a period of CABG care that would meet the requirements to be a CABG model episode in accordance with all provisions in subpart B if the FFS–CR participant were a CABG model participant.

CABG model means the EPM for CABG.

CABG model participant means an EPM participant that is an IPPS hospital (other than those hospitals specifically excepted under § 512.100(b)) with a CCN primary address in one of the geographic areas selected for participation in the CABG model in accordance with § 512.105(b), as of the date of selection or any time thereafter during any performance year.

CAH means a critical access hospital designated under subpart F of part 485 of this chapter.

CCN stands for CMS certification number.

CEC stands for Comprehensive ESRD Care Initiative.

CEHRT means certified electronic health record technology that meet the requirements of 45 CFR 170.102.

Chained anchor hospitalization means an anchor hospitalization that initiates an AMI model episode and has at least one subsequent inpatient-to-inpatient transfer.

Collaboration agent means an individual or entity that is not an EPM collaborator and that is either of the following:

(1) A PGP member that has entered into a distribution arrangement with the same PGP in which he or she is an owner or employee.

(2) An ACO participant or ACO provider/supplier that has entered into a distribution arrangement with the same ACO in which it is participating.

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.

CR means cardiac rehabilitation as defined in § 410.49(a) of this chapter, a physician-supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, psychosocial assessment, and outcomes assessment.

CR amount means the dollar amount determined by the number of CR/ICR services paid by Medicare to any provider or supplier for a beneficiary in an AMI or CABG model episode or AMI care period or CABG care period.

CR incentive payment means a payment made by CMS to an EPM–CR participant or FFS–CR participant for CR/ICR service use that is the sum of the CR amounts as determined in accordance with § 512.710.

CR incentive payment model means the model testing CR incentive payments for CR/ICR service use made in accordance with subpart H.

CR participant means all EPM–CR participants and FFS–CR participants.

CR performance year means one of the years in which the CR incentive payment model is being tested. Performance years for the CR incentive payment model correlate to calendar years with the exception of performance year 1, which is July 1, 2017 through December 31, 2017.

CR service count means the number of CR/ICR services paid by Medicare to any provider or supplier for a beneficiary in an AMI or CABG model episode or AMI care period or CABG care period.

Distribution arrangement means a financial arrangement between an EPM collaborator that is an ACO or PGP and a collaboration agent for the sole purpose of distributing some or all of a gainsharing payment received by the ACO or PGP.

Distribution payment means a payment from an EPM collaborator that is an ACO or PGP to a collaboration agent, under a distribution arrangement, composed only of gainsharing payments.

DME stands for durable medical equipment.

Downstream collaboration agent means an individual who is not an EPM collaborator or a collaboration agent and who is a PGP member that has entered into a downstream distribution arrangement with the same PGP in which he or she is an owner or employee, and where that PGP is a collaboration agent.

Downstream distribution arrangement means a financial arrangement between a collaboration agent that is both a PGP and an ACO participant and a downstream collaboration agent for the sole purpose of distributing some or all of a distribution payment received by the PGP.

Downstream distribution payment means a payment from a collaboration agent that is both a PGP and an ACO participant to a downstream collaboration agent, under a downstream distribution arrangement, composed only of distribution payments.

Effective discount factor means the discount factor established by the EPM participant's quality category as determined in § 512.315, that is applied to the episode benchmark price to calculate the quality-adjusted target price.

Episode attribution means the process of assigning financial responsibility for an EPM episode to an EPM participant.

Episode benchmark price means a dollar amount assigned to EPM episodes based on historical episode data (3 years of historical Medicare payment data grouped into EPM episodes according to the EPM episode definitions as discussed in § 512.300(b)) prior to the application of the effective discount factor, as described in § 512.300(d).

Episode payment model (EPM) means the AMI model, CABG model, SHFFT model, or another model with payment made on an episode basis in accordance with this part. For each section of regulations, a single model applies when reading the entire section.

EPM activities means activities related to promoting accountability for the quality, cost, and overall care for EPM beneficiaries, including managing and coordinating care; encouraging investment in infrastructure, enabling technologies, and redesigned care processes for high quality and efficient service delivery; the provision of items and services during an EPM episode in a manner that reduces costs and improves quality; or carrying out any other obligation or duty under the EPM.

EPM beneficiary means a beneficiary who meets the beneficiary inclusion criteria in § 512.230 and who is in an EPM episode.

EPM collaborator means an ACO or one of the following Medicare-enrolled individuals or entities that enters into a sharing arrangement:

(1) SNF.
(2) HHA.
(3) LTCH.
(4) IRF.
(5) Physician.
(6) Nonphysician practitioner.
(7) Provider or supplier of outpatient therapy services.
(8) PGP.
(9) Hospital.
(10) CAH.

EPM composite quality score means a score computed for each EPM participant's level of quality performance and improvement and successful reporting of voluntary data, if applicable, on specified EPM quality measures as described in § 512.315.

EPM–CR participant means an AMI or CABG model participant that is eligible to receive CR incentive payments from CMS in accordance with § 512.710.

EPM episode of care (or Episode) means all Medicare Part A and Part B items and services described in § 512.210(a) (and excluding the items and services described in § 512.210(b)) that are furnished to an EPM beneficiary described in § 512.240 that begins with the beneficiary's admission to an anchor hospitalization, with the day of discharge itself from the anchor hospitalization or from the final hospital in a chained anchor hospitalization being counted as the first day of the 90-day post-discharge period.

EPM participant means a Medicare provider or supplier that is eligible to receive payment from CMS on an episode basis for services rendered to EPM beneficiaries.

ESRD stands for end-stage renal disease.

FFS–CR beneficiary means a beneficiary attributed to an FFS–CR participant and receiving care during an AMI care period or CABG care period.

FFS–CR participant means a hospital that is not an EPM participant and that is eligible to receive CR incentive payments from CMS in accordance with § 512.710.

Gainsharing payment means a payment from an EPM participant to an EPM collaborator, under a sharing arrangement, composed of only reconciliation payments or internal cost savings or both.

HCAHPS stands for Hospital Consumer Assessment of Healthcare Providers and Systems.

HCPCS stands for CMS Common Procedure Coding System.

Health Insurance Claim Number (HICN) means the unique number assigned by the Social Security Administration to an individual for the purpose of identifying that individual as a Medicare beneficiary.

HHA means a Medicare-enrolled home health agency.

Historical episode payment means the expenditures for episodes that occurred during the historical period used to determine the EPM episode benchmark price.

Hospital means a provider subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

ICD–CM stands for International Classification of Diseases, Clinical Modification.

ICR means intensive cardiac rehabilitation as defined in § 410.49(a) of this chapter, a physician-supervised program that furnishes cardiac rehabilitation and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in § 410.49(c) of this chapter.

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 EPM participant resulting from care redesign undertaken by such participant in connection with providing items and services to beneficiaries within specific EPM episodes. Internal cost savings does not include savings realized by any individual or entity that is not the EPM participant.

Intracardiac procedures means procedures performed within the heart chambers, rather than within coronary artery blood vessels, through percutaneous access to blood vessels. These procedures are indicated for the treatment of congenital cardiac malformations, cardiac valve disease, and cardiac arrhythmias.

IPF stands for inpatient psychiatric facility.

IRF stands for inpatient rehabilitation facility.

LTCH stands for long-term care hospital.

MDH means a Medicare-dependent, small rural 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 a PGP and who has reassigned to the PGP his or her right to receive Medicare payment.

MSA stands for metropolitan statistical area and means a CBSA associated with at least one urbanized area that has a population of at least 50,000.

MS–DRG stands for Medicare severity diagnosis-related group, which is the classification of inpatient hospital discharges updated in accordance with § 412.10 of this chapter.

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) of this chapter).

(5) A clinical social worker (as defined at § 410.73(a) of this chapter).

(6) A registered dietician or nutrition professional (as defined at § 410.134 of this chapter).

NPI stands for National Provider Identifier.

NPRA means the net payment reconciliation amount determined in accordance with § 512.305(c).

OIG stands for the Department of Health and Human Services Office of Inspector General.

PAC stands for post-acute care.

PBPM stands for per-beneficiary-per-month.

PCI means percutaneous coronary intervention, a procedure used to open blocked arteries in the heart through percutaneous placement of a small wire mesh tube that keeps the artery open

and minimizes the risk of it later narrowing.

Performance year means one of the years in which the EPM is being tested. Performance years for the EPMs correlate to calendar years with the exception of performance year 1, which is July 1, 2017 through December 31, 2017.

Performance year 2 (DR) means the second, third, and fourth quarters of performance year 2, which is from April 1, 2018 to December 31, 2018, and during which an EPM participant assumes downside risk and would have Medicare repayment responsibility under the models.

Performance year 2 (NDR) means the first quarter of performance year 2, which is from January 1, 2018 to March 31, 2018, and during which an EPM participant assumes no downside risk and therefore would have no Medicare repayment responsibility under the models.

PFS means the Medicare Physician Fee Schedule authorized under section 1848 of the Social Security Act.

PGP stands for physician group practice.

Physician has the meaning set forth in section 1861(r) of the Act.

Post-anchor hospitalization portion means the part of an episode that occurs after the anchor or chained anchor hospitalization.

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 EPM episode.

Price MS–DRG means the MS–DRG that applies when establishing the EPM benchmark episode price that applies to an EPM episode. For episodes without a chained anchor hospitalization, the price MS–DRG is the anchor MS–DRG. For episodes with a chained anchor admission, the price MS–DRG is assigned based on § 512.300(c)(7).

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-adjusted target price means the dollar amount assigned to EPM episodes as the result of reducing the episode benchmark price by the EPM participant's effective discount factor based on the EPM participant's quality category, as described in § 512.315(b)(5), (c)(5) or (d)(5).

Quality improvement points are points that CMS adds to an EPM participant's EPM composite quality score for a measure if the EPM participant's performance improves from the previous performance year according to the relevant EPM measure improvement methodology.

Quality performance points are points that CMS adds to an EPM participant's EPM composite quality score for a measure based on the performance percentile scale and for successful submission of voluntary data if applicable to the EPM.

Reconciliation payment means a payment made by CMS to an EPM participant as determined in accordance with § 512.305(d).

Repayment amount means the amount owed by an EPM participant to CMS, as reflected on a reconciliation report.

RRC means a rural referral center that satisfies the criteria set forth in § 412.96 of this chapter.

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.

SCH means a sole community hospital that meets the classification criteria specified in § 412.92 of this chapter.

Sharing arrangement means a financial arrangement between an EPM participant and an EPM collaborator for the sole purpose of making gainsharing payments or alignment payments under the EPM.

SHFFT stands for surgical hip/femur fracture treatment and means surgical treatment for hip and femur fractures, other than hip replacements, consisting primarily of hip fixation procedures, with or without reduction of the fracture, as well as open and closed surgical approaches.

SHFFT model means the EPM for SHFFT.

SHFFT model participant means an EPM participant that is an IPPS hospital (other than those hospitals specifically excepted under § 512.100(b)) with a CCN primary address in one of the geographic areas selected for participation in a SHFFT model in accordance with § 512.105(a), as of the date of selection or any time thereafter during any performance year.

SNF stands for skilled nursing facility.

THA/TKA stands for total hip arthroplasty/total knee arthroplasty.

Therapist means one of the following as defined at § 484.4 of this chapter:

(1) Physical therapist.

(2) Occupational therapist.

(3) Speech-language pathologist.

TIN stands for taxpayer identification number.

Two-sided risk arrangement means an arrangement in which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, and is also liable for sharing losses incurred under the program or model, if it meets the criteria under which sharing losses occurs.

Subpart B—Episode Payment Model Participants

§ 512.100 EPM episodes being tested.

(a) *Initiation of an episode.* An episode is initiated when an EPM participant admits a Medicare beneficiary described in § 512.230 for an anchor hospitalization.

(b) *Hospital exclusions.* (1) A hospital is excluded from participating in EPMs for EPM anchor MS–DRGs that are included in BPCI episodes in which the hospital currently participates.

(2) These exclusions cease to apply as of the date that the hospital no longer meets the conditions specified in this paragraph (b) or September 30, 2018, whichever date is sooner.

(c) *Types of EPM episodes.* An EPM episode is initiated by a beneficiary's admission to an EPM participant for an anchor hospitalization that is paid under an EPM anchor MS–DRG and, in the case of the AMI model, with an AMI ICD–10–CM diagnosis code if the admission is under a PCI MS–DRG. The EPM anchor MS–DRGs and ICD–10–CM diagnosis codes for the EPM episodes are as follows:

(1) *Acute myocardial infarction (AMI).* (i) Discharge under an AMI MS–DRG (MS–DRGs 280 to 282); or

(ii) Discharge under a PCI MS–DRG (MS–DRGs 246 to 251) with an ICD–10–CM diagnosis code of AMI on the claim for the anchor hospitalization in the principal or secondary diagnosis code position.

(2) *Coronary artery bypass graft (CABG).* Discharge under a CABG MS–DRG (MS–DRGs 231 to 236).

(3) *Surgical hip/femur fracture treatment (SHFFT).* Discharge under a SHFFT MS–DRG (MS–DRG 480 to 482).

(d) *Identifying AMI historical episodes and EPM episodes with AMI ICD–CM diagnosis codes.* CMS develops a list of AMI ICD–9–CM and ICD–10–CM

diagnosis codes that identify the initiation of historical episodes or initiate AMI model episodes when reported in the principal or secondary diagnosis code position on the inpatient hospital claim for a historical hospitalization or the anchor hospitalization discharged under PCI MS–DRGs (MS–DRGs 246 to 251). The list of ICD–9–CM and ICD–10–CM diagnosis codes representing AMI is posted on the CMS Web site.

(1) On an annual basis, or more frequently as needed, CMS updates the list of ICD–10–CM diagnosis codes representing AMI to reflect coding changes or other issues brought to CMS's attention.

(2) CMS applies the following standard when revising the list of ICD–10–CM diagnosis codes representing AMI: The ICD–10–CM diagnosis code is sufficiently specific that it represents an AMI.

(3) CMS posts the following to the CMS Web site:

(i) Potential AMI ICD–10–CM diagnosis codes for public comment; and

(ii) A final AMI ICD–10–CM diagnosis code list after consideration of public comment.

(4) CMS excludes AMI historical episodes with PCI MS–DRGs and inpatient claims that contain intracardiac ICD–9–CM procedure codes. CMS excludes historical AMI model episodes discharged under PCI MS–DRGs with an AMI ICD–9–CM diagnosis code in the principal or secondary diagnosis code position on the inpatient hospital claim from the AMI historical episodes that set episode benchmark prices if there is an intracardiac ICD–9–CM procedure code in any procedure code field on the inpatient hospital claim. The intracardiac ICD–9–CM procedure codes are as follows:

(i) 35.52 (Repair of atrial septal defect with prosthesis, closed technique).

(ii) 35.96 (Percutaneous balloon valvuloplasty).

(iii) 35.97 (Percutaneous mitral valve repair with implant).

(iv) 37.26 (Catheter based invasive electrophysiologic testing).

(v) 37.27 (Cardiac mapping).

(vi) 37.34 (Excision or destruction of other lesion or tissue of heart, endovascular approach).

(vii) 37.36 (Excision, destruction, or exclusion of left atrial appendage).

(viii) 37.90 (Insertion of left atrial appendage device).

§ 512.105 Geographic areas.

(a) The SHFFT model shall be implemented in the same geographic areas as the CJR model as described under 42 CFR part 510.105.

(b) The geographic areas for inclusion in the CABG and AMI models will be obtained using a random sampling of certain MSAs in the United States. All counties within each of the selected MSAs are selected for inclusion in the AMI and CABG models. CMS excludes MSAs that met the following criteria between January 1, 2014 and December 31, 2014 from the possibility of being selected geographic areas. MSAs are excluded if they:

(1) Had fewer than 75 AMI episodes;

(2) Had fewer than 75 AMI episodes that were not attributable to BPCI Model 2 or 4 AMI, CABG or PCI episodes; or

(3) Had more than 50 percent of otherwise qualifying (BPCI or non BPCI) episodes attributable to a BPCI Model 2 or 4 AMI, CABG or PCI episodes.

(c) In all geographic areas where the AMI, CABG, or SHFFT models are being implemented, the accountable financial entity shall be an acute care IPPS hospital.

§ 512.110 Access to records and retention.

EPM participants, EPM collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities performing EPM activities must:

(a) Allow the Government, including CMS, OIG, HHS 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 of care criteria, billings, lists of EPM collaborators, sharing arrangements, distribution arrangements, downstream distribution arrangements, and the documentation required under §§ 512.500(d) and 512.525(d)) sufficient to enable the audit, evaluation, inspection, or investigation of the following:

(1) The individual's or entity's compliance with EPM requirements and, if applicable, the individual's or entity's compliance with CR incentive payment model requirements.

(2) The calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments.

(3) The obligation to repay any reconciliation payments or CR incentive payments, if applicable, owed to CMS.

(4) The quality of the services furnished to an EPM beneficiary during an EPM episode.

(5) The sufficiency of EPM beneficiary notifications.

(6) The accuracy of the EPM participant's submissions under CEHRT use requirements.

(b) Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the EPM participant's participation in the EPM or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(1) CMS determines a particular record or group of records should be retained for a longer period and notifies the EPM participant at least 30 calendar days before the disposition date; or

(2) There has been a dispute or allegation of fraud or similar fault against the EPM participant, EPM collaborator, collaboration agent, downstream collaboration agent, or any other individual or entity performing EPM activities in which case the records must be maintained for 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

§ 512.120 EPM participant CEHRT track requirements.

(a) *EPM CEHRT use.* For performance year 2 (DR) and performance years 3–5, EPM participants choose either of the following:

(1) *CEHRT use.* EPM participants attest in a form and manner required by CMS to their use of CEHRT as defined in section 414.1305 to document and communicate clinical care with patients and other health professionals.

(2) *No CEHRT use.* EPM participants do not attest in a form and manner required by CMS to their use of CEHRT as defined in § 414.1305 to document and communicate clinical care with patients and other health professionals.

(b) *Clinician financial arrangements list.* Each EPM participant that chooses CEHRT use as provided in paragraph (a)(1) of this section must submit to CMS a clinician financial arrangements list in a form and manner specified by CMS on a no more than quarterly basis. The list must include the following information on individuals for the period of the EPM performance year specified by CMS:

(1) *EPM collaborators.* For each EPM collaborator who is a physician, nonphysician practitioner, or provider of outpatient therapy services during the period of the EPM performance year specified by CMS:

(i) The name, TIN, and NPI of the EPM collaborator.

(ii) The start date and, if applicable, end date, for the sharing arrangement between the EPM participant and the EPM collaborator.

(2) *Collaboration agents.* For each collaboration agent who is a physician or nonphysician practitioner of a PGP that is an EPM collaborator during the period of the EPM performance year specified by CMS:

(i) The TIN of the PGP that is the EPM collaborator, and the name and NPI of the physician or nonphysician practitioner.

(ii) The start date and, if applicable, end date, for the distribution arrangement between the EPM collaborator that is a PGP and the physician or nonphysician practitioner who is a PGP member.

(3) *Downstream collaboration agents.* For each downstream collaboration agent who is a physician or nonphysician practitioner member of a PGP that is also an ACO participant in an ACO that is an EPM collaborator during the period of the EPM performance year specified by CMS:

(i) The TIN of the PGP that is the ACO participant, and the name and NPI of the physician or nonphysician practitioner.

(ii) The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent that is both PGP and an ACO participant and the physician or nonphysician practitioner who is a PGP member.

(4) *Attestation to no individuals.* If there are no individuals that meet the requirements to be reported, as specified in paragraphs (b)(1) through (3) of this section, the EPM participant must attest in a form and manner required by CMS that there are no individuals to report on the clinician financial arrangements list.

(c) *Documentation requirements.* (1) Each EPM participant that chooses CEHRT use as provided in paragraph (a)(1) of this section must maintain documentation of their attestation to CEHRT use and clinician financial arrangements lists.

(2) The EPM participant must retain and provide access to the required documentation in accordance with § 512.110.

Subpart C—Scope of Episodes

§ 512.200 Time periods for EPM episodes.

All AMI, CABG, and SHFFT episodes begin on or after July 1, 2017 and end on or before December 31, 2021.

§ 512.210 Included and excluded services.

(a) *Included services for an EPM.* All Medicare Parts A and B items and services are included in the EPM episode, except as specified in paragraph (b) of this section. These services include, but are not limited to, the following:

(1) Physicians' services.

(2) Inpatient hospital services.

(3) IPF services.

(4) LTCH services.

(5) IRF services.

(6) SNF services.

(7) HHA services.

(8) Hospital outpatient services.

(9) Independent outpatient therapy services.

(10) Clinical laboratory services.

(11) DME.

(12) Part B drugs and biologicals.

(13) Hospice.

(14) PBPM payments under models tested under section 1115A of the Act.

(b) *Excluded services.* The following items, services, and payments are excluded from the EPM episode:

(1) Hemophilia clotting factors provided in accordance with § 412.115 of this chapter.

(2) New technology add-on payments for medical devices 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 MS–DRG that initiates the EPM episode, or price anchor MS–DRG as applicable, 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 unrelated to a condition likely to have been affected by care during the EPM episode, such as prostatectomy.

(D) Acute disease surgical unrelated to a condition resulting from or likely to have been affected by care during the EPM episode, such as appendectomy.

(ii) Medicare Part B services, as identified by the principal ICD–CM diagnosis code on the claim that groups to the following categories of diagnoses:

(A) Acute disease diagnoses unrelated to a condition resulting from or likely to have been affected care during the EPM episode, 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 care during the EPM episode or whether substantial services were likely to be provided for the chronic condition during the EPM episode.

(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 for an EPM, as described in paragraph (b)(4) of this section.

(iv) All PBPM model payments funded from CMS' Innovation Center appropriation.

(c) *Updating the lists of excluded services for EPMs.* (1) The EPM lists that are based on anchor MS–DRG, or price MS–DRG, as applicable, of excluded MS–DRGs, ICD–9–CM and ICD–10–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 EPM lists of excluded services to reflect annual coding changes or other issues brought to CMS' attention.

(3) CMS applies the following standards when revising the EPM lists of excluded services for reasons other than to reflect annual coding changes:

(i) Items or services that are directly related to the EPM episode or the quality or safety of the EPM episode care would be included in the EPM episode.

(ii) Items or services for chronic conditions that may be affected by the EPM episode care would be related and included in the EPM episode.

(iii) Items and services for chronic conditions that are generally not affected by the EPM episode care would be excluded from the EPM episode.

(iv) Items and services for acute clinical conditions not arising from existing, EPM episode-related chronic clinical conditions or complications of EPM episode care would be excluded from the EPM episode.

(v) PBPM payments under CMS models determined to be primarily used for care coordination or care management services for clinical conditions in EPM excluded categories of diagnoses, as described in paragraph (b)(4)(iii) of this section would be excluded from the EPM episode.

(4) CMS posts the following on the CMS Web site:

(i) Potential revisions to the EPM exclusion lists to allow for public comment; and

(ii) Updated EPM exclusion lists after consideration of public comment.

§ 512.230 Beneficiary inclusion criteria.

EPM episode care is furnished to beneficiaries who meet all of the following criteria upon admission to the anchor hospitalization:

(a) Enrolled in Medicare Part A and Part B.

(b) Eligibility for Medicare is not based on end-stage renal disease, as described in § 406.13 of this chapter.

(c) Not enrolled in any managed care plan (for example, Medicare Advantage, health care prepayment plans, or cost-based health maintenance organizations).

(d) Not covered under a United Mine Workers of America health care plan.

(e) Have Medicare as their primary payer pursuant to the requirements in 42 CFR 411.20, *et seq.*

(f) Not aligned to an ACO in the Next Generation ACO model or an ACO in a track of the Comprehensive ESRD Care Initiative incorporating downside risk for financial losses.

(g) Not under the care of an attending or operating physician, as designated on the inpatient hospital claim, who is a member of a physician group practice that initiates BPCI Model 2 episodes at the EPM participant for the MS–DRG that would be the anchor MS–DRG under the EPM.

(h) Not already in any BPCI model episode.

(i) Not already in an AMI; SHFFT; CABG; or CJR model episode with an episode definition that does not exclude the MS–DRG that would be the anchor MS–DRG under the EPM.

§ 512.240 Determination of the EPM episode.

(a) *AMI Model*—(1) *General.* The AMI model episode begins with the admission of a Medicare beneficiary as described in § 512.230 to an AMI model participant for an anchor hospitalization.

(i) If there is no chained anchor hospitalization, then the AMI model episode 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.

(ii) If there is a chained anchor hospitalization, then the AMI model episode ends on the 90th day after the date of discharge from the final hospitalization in the chained anchor hospitalization, with the day of discharge itself being counted as the first day in the 90-day post-discharge period.

(2) *AMI model episode attribution in chained anchor hospitalizations.* AMI model episodes that include a chained anchor hospitalization are attributed to the AMI model participant that initiated the AMI model episode. The methodology for assigning the price MS–DRG in these circumstances is specified in § 512.300(c)(7).

(3) *Cancellation of an AMI model episode.* The AMI model episode is canceled and is not included in the determination of NPRA as specified in § 512.305 if the beneficiary does any of the following during the episode:

(i) Ceases to meet any criterion listed in § 512.230(a) through (f).

(ii) Dies during the anchor hospitalization.

(iii) Is discharged from the final hospital in a chained anchor hospitalization under an MS–DRG that is not an AMI MS–DRG (MS–DRGs 280 to 282), PCI MS–DRG (MS–DRGs 246 to 251), or CABG MS–DRG (MS–DRGs 231 to 236), regardless of whether the final transfer hospital is an AMI or CABG model participant.

(iv) Initiates any BPCI model episode.

(b) *CABG Model*—(1) *General.* The CABG model episode begins with the admission of a Medicare beneficiary as described in § 512.230 to a CABG model participant 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.

(2) *Cancellation of a CABG model episode.* The CABG model episode is canceled and is not included in the determination of NPRA as specified in § 512.305 if the beneficiary does any of the following during the episode:

(i) Ceases to meet any criterion listed in § 512.230(a) through (f).

(ii) Dies during the anchor hospitalization.

(iii) Initiates any BPCI model episode.

(c) *SHFFT Model*—(1) *General.* The SHFFT model episode begins with the admission of a Medicare beneficiary as described in § 512.230 to a SHFFT model participant 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.

(2) *Cancellation of a SHFFT model episode.* The SHFFT model episode is canceled and is not included in the determination of NPRA as specified in § 512.305 if the beneficiary does any of the following during the episode:

(i) Ceases to meet any criterion listed in § 512.230 (a) through (f).

(ii) Dies during the anchor hospitalization.

(iii) Initiates any BPCI model episode.

Subpart D—Pricing and Payment

§ 512.300 Determination of episode quality-adjusted target prices and actual episode payments.

(a) *General.* CMS establishes episode quality-adjusted target prices and calculates actual episode payments for EPM participants for each performance year of the EPMs as specified in this section.

(b) *Calculating episode quality-adjusted target prices.* Episode quality-adjusted target prices and actual episode payments are calculated for episodes according to the following:

(1) For episodes involving AMI, MS–DRGs

(i) 280 (Acute myocardial infarction, discharged alive with MCC)

(ii) 281 (Acute myocardial infarction, discharged alive with CC)

(iii) 282 (Acute myocardial infarction, discharged alive without CC/MCC)

(iv) 246 (Perc cardiovasc proc with drug-eluting stent with MCC or 4+ vessels/stents)

(v) 247 (Perc cardiovasc proc with drug-eluting stent without MCC)

(vi) 248 (Perc cardiovasc proc with non-drug-eluting stent with MCC or 4+ vessels/stents)

(vii) 249 (Perc cardiovasc proc with non-drug-eluting stent without MCC)

(viii) 250 (Perc cardiovasc proc without coronary artery stent with MCC)

(ix) 251 (Perc cardiovasc proc without coronary artery stent without MCC).

(2) For episodes involving CABG, MS–DRGs

(i) 231 (Coronary bypass with PTCA with MCC)

(ii) 232 (Coronary bypass with PTCA without MCC)

(iii) 233 (Coronary bypass with cardiac cath with MCC)

(iv) 234 (Coronary bypass with cardiac cath without MCC)

(v) 235 (Coronary bypass without cardiac cath with MCC)

(vi) 236 (Coronary bypass without cardiac cath without MCC)

(3) For episodes involving SHFFT, MS–DRGs

(i) 480 (Hip and femur procedures except major joint with MCC)

(ii) 481 (Hip and femur procedures except major joint with CC)

(iii) 482 (Hip and femur procedures except major joint without CC or MCC)

(c) *Calculating quality-adjusted target prices.* CMS calculates quality adjusted target prices as specified in § 512.300(c)(1) through (13).

(1) *Calculation of the historical expenditures.* CMS calculates historical expenditure calculations based on the following calendar years:

(i) Episodes beginning in 2013 through 2015 for performance years 1 and 2.

(ii) Episodes beginning in 2015 through 2017 for performance years 3 and 4.

(iii) Episodes beginning in 2017 through 2019 for performance year 5.

(2) *Calculation of the quality-adjusted target prices.* CMS calculates quality-adjusted target prices based on a blend of each EPM-participant hospital-

specific and regional historical episode expenditures.

(i) The region corresponds to the U.S. Census Division associated with the primary address of the CCN of the EPM participant and the regional component is based on episodes occurring at all acute care hospitals in said region, except as follows.

(ii) In cases where an MSA selected for participation in an EPM spans more than one U.S. Census Division, the entire MSA is grouped into the U.S. Census Division where the largest city by population in the MSA is located for quality-adjusted target price and episode payment calculations.

(3) *Calculation of the quality-adjusted target price blend.* The quality-adjusted target price blend consists of the following:

(i) Two-thirds of the EPM participant'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 EPM participant'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.

(4) *Exception for low-volume hospitals.* (i) For the SHFFT model, quality-adjusted target prices for participants with fewer than 50 SHFFT model episodes in total across the 3 historical years of data used to calculate the quality-adjusted target price are based on 100 percent regional historical episode payments.

(ii) For the AMI model, quality-adjusted target prices for price MS–DRGs 280–282 for participants with fewer than 75 AMI model episodes with price MS–DRGs 280–282 in total across the 3 historical years of data used to calculate the quality-adjusted target price are based on 100 percent regional historical episode payments.

(iii) For the AMI model, quality-adjusted target prices for price MS–DRGs 246–251 for participants with fewer than 125 AMI model episodes with price MS–DRGs 246–251 in total across the 3 historical years of data used to calculate the quality-adjusted target price are based on 100 percent regional historical episode payments.

(iv) For the CABG model, quality-adjusted target prices for participants with fewer than 50 CABG model episodes in total across the 3 historical years of data used to calculate the quality-adjusted target price are based on 100 percent regional historical episode payments.

(5) *Exception for recently merged or split hospitals.* EPM-participant hospital-specific historical episode payments for EPM participants 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).

(6) *Episodes that straddle performance years or payment updates.* Where an episode straddles performance years or payment updates, the quality-adjusted target price is based on the quality-adjusted target price for the type of episode as of the date of admission for the anchor hospitalization.

(7) *Adjustments for certain hospitalizations under the AMI and CABG models*—(i) *Adjustments for chained anchor hospitalizations that initiate AMI model episodes with any of AMI MS–DRGs 280–282 or PCI MS–DRGs 246–251.* The episode benchmark price for a chained anchor hospitalization is assigned based on the price MS–DRG designated in accordance with a hierarchy as follows:

(A) If the chained anchor hospitalization does not include CABG MS–DRGs 231–236 within the chain, the price MS–DRG is the AMI or PCI MS–DRG with the highest IPPS weight, subject to possible adjustment for readmission to a CABG MS–DRG as specified in paragraph (c)(7)(iii) of this section.

(B) If the chained anchor hospitalization includes any of CABG MS–DRGs 231–236, the price MS–DRG is the CABG MS–DRG with the highest IPPS weight with the episode benchmark price determined in accordance with paragraph (c)(7)(ii) of this section.

(C) If the final discharge for a chained anchor hospitalization includes an MS–DRG other than AMI MS–DRG 280–282, PCI MS–DRG 246–251, or CABG MS–DRG 231–236, the episode is canceled for purposes of the AMI model and services furnished prior to and following the episode cancellation would continue to be paid by Medicare as usual.

(ii) *Adjustments for CABG model episodes with price MS–DRGs 231–236.* The episode benchmark price for an episode with CABG price MS–DRG 231–236 is set based on the sum of expenditures during the anchor hospitalization portion and post-anchor hospitalization portion of the episode as follows:

(A) The anchor hospitalization portion of the episode benchmark price is set based on the CABG price MS–DRG at discharge.

(B) The post-anchor hospitalization portion of the episode benchmark price is set separately for episodes:

(1) With AMI ICD–CM diagnosis code on the anchor inpatient claim and CABG price MS–DRG with major complication or comorbidity (231, 233, or 235).

(2) With AMI ICD–CM diagnosis code on the anchor inpatient claim and CABG price MS–DRG without major complication or comorbidity (232, 234, or 236).

(3) Without AMI ICD–CM diagnosis code on the anchor inpatient claim and CABG price MS–DRG with major complication or comorbidity (231, 233, or 235).

(4) Without AMI ICD–CM diagnosis code on the anchor inpatient claim and CABG price MS–DRG without major complication or comorbidity (232, 234, or 236).

(iii) *Adjustments for Certain AMI Model Episodes with CABG Readmissions.* The episode benchmark price for an AMI model episode with AMI price MS–DRG 280–282 or PCI price MS–DRG 246–251 with a readmission to any of CABG price MS–DRGs 231–236 is the sum of the anchor hospitalization portion of the CABG episode benchmark price corresponding to the MS–DRG of the CABG readmission and the episode benchmark price for the corresponding price MS–DRG that would be applied to the episode if it did not include a CABG readmission.

(8) *Inclusion of reconciliation payments and Medicare repayments.* CMS will include certain reconciliation payments and Medicare repayments when updating quality adjusted target prices.

(i) *Inclusion of reconciliation payments and Medicare repayments in BPCI initiative.* Reconciliation payments and Medicare repayments under § 512.305(d)(2) and (3) and those from episodes in the BPCI initiative are included when updating quality-adjusted target prices for performance years 3–5, subject to the adjustment for CABG model episodes in paragraph (c)(8)(ii) of this section.

(ii) *Inclusion of reconciliation payments and Medicare repayments in CABG model episodes.* When updating prices for CABG episodes, Reconciliation payments and Medicare repayments under § 512.305(d)(2) and § 512.305(d)(3) and from episodes included in the BPCI initiative will be apportioned proportionally to the anchor hospitalization and post-anchor hospitalization portions of historical

CABG episodes. The proportions will be based on based on regional average historical episode payments that occurred during the anchor hospitalization portion of CABG model episodes and regional average historical episode payments that occurred during the post-anchor anchor hospitalization portion of CABG model episodes that were initiated during the three historical years.

(9) *Communication of quality-adjusted target prices.* CMS communicates quality-adjusted target prices to EPM participants prior to the beginning of the performance period in which they apply.

(10) *Applicable time period for updating quality-adjusted target prices.* In general quality-adjusted target prices are updated to account for Medicare payment updates no less than 2 times per year, for updated quality-adjusted target prices effective October 1 and January 1, and at other intervals if necessary as determined by CMS.

(i) For CABG model episodes, quality-adjusted target prices are updated by separately updating the anchor hospitalization portion of the episode benchmark price and the post-anchor hospitalization portion of the episode benchmark price and then applying the effective discount factor.

(ii) [Reserved].

(11) *Trending of historical expenditure data.* CMS trends historical expenditure data by applying separate national trend factors to episode payments in the scenarios described below. A trend factor is calculated for each of the first two years in the historical period based on the ratio of national average episode payments in the third year of the historical period to national average episode payments in each of the first 2 years in the historical period, for the following scenarios:

(i) Separately for each SHFFT price MS–DRG 480–482.

(ii) Separately for each AMI price MS–DRG 280–282 and PCI price MS–DRG 246–251 for AMI model episodes without CABG readmissions.

(iii) For CABG model episodes, separately for the anchor hospitalization portion and post-anchor hospitalization portion as follows:

(A) For the anchor hospitalization portion of CABG model episodes, separately for each CABG price MS–DRG 231–236.

(B) For the post-anchor hospitalization portion of CABG model episodes, separately for episodes:

(1) With AMI ICD–CM diagnosis code on the anchor inpatient claim and CABG price MS–DRG with major complication or comorbidity (231, 233, or 235).

(2) With AMI ICD–CM diagnosis code on the anchor inpatient claim and CABG price MS–DRG without major complication or comorbidity (232, 234, or 236).

(3) Without AMI ICD–CM diagnosis code on the anchor inpatient claim and CABG price MS–DRG with major complication or comorbidity (231, 233, or 235).

(4) Without AMI ICD–CM diagnosis code on the anchor inpatient claim and CABG price MS–DRG without major complication or comorbidity (232, 234, or 236).

(12) *Normalizing for wage variation.* CMS applies the CMS Price (Payment) Standardization Detailed Methodology to remove wage level differences in calculating EPM-episode benchmark prices and actual EPM-episode payments. CMS reintroduces wage index variations by multiplying the blended and updated historical payments by a wage normalization factor of 0.7 * IPPS wage index + 0.3.

(13) *Combining episodes to set stable benchmark and quality-adjusted target prices.* For purposes of having sufficient episode volume to set stable EPM episode benchmark and quality-adjusted target prices, where applicable, CMS aggregates EPM episodes and portions of EPM episodes across dimensions that include anchor MS–DRGs, the presence of an AMI ICD–CM diagnosis code on the anchor inpatient claim, and the presence of a major complication or comorbidity for anchor CABG MS–DRGs.

(i) For each EPM, CMS combines episodes for anchor MS–DRGs adjusted for severity and hospital-specific and region-specific weights both for EPM participants and IPPS hospitals within each region for the purposes of blending EPM-participant hospital-specific components of the episode benchmark price and region-specific components of the episode benchmark price as follows:

(A) For SHFFT model episodes, CMS combines episodes with price MS–DRGs 480–482.

(B) For AMI model episodes with AMI price MS–DRGs in 280–282 or PCI price MS–DRGs 246–251 and without readmissions for CABG MS–DRGs, episodes with AMI price MS–DRGs 280–282 are grouped separately from episodes with PCI price MS–DRGs 246–251.

(C) For CABG model episodes with CABG price MS–DRGs in 231–236, CMS separately groups the anchor hospitalization portion and the post-anchor hospitalization portion.

(1) For the anchor hospitalization portion of CABG model episodes, the anchor hospitalization portion is grouped by the CABG price MS–DRG.

(2) For the post-anchor hospitalization portion of CABG model episodes, the post-anchor hospitalization portion is grouped by episodes:

(i) With AMI ICD–CM diagnosis code on the anchor inpatient claim and price MS–DRG with major complication or comorbidity (231, 233, or 235).

(ii) With AMI ICD–CM diagnosis code on the anchor inpatient claim and price MS–DRG without major complication or comorbidity (232, 234, or 236).

(iii) Without AMI ICD–CM diagnosis code on the anchor inpatient claim and price MS–DRG with major complication or comorbidity (231, 233, or 235).

(iv) Without AMI ICD–CM diagnosis code on the anchor inpatient claim and price MS–DRG without major complication or comorbidity (232, 234, or 236).

(ii) After blending EPM-participant hospital-specific and regional-specific components of the combined episodes, CMS separates episodes to calculate episode benchmark prices according to the episode price MS–DRG, subject to adjustments described in § 512.300(c)(7).

(d) *Effective discount factor.* An EPM participant's quality-adjusted target prices incorporate an effective discount factor to reflect Medicare's portion of reduced expenditures from the EPM as described in this section.

(1) *Effective discount factor for reconciliation payments.* The effective discount factor for reconciliation payment in all performance years is determined by the EPM participant's quality category as provided in § 512.315(b)(5), (c)(5), and (d)(5).

(2) *Applicable discount factor for repayment amounts.* The applicable discount factor for repayment amounts is—

(i) Not applicable in performance year 1 and performance year 2 (NDR), as the requirement for EPM participant repayment is waived.

(ii) In performance year 2 (DR) and performance year 3 when partial EPM participant repayment applies, as determined by the EPM participant's quality category as provided in § 512.315(b)(5), (c)(5), and (d)(5).

(iii) Not applicable in performance years 4 and 5 when full EPM participant repayment applies, as determined by the effective discount factor that applies to repayment amounts as specified in paragraph (d)(1) of this section.

(e) *Exceptions that apply to both quality-adjusted target prices and actual episode payments*—(1) *Exception for*

high episode payment. For each EPM, actual episode payments and historical episode payments are capped at 2 standard deviations above the mean regional episode payment for the EPM-participant hospital-specific and regional components of the quality-adjusted target price under the applicable model, as well as for calculating actual episode payments under the applicable EPM during a performance year, subject to the exceptions noted in paragraphs (e)(1)(i) through (iv) of this section.

(i) For AMI model episodes with price MS–DRGs 280–282 or PCI price MS–DRGs 246–251 without readmission for CABG MS–DRGs 231–236, payments are capped separately based on the price MS–DRG.

(ii) For CABG model episodes with price CABG MS–DRGs 231–236, episode payments during the anchor hospitalization portion are capped separately from episode payments during the post-anchor hospitalization portion as follows.

(A) Payments during the anchor hospitalization portion are capped based on the CABG price MS–DRG 231–236.

(B) Payments during the post-anchor hospitalization portion are capped separately for episodes:

(1) With an AMI ICD–CM diagnosis code on the anchor inpatient claim and CABG price MS–DRG with major complication or comorbidity (231, 233, or 235).

(2) With an AMI ICD–CM diagnosis code on the anchor inpatient claim and CABG price MS–DRG without major complication or comorbidity (232, 234, or 236).

(3) Without an AMI ICD–CM diagnosis code on the anchor inpatient claim and CABG price MS–DRG with major complication or comorbidity (231, 233, or 235).

(4) Without an AMI ICD–CM diagnosis code on the anchor inpatient claim and CABG price MS–DRG without major complication or comorbidity (232, 234, or 236).

(iii) For AMI model episodes with a CABG price MS–DRG 231–236, payments are capped separately for those payments that occurred during the chained anchor hospitalization and for those payments that occurred after the chained anchor hospitalization.

(A) For the chained anchor hospitalization portion of the episode, the cap is applied based on the anchor hospitalization portion of a CABG episode for the corresponding price MS–DRG.

(B) For the post-anchor hospitalization portion of the episode, the cap is applied based on the post-anchor hospitalization portion of a CABG episode for the corresponding price MS–DRG with AMI ICD–CM diagnosis code.

(iv) For AMI episodes with either AMI price MS–DRG 280–282 or PCI price MS–DRG 246–251 and with readmission for a CABG MS–DRG 231–236, the cap is applied separately to the payments during the CABG readmission and all other payments during the episode.

(A) For payments during the CABG readmission portion of the episode, the cap is applied for the anchor hospitalization portion of a CABG episode for the corresponding CABG readmission MS–DRG.

(B) For all other payments during the episode, the cap is applied to the AMI model episodes with AMI price MS–DRG 280–282 or PCI price MS–DRGs 246–251 and without readmission for CABG MS–DRGs corresponding to the AMI price MS–DRG.

(2) *Exclusion of incentive programs and add-on payments under existing Medicare payment systems.* Certain incentive programs and add-on payments are excluded by CMS' application of the CMS Price (Payment) Standardization Detailed Methodology used for the Medicare spending per beneficiary measure in the Hospital Value-Based Purchasing Program and Physician Value-Based Payment Modifier Program as specified in § 414.1235(a)(6) and (c)(1) of this chapter.

(f) *Allocation of payments for services that straddle the episode*—(1) *General.* Services included in the episode that begin before the start of or continue beyond the end of an EPM episode are prorated so that only the portion attributable to care furnished during the episode are included in the calculation of actual episode payments.

(2) *Proration of services.* Payments for services that straddle the episode are prorated using the following methodology:

(i) *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.

(ii) *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 (determined in § 512.307(c)).

§ 512.305 Determination of the NPRA and reconciliation process.

(a) *General.* Providers and suppliers furnishing items and services included in the EPM episode bill for such items and services in accordance with existing rules and as if this part were not in effect.

(b) *Annual reconciliation.* CMS annually performs the processes described in paragraphs (c) and (d) of this section to determine actual episode payments for each EPM episode for the performance year (except for episodes that have been canceled in accordance with § 512.240(a)(3), (b)(2), and (c)(2)) and determines the amount of a reconciliation payment to or Medicare repayment amount from EPM participants, if any, for that performance year.

(c) *Annual reconciliation to establish NPRA.* (1) Beginning 2 months after the end of each performance year and using the most recent claims data available, CMS performs a reconciliation calculation to establish an NPRA for each EPM participant based on the following process.

(2) CMS—

(i) Assesses whether EPM participants are in an acceptable or better quality category under § 512.315; and

(ii) Calculates the NPRA for each EPM participant for each performance year, including separately for episodes ending during the performance year 2 (DR) portion and episodes ending during the performance year 2 (NDR) portion of performance year 2, by comparing the quality-adjusted target prices and the

EPM participant's actual episode payments for the performance year or portion of that performance year as described in § 512.300 as follows:

(A) Determines actual EPM episode payments for each EPM episode included in the performance year or portion of that performance year.

(B) Multiplies the quality-adjusted target price by the number of non-canceled EPM episodes included in the performance year or portion of that performance year to which that episode quality-adjusted price applies and aggregates these amounts.

(C) Subtracts the amount determined under paragraph (c)(2)(ii)(A) of this section from the amount determined under paragraph (c)(2)(ii)(B) of this section.

(iii) Applies the following:

(A) *Limitation on loss.* Except as provided in paragraph (c)(2)(iii)(C) of this section, the total amount of the NPRA and subsequent reconciliation calculation for a performance year or portion of that performance year cannot exceed the following:

(1) For performance year 2 (NDR) only, 0 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(2) For performance year 2 (DR) only, 5 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(3) For performance year 3, 10 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(4) For performance years 4 and 5, 20 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(B) *Limitation on gain.* The total amount of the NPRA and subsequent reconciliation calculation for a performance year cannot exceed the following:

(1) For performance years 1 and 2, 5 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(2) For performance year 3, 10 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(3) For performance years 4 and 5, 20 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(C) *Financial loss limits for rural hospitals, SCHs, MDHs, and RRCs.* If an EPM participant is a rural hospital, SCH, MDH or RRC, then for performance year 2 (DR), the total sum of the NPRA and subsequent reconciliation calculation cannot exceed 3 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section. For performance years 3 through 5, the total cannot exceed 5 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section.

(D) *Application of limitations on losses and gains.* CMS establishes limits on losses and gains specifically with respect to and separately for each EPM. For performance year 2, CMS establishes limits on losses for each EPM separately for the performance year 2 (DR) and performance year 2 (NDR) portions of that performance year.

(d) *Determination of reconciliation or repayment amount*—(1) *General.* (i) Subject to paragraphs (c)(2)(iii)(B) and (d)(1)(iv) of this section, for performance year 1, the reconciliation payment (if any) is equal to the NPRA.

(ii) Subject to paragraphs (c)(2)(iii)(A) through (c)(2)(iii)(C) and (d)(1)(iv) of this section, for performance year 2, results from the subsequent reconciliation calculation for a prior year's reconciliation, as described in § 512.307, and the post-episode spending and ACO overlap calculations, as described in § 512.307(b) and (c), are added to the sum of NPRA for performance year 2 (NDR) and NPRA for performance year 2 (DR) in order to determine the reconciliation or repayment amount.

(iii) Subject to paragraphs (c)(2)(iii)(A) through (C) and (d)(1)(iv) of this section, for performance years 3 through 5, results from the subsequent reconciliation calculation for a prior year's reconciliation, as described in § 512.307, and the post-episode spending and ACO overlap calculations, as described in § 512.307(b) and (c), are added to the current year's NPRA in order to determine the reconciliation or repayment amount.

(iv) The reconciliation or repayment amount may be adjusted as described in § 512.460(b)(5).

(2) *Reconciliation payment.* If the amount described in paragraph (d)(1) of this section is positive and the EPM participant quality category as described in § 512.315 is acceptable, good, or excellent, Medicare pays the EPM participant a reconciliation payment in an amount equal to the amount described in paragraph (d)(1) of this section. If the EPM participant's quality category as described in § 512.315 is unacceptable, the EPM participant is not eligible to be paid a reconciliation payment.

(3) *Repayment amount.* If the amount described in paragraph (d)(1) of this section is negative, the EPM participant pays to Medicare an amount equal to the amount described in paragraph (d)(1) of this section, in accordance with § 405.371 of this chapter. CMS waives this requirement for performance year 1.

(e) *EPM participants found to be engaged in inappropriate and systemic under delivery of care.* If the EPM participant is found to be engaged in an inappropriate and systemic under delivery of care as specified in § 512.460(b)(1)(i)(C), the quality of the care provided must be considered to be seriously compromised and the EPM participant must be ineligible to receive or retain a reconciliation payment for any period in which such under delivery of care was found to occur.

(f) *Reconciliation report.* (1) CMS issues each EPM participant a reconciliation report for the performance year. Each reconciliation report contains the following:

(i) Information on the EPM participant's composite quality score described in § 512.315.

(ii) The total actual episode payments for the EPM participant.

(iii) The NPRA.

(iv) Whether the EPM participant is eligible for a reconciliation payment or must make a repayment to Medicare.

(v) The NPRA and subsequent reconciliation calculation amount for the previous performance year, as applicable.

(vi) The post-episode spending amount and ACO overlap calculation for the previous performance year, as applicable.

(vii) The reconciliation payment or repayment amount.

(2) For performance year 2, the reconciliation report would also include information separately for the performance year 2 (DR) and performance year 2 (NDR) portions of that year.

§ 512.307 Subsequent calculations.

(a) *Subsequent reconciliation calculation.* (1) Fourteen months after the end of each performance year, CMS performs an additional calculation, which accounts for changes since the calculation of the initial NPRA, using claims data available at that time, to account for final claims run-out and any additional episode cancellations due to overlap or other reasons as specified in sections § 512.240(a)(3), (b)(2), and (c)(2).

(2) The additional calculation occurs concurrently with the reconciliation process for the most recent performance year and determines the subsequent calculation amount as follows:

(i) For performance years other than performance year 2, if the result of the subsequent reconciliation calculation is different than zero, CMS applies the stop-loss and stop-gain limits in

§ 512.305 (c)(2)(iii)(A) through (C) to the calculations in aggregate for that performance year (the initial reconciliation from section § 512.305(c)(2)(ii)(C), before application of the stop-loss and stop-gain limits, and the subsequent reconciliation calculation) to ensure the calculations in aggregate do not exceed the stop-loss or stop-gain limits. CMS then takes the difference between that amount and the initial NPRA after application of the stop-loss and stop-gain limits in section § 512.305 (c)(2)(iii)(A) through (C) to determine the subsequent calculation amount.

(ii) For performance year 2, CMS performs the subsequent reconciliation calculations separately for performance year 2 (NDR) and performance year 2 (DR) and then combines these amounts to determine the subsequent reconciliation calculation for performance year 2 as follows:

(A) If the results of the subsequent reconciliation calculation for performance year 2 (NDR) is different than zero, CMS applies the stop-loss and stop-gain limits in § 512.305 (c)(2)(iii)(A) through (C) to the calculations in aggregate for performance year 2 (NDR) (the initial reconciliation from § 512.305(c)(2)(ii)(C), not including application of the stop-loss and stop-gain limits, and the subsequent reconciliation calculation) to ensure the calculations in aggregate do not exceed the stop-loss or stop-gain limits. CMS then takes the difference between that amount and the initial NPRA after application of the stop-loss and stop-gain limits in section § 512.305 (c)(2)(iii)(A) through (C) to calculate the subsequent calculation amount for performance year 2 (NDR).

(B) If the results of the subsequent reconciliation calculation for performance year 2 (DR) is different than zero, CMS applies the stop-loss and stop-gain limits in § 512.305 (c)(2)(iii)(A) through (C) to the calculations in aggregate for performance year 2 (DR) (the initial reconciliation from section § 512.305(c)(2)(ii)(C), prior to application of the stop-loss and stop-gain limits, and the subsequent reconciliation calculation) to ensure the calculations in aggregate do not exceed the stop-loss or stop-gain limits. CMS then takes the difference between that amount and the initial NPRA after application of the stop-loss and stop-gain limits in section § 512.305(c)(2)(iii)(A) through (C) to calculate the subsequent calculation amount for performance year 2 (DR).

(C) The subsequent calculation amount for performance year 2 is the sum of paragraphs (a)(2)(ii)(A) and (a)(2)(ii)(B) in this section.

(iii) 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.

(iv) Because EPM participants do 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.

(b) *Additional calculations to determine the reconciliation payment or repayment amount.* CMS will reduce the reconciliation payment or increase the repayment amount for the subsequent performance year to account for shared savings paid to the ACO in the prior performance year by the amount of the EPM discount factor paid out to the ACO as shared savings in the prior performance year. This adjustment is only made when the EPM participant is a participant or provider/supplier in the ACO and the EPM beneficiary is assigned or aligned to one of the following ACO models or programs:

(1) The Medicare Shared Savings Program.

(2) The Comprehensive ESRD Care Initiative (excluding a track with downside risk).

(c) *Increases in post-episode spending.* If the average post-episode Medicare Parts A and B payments for an EPM participant in the prior performance year is greater than 3 standard deviations above the regional average post-episode payments for the same performance year, then the spending amount exceeding three standard deviations above the regional average post-episode payments for the same performance year is added to the calculation of the reconciliation or repayment amount for the subsequent performance year.

§ 512.310 Appeals process.

(a) *Notice of calculation error (first level of appeal).* Subject to the limitations on review in subpart D of this part, if an EPM participant wishes to dispute calculations involving a matter related to payment, a CR incentive payment, reconciliation amounts, repayment amounts, or determinations associated with quality measures affecting payment, the EPM participant is required to provide written notice of the error, in a form and manner specified by CMS.

(1) Unless the EPM participant provides such notice, CMS deems final the reconciliation report and CR incentive payment report 45 calendar days after the reconciliation report or CR incentive payment report is issued and proceeds with the payment or repayment processes as applicable.

(2) If CMS receives a notice of a calculation error within 45 calendar days of the issuance of the reconciliation report or CR incentive payment report, 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 EPM participant.

(3) Only EPM participants may use the notice of calculation error process described in this part.

(b) *Dispute resolution process (second level of appeal).* (1) If the EPM participant is dissatisfied with CMS's response to the notice of a calculation error, the EPM participant may request a reconsideration review in a form and manner as specified by CMS.

(2) The reconsideration request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the EPM participant's assertion that CMS or its representatives did not accurately calculate the NPRA, the reconciliation payment, the CR incentive payment, or the repayment amount in accordance with subpart D of this part.

(3) If CMS does not receive a request for reconsideration from the EPM participant within 10 calendar days of the issue date of CMS's response to the EPM participant's notice of calculation error, then CMS's response to the calculation error is deemed final and CMS proceeds with the applicable processes, as described in subpart D of this part.

(4) The CMS reconsideration official notifies the EPM participant in writing within 15 calendar days of receiving the EPM participant'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 the EPM.

(7) The CMS reconsideration official issues a written determination within 30 days of the review. The determination is final and binding.

(8) Only EPM participants may use the dispute resolution process described in this part.

(c) *Exception to the notice of calculation error process.* If the EPM participant contests a matter that does not involve an issue contained in, or a calculation which contributes to, a reconciliation report or CR incentive payment report a notice of calculation error is not required. In these instances, if CMS does not receive a request for reconsideration from the EPM participant within 10 calendar days of the notice of the initial determination, the initial determination is deemed final and CMS proceeds with the action indicated in the initial determination.

(d) *Notice of an EPM participant's termination from the EPM.* If an EPM participant receives notification that it has been terminated from the EPM and wishes to appeal such termination, it must provide a written request for reconsideration to CMS requesting review of the termination within 10 calendar days of the notice. CMS has 30 days to respond to the EPM participant's request for review. If the EPM participant fails to notify CMS, the termination is deemed final.

(e) *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 to expand 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 (e)(1) or (2) of this section.

§ 512.315 Composite quality scores for determining reconciliation payment eligibility and effective and applicable discount factors.

(a) *General.* An EPM participant's eligibility for a reconciliation payment under § 512.305, and the determination of effective discount factors and applicable discount factors for reconciliation and repayment, respectively, under paragraphs (b)(5), (c)(5), and (d)(5) of this section, for a performance year depend on the EPM participant's EPM composite quality score (including any quality performance points and quality improvement points earned) for that performance year.

(b) *AMI model*—(1) *AMI model composite quality score.* CMS calculates an AMI model composite quality score for each AMI model participant for each performance year, which equals the sum of the following:

(i) The AMI model participant's quality performance points for the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (NQF #0230) measure described in § 512.411(a)(1). This measure is weighted at 50 percent of the AMI model composite quality score.

(ii) The AMI model participant's quality performance points for the Excess Days in Acute Care after Hospitalization for AMI measure described in § 512.411(a)(2). This measure is weighted at 20 percent of the AMI model composite quality score.

(iii) The AMI model participant's quality performance points for the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166) measure described in § 512.411(a)(3). This measure is weighted at 20 percent of the AMI model composite quality score.

(iv) Any additional quality improvement points the AMI model participant may earn as a result of demonstrating improvement on the quality measures in § 512.411(a), as described in paragraph (b)(3) of this section.

(v) If applicable, 2 additional points for successful Hybrid Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #2473) measure voluntary data submission as described in § 512.411(b)(2). Successful submission is weighted at 10 percent of the AMI model composite quality score.

(2) *AMI model quality performance points.* CMS computes quality performance points for each quality measure based on the AMI model participant's performance percentile relative to the national distribution of all subsection (d) hospitals that are eligible for payment under the IPPS and meet the minimum measure patient case or survey count.

(i) For the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (NQF #0230) measure described in § 512.411(a)(1), CMS assigns the AMI model participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(A) 10.00 points for ≥ 90th.
(B) 9.25 points for ≥ 80th and < 90th.
(C) 8.50 points for ≥ 70th and < 80th.
(D) 7.75 points for ≥ 60th and < 70th.
(E) 7.00 points for ≥ 50th and < 60th.
(F) 6.25 points for ≥ 40th and < 50th.
(G) 5.50 points for ≥ 30th and < 40th.
(H) 0.00 points for < 30th.

(ii) For the Excess Days in Acute Care after Hospitalization for AMI measure described in § 512.411(a)(2), CMS assigns the AMI model participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(A) 4.00 points for ≥ 90th.
(B) 3.70 points for ≥ 80th and < 90th.
(C) 3.40 points for ≥ 70th and < 80th.
(D) 3.10 points for ≥ 60th and < 70th.
(E) 2.80 points for ≥ 50th and < 60th.
(F) 2.50 points for ≥ 40th and < 50th.
(G) 2.20 points for ≥ 30th and < 40th.
(H) 0.00 points for < 30th.

(iii) For the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166) measure described in § 512.411(a)(3), CMS assigns the AMI model participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(A) 4.00 points for ≥ 90th.
(B) 3.70 points for ≥ 80th and < 90th.
(C) 3.40 points for ≥ 70th and < 80th.
(D) 3.10 points for ≥ 60th and < 70th.
(E) 2.80 points for ≥ 50th and < 60th.
(F) 2.50 points for ≥ 40th and < 50th.
(G) 2.20 points for ≥ 30th and < 40th.
(H) 0.00 points for < 30th.

(3) *AMI model quality improvement points.* If an AMI model participant's own improvement in the participant's measure point estimate from the previous year on an individual measure described in § 512.411(a), regardless of the participant's measure point estimate starting and ending values, falls into the top 10 percent of all subsection (d) hospitals that are eligible for payment under the IPPS based on the national distribution of measure improvement

over the most recent two years, then the AMI model participant is eligible to receive quality improvement points up to 10 percent of the total available points for that measure. The AMI model composite quality score is capped at 20 points.

(4) *Exception for AMI model participants without a measure value.* In the case of an AMI model participant 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 AMI model participant for the individual measure.

(i) An AMI model participant does not have a measure value for the—

(A) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (NQF #0230) measure described in § 512.411(a)(1) if the participant does not meet the minimum 25 case count.

(B) Excess Days in Acute Care after Hospitalization for AMI measure described in § 512.411(a)(2) if the participant does not meet the minimum 25 case count.

(C) Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166) measure described in § 512.411(a)(3) if the participant does not meet the minimum of 100 completed surveys and does not have 4 consecutive quarters of HCAHPS data.

(D) Measures described in paragraphs (4)(i)(A) through (C) of this section, if CMS identifies an error in the data used to calculate the measure and suppresses the measure value.

(5) *Establishing AMI model reconciliation payment eligibility and effective and applicable discount factors.* CMS determines reconciliation payment eligibility and the effective discount factor for reconciliation payments in all performance years and repayment amounts in performance years 4 and 5, as well as the applicable discount factor for repayment amounts in performance years 2 (DR) and 3, for AMI model participants based on the AMI model composite quality score described in paragraph (b)(1) of this section.

(i) Reconciliation payment eligibility requires an acceptable or better quality category, defined as an AMI model composite quality score of greater than or equal to 3.6.

(ii) Effective discount factor for reconciliation payments.

(A) A 3.0 percentage point effective discount factor for AMI model participants in the unacceptable or acceptable category, defined as an AMI model composite quality score that is less than 6.9.

(B) A 2.0 percentage point effective discount factor for AMI model participants in the good quality category, defined as an AMI model composite quality score that is greater than or equal to 6.9 and less than or equal to 14.8.

(C) A 1.5 percentage point effective discount factor for AMI model participants in the excellent quality category, defined as an AMI model composite quality score that is greater than 14.8.

(iii) Applicable discount factor for repayment amount in performance years 2 (DR) and 3.

(A) A 2.0 percentage point applicable discount factor for AMI model participants in the unacceptable or acceptable quality category, defined as an AMI model composite quality score of less than 6.9.

(B) A 1.0 percentage point applicable discount factor for AMI model participants in the good quality category, defined as an AMI model composite quality score that is greater than or equal to 6.9 and less than or equal to 14.8.

(C) A 0.5 percentage point applicable discount factor for AMI model participants in the excellent quality category, defined as an AMI model composite quality scores that is greater than 14.8.

(c) *CABG model*—(1) *CABG model composite quality score.* CMS calculates a CABG model composite quality score for each CABG model participant for each performance year, which equals the sum of the following:

(i) The CABG model participant's quality performance points for the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF# 2558) measure described in § 512.412(a)(1). This measure is weighted at 75 percent of the CABG model composite quality score.

(ii) The CABG model participant's quality performance points for the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166) measure described in § 512.412(a)(2). This measure is weighted at 25 percent of the CABG model composite quality score.

(iii) Any additional quality improvement points the CABG model participant may earn as a result of demonstrating improvement on the quality measures in paragraphs (b)(1)(i) and (ii) of this section, as described in paragraph (c)(3) of this section.

(2) *CABG model quality performance points.* CMS computes quality performance points for each quality measure based on the CABG model participant's performance percentile relative to the national distribution of all subsection (d) hospitals that are eligible for payment under the IPPS and meet the minimum measure patient case or survey count.

(i) For the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF# 2558) measure described in § 512.412(a)(1), CMS assigns the CABG model participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(A) 15.00 points for ≥ 90th.
(B) 13.88 points for ≥ 80th and < 90th.
(C) 12.75 points for ≥ 70th and < 80th.
(D) 11.63 points for ≥ 60th and < 70th.
(E) 10.50 points for ≥ 50th and < 60th.
(F) 9.38 points for ≥ 40th and < 50th.
(G) 8.25 points for ≥ 30th and < 40th.
(H) 0.00 points for < 30th.

(ii) For the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166) measure described in § 512.412(a)(2), CMS assigns the CABG model participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(A) 5.00 points for ≥ 90th.
(B) 4.63 points for ≥ 80th and < 90th.
(C) 4.25 points for ≥ 70th and < 80th.
(D) 3.88 points for ≥ 60th and < 70th.
(E) 3.50 points for ≥ 50th and < 60th.
(F) 3.13 points for ≥ 40th and < 50th.
(G) 2.75 points for ≥ 30th and < 40th.
(H) 0.00 points for < 30th.

(3) *CABG model quality improvement points.* If a CABG model participant's own improvement in the participant's measure point estimate from the previous year on an individual measure described in § 512.412(a), regardless of the participant's measure point estimate starting and ending values, falls into the top 10 percent of all subsection (d) hospitals that are eligible for payment under the IPPS based on the national distribution of measure improvement over the most recent two years, then the CABG model participant is eligible to receive quality improvement points up to 10 percent of the total available points for that measure. The total CABG model composite quality score is capped at 20 points.

(4) *Exception for CABG model participants without a measure value.* In the case of a CABG model participant 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.

(i) A CABG model participant does not have a measure value for the—

(A) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF# 2558) measure described in § 512.412(a)(1) if the CABG model participant does not meet the minimum 25 case count.

(B) Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166) measure described in § 512.412(a)(2) if the CABG model participant does not meet the minimum of 100 completed surveys and does not have 4 consecutive quarters of HCAHPS data.

(C) Measures described in paragraphs (c)(4)(i)(A) and (c)(4)(i)(B) of this section, if CMS identifies an error in the data used to calculate the measure and suppresses the measure value.

(5) *Establishing CABG model reconciliation payment eligibility and effective and applicable discount factors.* CMS determines reconciliation payment eligibility and the effective discount factor for reconciliation payments in all performance years and repayment amounts in performance years 4 and 5, as well as applicable discount factor for repayment amounts in performance years 2 (DR) and 3, for CABG model participants based on the CABG model composite quality score described in paragraph (c)(1) of this section.

(i) Reconciliation payment eligibility requires an acceptable or better quality category, defined as a CABG model composite quality score of greater than or equal to 2.8.

(ii) Effective discount factor for reconciliation payments.

(A) A 3.0 percentage point effective discount factor for CABG model participants in the unacceptable or acceptable quality category, defined as a CABG model composite quality score that is less than 4.8.

(B) A 2.0 percentage point effective discount factor for CABG model participants in the good quality category, defined as a CABG model composite quality score that is greater than or equal to 4.8 and less than or equal to 17.5.

(C) A 1.5 percentage point effective discount factor for CABG model participants in the excellent quality category, defined as a CABG model composite quality score that are greater than 17.5.

(iii) Applicable discount factor for repayment amount in performance years 2 (DR) and 3.

(A) A 2.0 percentage point applicable discount factor for CABG model participants in the unacceptable or acceptable quality category, defined as a CABG model composite quality score of less than 4.8.

(B) A 1.0 percentage point applicable discount factor for CABG model participants in the good quality category, defined as a CABG model composite quality score that is greater than or equal to 4.8 and less than or equal to 17.5.

(C) A 0.5 percentage point applicable discount factor for CABG model participants in the excellent quality category, defined as a CABG model composite quality scores that is greater than 17.5.

(d) *SHFFT model*—(1) *SHFFT model composite quality score.* CMS calculates a SHFFT model composite quality score for each SHFFT model participant for each performance year, which equals the sum of the following:

(i) The SHFFT model participant's quality performance points for the Hospital-Level Risk-Standardized Complication Rate following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (NQF #1550) measure described in § 512.413(a)(1). This measure is weighted at 50 percent of the SHFFT model composite quality score.

(ii) The SHFFT model participant's quality performance points for the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166) measure described in § 512.413(a)(2). This measure is weighted at 40 percent of the SHFFT model composite quality score.

(iii) Any additional quality improvement points the SHFFT model participant may earn as a result of demonstrating improvement on either or both of the quality measures in paragraphs (d)(1)(i) and (ii) of this section, as described in paragraph (d)(3) of this section.

(iv) If applicable, 2 additional points for successful THA/TKA voluntary data submission of patient-reported outcomes and limited risk variable data, as described in § 512.413(b)(2). Successful submission is weighted at 10 percent of the SHFFT model composite quality score.

(2) *SHFFT model quality performance points.* CMS computes quality performance points for each quality measure based on the SHFFT model participant's performance percentile on that measure relative to the national distribution of all subsection (d) hospitals that are eligible for payment under the IPPS and meet the minimum measure patient case or survey count.

(i) For the Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (NQF #1550) measure described in § 512.413(a)(1), CMS assigns the SHFFT model participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(A) 10.00 points for ≥ 90th.
(B) 9.25 points for ≥ 80th and < 90th.
(C) 8.50 points for ≥ 70th and < 80th.
(D) 7.75 points for ≥ 60th and < 70th.
(E) 7.00 points for ≥ 50th and < 60th.
(F) 6.25 points for ≥ 40th and < 50th.
(G) 5.50 points for ≥ 30th and < 40th.
(H) 0.00 points for < 30th.

(ii) For the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166) measure described in § 512.413(a)(2), CMS assigns the SHFFT model participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(A) 8.00 points for ≥ 90th.
(B) 7.40 points for ≥ 80th and < 90th.
(C) 6.80 points for ≥ 70th and < 80th.
(D) 6.20 points for ≥ 60th and < 70th.
(E) 5.60 points for ≥ 50th and < 60th.
(F) 5.00 points for ≥ 40th and < 50th.
(G) 4.40 points for ≥ 30th and < 40th.
(H) 0.00 points for < 30th.

(3) *SHFFT quality improvement points.* If a SHFFT model participant's quality performance percentile on an individual measure described in § 512.413(a) increases from the previous performance year by at least 2 deciles on the performance percentile scale, then the SHFFT model participant is eligible to receive quality improvement points up to 10 percent of the total available points for that individual measure. The total SHFFT model composite quality score is capped at 20 points.

(4) *Exception for SHFFT model participants without a measure value.* In the case of a SHFFT model participant 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 participant for the individual measure.

(i) A SHFFT model participant does not have a measure value for the—

(A) Hospital-Level Risk-Standardized Complication Fate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (NQF #1550) measure described in § 510.413(a)(1) if the participant does not meet the minimum 25 case count; or

(B) Hospital Consumer Assessment of Healthcare Providers and Systems

Survey measure (NQF #0166) described in § 510.413(a)(2) if the participant does not meet the minimum of 100 completed surveys and does not have 4 consecutive quarters of HCAHPS data.

(C) Measures described in paragraphs (d)(4)(i)(A) and (d)(4)(i)(B) of this section, if CMS identifies an error in the data used to calculate the measure and suppresses the measure value.

(5) *Establishing SHFFT model reconciliation payment eligibility and effective and applicable discount factors.* CMS determines reconciliation payment eligibility and the effective discount factor for reconciliation payments in all performance years and repayment amounts in performance years 4 and 5, as well as the applicable discount factor for repayment amounts in performance years 2 (DR) and 3, for SHFFT model participants based on the SHFFT model composite quality score described in paragraph (d)(1) of this section.

(i) Reconciliation payment eligibility requires an acceptable or better quality category, defined as a SHFFT model composite quality score of greater than or equal to 5.0.

(ii) Effective discount factor for reconciliation payments.

(A) A 3.0 percentage point effective discount factor for SHFFT model participants in the unacceptable or acceptable quality category, defined as a SHFFT model composite quality score that is less than 6.9.

(B) A 2.0 percentage point effective discount factor for SHFFT model participants in the good quality category, defined as a SHFFT model composite quality score that is greater than or equal to 6.9 and less than or equal to 15.0.

(C) A 1.5 percentage point effective discount factor for SHFFT model participants in the excellent quality category, defined as a SHFFT model composite quality score that are greater than 15.0.

(iii) Applicable discount factor for repayment amount in performance years 2 (DR) and 3.

(A) A 2.0 percentage point applicable discount factor for SHFFT model participants in the unacceptable or acceptable quality category, defined as a SHFFT model composite quality score of less than 6.9.

(B) A 1.0 percentage point applicable discount factor for SHFFT model participants in the good quality category, defined as a SHFFT model composite quality score that is greater than or equal to 6.9 and less than or equal to 15.0.

(C) A 0.5 percentage point applicable discount factor for SHFFT model participants in the excellent quality category, defined as a SHFFT model composite quality scores that is greater than 15.0.

§ 512.320 Treatment of incentive programs or add-on payments under existing Medicare payment systems.

No EPM replaces any existing Medicare incentive programs or add-on payments. The quality-adjusted target prices and NPRAs for an EPM participant under such models are independent of, and do not affect, any incentive programs or add-on payments under existing Medicare payment systems.

§ 512.350 Data sharing.

(a) *General.* CMS makes available to EPM participants, through the most appropriate means, data that CMS determines may be useful to EPM participants to do the following:

(1) Determine appropriate ways to increase the coordination of care.

(2) Improve quality.

(3) Enhance efficiencies in the delivery of care.

(4) Otherwise achieve the goals of the models described in this section.

(b) *Beneficiary-identifiable data.* (1) CMS makes beneficiary-identifiable data available to an EPM participant in accordance with applicable privacy laws and only in response to the EPM participant's request for such data for a beneficiary who has been furnished a billable service by the EPM participant corresponding to the episode definitions for the EPM.

(2) The minimum data necessary to achieve the goals of the EPM, as determined by CMS, may be provided under this section for an EPM participant's baseline period and as frequently as on a quarterly basis throughout the EPM participant's participation in an EPM.

Subpart E—Quality Measures, Beneficiary Protections, and Compliance Enforcement

§ 512.400 Quality measures and reporting—general.

(a) *Reporting of quality measures.* Quality measures are used for public reporting, for determining whether an EPM participant is eligible for reconciliation payments under § 512.305(d)(1)(iii)), and for assigning the effective and applicable discount factors for the performance year to an EPM participant as described in § 512.315(b)(5), (c)(5), and (d)(5).

(b) *Quality measures.* Quality measures differ by EPM.

(c) *Public reporting.* CMS—

(1) Makes the required quality measurement results for each EPM participant in each performance year publicly available on the CMS Web site in a form and manner as determined by CMS;

(2) Shares each EPM participant's quality metrics with the participant prior to display on the CMS Web site; and

(3) Does not publicly report the voluntary measure data submitted under an EPM in § 512.411(b) or § 512.413(b) but does indicate whether an EPM participant has voluntarily submitted such data.

§ 512.411 Quality measures and reporting for AMI model.

(a) *Required measures.* (1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (NQF #0230) (MORT–30–AMI).

(2) Excess Days in Acute Care after Hospitalization for AMI (AMI Excess Days).

(3) HCAHPS Survey (NQF #0166).

(b) *Voluntary measure.* (1) Voluntary Hybrid Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #2473) (Hybrid AMI Mortality).

(2) To be eligible to receive the additional points added to the AMI composite quality score for successful voluntary data submission of clinical electronic health record data, as described in § 512.411(b)(1), AMI model participants must submit the clinical electronic health record data requested by CMS related to each eligible AMI anchor hospitalization during the performance period. The data must be submitted within 60 days of the end of the most recent performance period and be accompanied by the limited risk variable data (five elements finalized) as outlined in § 512.315(b)(1)(iv).

(i) For each eligible AMI anchor hospitalization, all five risk variable data elements are required to be submitted. The five risk variables are as follows:

(A) Age.

(B) First-captured heart rate measured within 2 hours of a patient presenting to the hospital.

(C) First-captured systolic blood pressure measured within 2 hours of a patient presenting to the hospital.

(D) First-captured troponin values measured within 24 hours of a patient presenting to the hospitals.

(E) First-captured creatinine values measured within 24 hours of a patient presenting to the hospitals.

(ii) For each eligible AMI anchor hospitalization, six linking variables are

required to merge the electronic health record data with the CMS claims data:

(A) AMI model participant CCN.

(B) Medicare Health Insurance Claim Number.

(C) Sex.

(D) Date of birth.

(E) Admission date.

(F) Discharge date.

(iii) For years 1 through 5 of the AMI model an increasing amount of data are requested by CMS for each performance period as follows:

(A) *Year 1.* Submit electronic health record data on > 50% of eligible AMI anchor hospitalizations between July 1, 2017 and August 31, 2017.

(B) *Year 2.* Submit electronic health record data on over 90% of eligible AMI anchor hospitalizations between September 1, 2017 and June 30, 2018.

(C) *Year 3.* Submit electronic health record data on over 90% of eligible AMI anchor hospitalizations between July 1, 2018 and June 30, 2019.

(D) *Year 4.* Submit electronic health record data on over 90% of eligible AMI anchor hospitalizations between July 1, 2019 and June 30, 2020.

(E) *Year 5.* Submit electronic health record data on over 90% of eligible AMI anchor hospitalizations between July 1, 2020 and June 30, 2021.

§ 512.412 Quality measures and reporting for CABG model.

(a) *Required measures.* (1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF# 2558) (MORT–30–CABG).

(2) HCAHPS Survey (NQF #0166).

(b) [Reserved].

§ 512.413 Quality measures and reporting for SHFFT model.

(a) *Required measures.* (1) Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (NQF #1550) (Hip/Knee Complications).

(2) HCAHPS Survey (NQF #0166).

(b) *Voluntary measure.* (1) Patient-reported outcomes and limited risk variable data following elective primary THA/TKA.

(2) To be eligible to receive the additional points added to the SHFFT model composite quality score for successful voluntary data submission of patient-reported outcomes and limited risk variable data, as described in § 512.315(d)(1)(iv), SHFFT model participants 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 § 512.315(d)(1)(iv).

(i) For each eligible procedure all eleven risk variable data elements are required to be submitted. The eleven risk variables are as follows:

(A) Date of birth.

(B) Race.

(C) Ethnicity.

(D) Date of admission to anchor hospitalization.

(E) Date of eligible THA/TKA procedure.

(F) Medicare Health Insurance Claim Number.

(G) Body mass index.

(H) Use of chronic (≥ 90 days) narcotics.

(I) Total painful joint count.

(J) Quantified spinal pain.

(K) Single Item Health Literacy Screening (SILS2) questionnaire.

(ii) Participants must also submit the amount of requested THA/TKA patient-reported outcomes data required for each year of the SHFFT model in order to be considered successful in submitting voluntary data.

(A) The amount of requested THA/TKA patient-reported outcomes data to submit, in order to be considered successful increases each subsequent year of the SHFFT model over the 5 years of the model.

(B) A phase-in approach that determines the amount of requested THA/TKA patient-reported outcomes data to submit over the 5 years of the SHFFT model is 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:

(1) Greater than or equal to 60 percent of eligible procedures or greater than or equal to 75 percent eligible patients during the data collection period.

(2) Submission of requested THA/TKA PRO and limited risk variable data is completed within 60 days of the most recent performance period.

(iii) For years 1 through 5 of the model an increasing amount of data is requested by CMS for each performance period as follows:

(A) *Year 1 (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, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(B) *Year 2 (2018).* Submit—

(1) Post-operative data on primary elective THA/TKA procedures for ≥ 60 percent or ≥ 75 procedures performed between September 1, 2016 and June 30, 2017; and

(2) 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.

(C) *Year 3 (2019).* Submit—

(1) Post-operative data on primary elective THA/TKA procedures for ≥ 70% or ≥ 100 procedures performed between July 1, 2017 and June 30, 2018; and

(2) 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.

(D) *Year 4 (2020).* Submit—

(1) Post-operative data on primary elective THA/TKA procedures for ≥ 80% or ≥ 200 procedures performed between July 1, 2018 and June 30, 2019; and

(2) 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.

(E) *Year 5 (2021).* Submit—

(1) Post-operative data on primary elective THA/TKA procedures for ≥ 80% or ≥ 200 procedures performed between July 1, 2019 and June 30, 2020; and

(2) Pre-operative data on primary elective THA/TKA procedures for ≥ 80% or ≥ 200 procedures performed between July 1, 2020 and June 30, 2021, unless CMS requests a more limited data set, in which case, submit all requested data elements.

§ 512.450 Beneficiary choice and beneficiary notification.

(a) *Beneficiary choice.* The EPMs do 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 take into account patient and family preferences when they are expressed.

(2) Participant hospitals may not charge any episode payment model 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 § 512.240 of his or her inclusion in the episode payment model. The notice must be upon admission to the participant hospital or immediately following the decision to schedule a procedure or provide services which would result in a patient being discharged under a covered episode. In circumstances where, due to the patient's condition, it may not be feasible to provide notification at such times, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable but no later than discharge from the hospital accountable for the episode. The hospital must be able to generate a list of all beneficiaries receiving such notification including the date on which the notification was provided to the beneficiary to CMS or its designee upon request for monitoring purposes. 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 sharing arrangement.

(2) *Physician, non-physician practitioner, and PGP provision of notice.* A participant hospital must require any physician, non-physician practitioner, or PGP that is an episode payment model collaborator to provide written notice of the structure of the model and the existence of the physician's or PGP's sharing arrangement with the participant hospital to any Medicare beneficiary that meets the criteria specified in § 512.240. The notice must be provided at the time that the decision to undergo a procedure or service covered under an episode payment model is made. In circumstances where, due to the patient's condition, it may not be feasible to provide notification at such times, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable but no later than discharge from the hospital accountable for the episode. The physician or PGP must be able to generate a list of all beneficiaries receiving such notification including the date on which the notification was provided to the beneficiary to CMS upon request for monitoring purposes.

(3) *PAC provider/supplier notification.* A participant hospital must require any provider or supplier, other than the treating physician or member of a PGP discussed in paragraph (b)(2) of this section, with whom it has executed a sharing arrangement 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 § 512.240. The notice must be provided no later than the time at which the beneficiary first receives services from the provider or supplier during the episode payment model episode of care. In circumstances where, due to the patient's condition, it may not be feasible to provide notification at such times, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable but no later than discharge from the hospital accountable for the episode. The PAC provider/supplier must be able to generate a list of all beneficiaries receiving such notification including the date on which the notification was provided to the beneficiary to CMS upon request for monitoring purposes.

(4) *Collaborating hospital notification.* An EPM participant must require any hospital that is an EPM collaborator to provide written notice of the structure of the model and the existence of the hospital's sharing arrangement with the EPM participant to any Medicare beneficiary that meets the criteria specified in § 512.240. The notice must be upon admission to the collaborating hospital, or immediately following the decision to undertake a procedure or provide services covered under an EPM, whichever occurs later. In circumstances where, due to the patient's condition, it may not be feasible to provide notification at such times, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable but no later than discharge from the hospital accountable for the episode. Hospitals must be able to generate a list of all beneficiaries receiving such notification including the date on which the notification was provided to the beneficiary to CMS, or its designees, upon request for monitoring purposes.

(5) *ACO notification.* An EPM participant must require any ACO that is an EPM collaborator to require their ACO participants for which the ACO has an ACO distribution arrangement as well as the ACO's providers and suppliers to provide written notice of the structure of the model and the existence of the ACO's sharing arrangement with the EPM participant to any Medicare beneficiary that meets the criteria specified in § 512.240. The notice must be provided no later than the time at which the beneficiary first receives services from the ACO participant and/or an ACO PGP collaboration agent during the EPM episode. In circumstances where, due to the patient's condition, it may not be feasible to provide notification at such times, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable but no later than discharge from the hospital accountable for the episode. ACOs must be able to generate a list of all beneficiaries receiving such notification including the date on which the notification was provided to the beneficiary to CMS, or its designees, upon request for monitoring purposes.

(6) *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 § 512.610, the hospital must notify the beneficiary in accordance with paragraph (b)(6)(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.

(7) Lists of beneficiaries that receive notifications must be retained and provided access to CMS, or its designees, in accordance with § 512.110.

§ 512.460 Compliance enforcement.

(a) *General.* EPM participants 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 applicable payment, coverage, program integrity, or other requirements under this chapter (such as those in parts 412 and 482 of 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 an EPM participant or its related EPM collaborators, collaboration agents, or downstream collaboration agents does any of the following:

(i) Fails to comply with any requirements of this part or is identified as noncompliant through monitoring by HHS (including CMS and OIG) of the applicable model, including but not limited to any of the following:

(A) Avoiding potentially high cost or high severity patients.

(B) Targeting potentially low cost or low severity 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 sharing arrangements.

(ii) Has signed a sharing arrangement, distribution arrangement, or downstream distribution arrangement that 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 applicable episode payment model, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of EPM.

(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.

(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 EPM.

(2) Remedial actions include the following:

(i) Issuing a warning letter to the EPM participant.

(ii) Requiring the EPM participant to develop a corrective action plan, commonly referred to as a CAP.

(iii) Reducing or eliminating the EPM participant's reconciliation payment.

(iv) Reducing or eliminating the EPM participant's CR incentive payment.

(v) Requiring the EPM participant to terminate a sharing arrangement with an EPM collaborator and prohibit further engagement by the EPM participant in sharing arrangements with the EPM collaborator.

(vi) Terminating the EPM participant's participation in the EPM. Where a participant is terminated from an EPM, the EPM participant will remain liable for all negative NPRA generated from episodes of care that occurred prior to termination.

(3) CMS may add 25 percent to a repayment amount on an EPM participant's reconciliation report if all of the following conditions are true:

(i) CMS has required a corrective action plan from the EPM participant.

(ii) The EPM participant owes a repayment amount to CMS.

(iii) The EPM participant fails to timely comply with the corrective action plan or is noncompliant with the EPM's requirements.

Subpart F—Financial Arrangements and Beneficiary Incentives

§ 512.500 Sharing arrangements under the EPM.

(a) *General.* (1) An EPM participant may enter into a sharing arrangement with an EPM collaborator to make a gainsharing payment, or to receive an alignment payment, or both. An EPM participant must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement.

(2) A sharing arrangement must comply with the provisions of this section and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

(3) The EPM participant must develop, maintain, and use a set of written policies for selecting individuals and entities to be EPM collaborators. These policies must contain criteria related to, and inclusive of, the quality of care delivered by the potential EPM collaborator. The selection criteria cannot be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent.

(4) If an EPM participant enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the EPM.

(b) *Requirements.* (1) A sharing arrangement must be in writing and signed by the parties, and entered into before care is furnished to EPM beneficiaries under the sharing arrangement.

(2) Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.

(3) The sharing arrangement must require the EPM collaborator and its employees, contractors (including collaboration agents), and subcontractors (including downstream collaboration agents) to comply with the following:

(i) 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);

(ii) All applicable Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the sharing arrangement; and

(iii) All other applicable laws and regulations.

(4) The sharing arrangement must require the EPM collaborator to have a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the EPM.

(5) The sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(6) The board or other governing body of the EPM participant must have responsibility for overseeing the EPM participant's participation in the EPM, its arrangements with EPM collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the EPM.

(7) The written agreement memorializing a sharing arrangement must specify the following:

(i) The purpose and scope of the sharing arrangement.

(ii) The identities and obligations of the parties, including specified EPM activities and other services to be performed by the parties under the sharing arrangement;

(iii) The date of the sharing arrangement.

(iv) Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out EPM activities.

(v) The financial or economic terms for payment, including the following:

(A) Eligibility criteria for a gainsharing payment.

(B) Eligibility criteria for an alignment payment.

(C) Frequency of gainsharing or alignment payment.

(D) Methodology and accounting formula for determining the amount of a gainsharing payment that is substantially based on quality of care and the provision of EPM activities.

(E) Methodology and accounting formula for determining the amount of an alignment payment.

(8) The sharing arrangement must not—

(i) Induce the EPM participant, EPM collaborator, or any employees, contractors, or subcontractors of the EPM participant or EPM collaborator to reduce or limit medically necessary services to any Medicare beneficiary; or

(ii) Restrict the ability of an EPM collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.

(c) *Gainsharing payment, alignment payment, and internal cost savings conditions and restrictions.* (1) Gainsharing payments, if any, must—

(i) Be derived solely from reconciliation payments, or internal cost savings, or both;

(ii) Be distributed on an annual basis (not more than once per calendar year);

(iii) Not be a loan, advance payment, or payment for referrals or other business; and

(iv) Be clearly identified as a gainsharing payment at the time it is paid.

(2)(i) To be eligible to receive a gainsharing payment, an EPM collaborator must meet quality of care criteria for the performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment. The quality of care criteria must be established by the EPM participant and directly related to EPM episodes.

(ii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, an EPM collaborator other than a PGP or an ACO must have directly furnished a billable item or service to an EPM beneficiary during an EPM episode that occurred in the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount.

(iii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, an EPM collaborator that is a PGP 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 an EPM beneficiary during an EPM episode that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount; and

(B) The PGP must have contributed to EPM activities and been clinically involved in the care of EPM beneficiaries during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. For example, a PGP might have been clinically involved in the care of EPM beneficiaries by—

(1) Providing care coordination services to EPM beneficiaries during and/or after inpatient admission;

(2) Engaging with an EPM participant in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care for EPM episodes and reduce EPM episode spending; or

(3) In coordination with other providers and suppliers (such as members of the PGP, the EPM participant, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of EPM beneficiaries.

(iv) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, an EPM collaborator that is an ACO must meet the following criteria:

(A) The ACO must have had an ACO provider/supplier that directly furnished, or an ACO participant that billed for, an item or service that was rendered to an EPM beneficiary during an EPM episode that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount; and

(B) The ACO must have contributed to EPM activities and been clinically involved in the care of EPM beneficiaries during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. For example, an ACO might be have been clinically involved in the care of EPM beneficiaries by—

(1) Providing care coordination services to EPM beneficiaries during and/or after inpatient admission;

(2) Engaging with an EPM participant in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care and reduce spending for EPM episodes; or

(3) In coordination with providers and suppliers (such as ACO participants, ACO providers/suppliers, the EPM participant, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of EPM beneficiaries.

(3)(i) The methodology for accruing, calculating and verifying internal cost savings must be transparent, measurable, and verifiable in

accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(ii) The methodology used to calculate internal cost savings must reflect the actual, internal cost savings achieved by the EPM participant through the documented implementation of EPM activities identified by the EPM participant and must exclude:

(A) Any savings realized by any individual or entity that is not the EPM participant; and

(B) ''Paper'' savings from accounting conventions or past investment in fixed costs.

(4) The total amount of a gainsharing payment for a performance year paid to certain individuals and entities that are EPM collaborators must not exceed the following:

(i) In the case of an EPM collaborator who is a physician or nonphysician practitioner, 50 percent of the Medicare-approved amounts under the PFS for items and services furnished by that physician or nonphysician practitioner to the EPM participant's EPM beneficiaries during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made.

(ii) In the case of an EPM collaborator that is a PGP, 50 percent of the Medicare-approved amounts under the PFS for items and services billed by the PGP and furnished to the EPM participant's EPM beneficiaries by members of the PGP during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made.

(5) The amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of EPM activities. The methodology may take into account the amount of such EPM activities provided by an EPM collaborator relative to other EPM collaborators.

(6) For a performance year, the aggregate amount of all gainsharing payments that are derived from a reconciliation payment must not exceed the amount of the reconciliation payment the EPM participant receives from CMS.

(7) No entity or individual, whether a party to a sharing arrangement 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 past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent.

(8) An EPM participant must not make a gainsharing payment to an EPM 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 EPM episodes or other integrity problems.

(9) The sharing arrangement must require the EPM participant to recoup any gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation report or was based on the submission of false or fraudulent data.

(10) Alignment payments from an EPM collaborator to an EPM participant may be made at any interval that is agreed upon by both parties, and must not be—

(i) Issued, distributed, or paid prior to the calculation by CMS of a repayment amount reflected in a reconciliation report;

(ii) Loans, advance payments, or payments for referrals or other business; or

(iii) Assessed by an EPM participant if it does not owe a repayment amount.

(11) The EPM participant must not receive any amounts under a sharing arrangement from an EPM collaborator that are not alignment payments.

(12) For a performance year, the aggregate amount of all alignment payments received by the EPM participant must not exceed 50 percent of the EPM participant's repayment amount.

(13) The aggregate amount of all alignment payments from an EPM collaborator to the EPM participant may not be greater than—

(i) With respect to an EPM collaborator other than an ACO, 25 percent of the EPM participant's repayment amount; or

(ii) With respect to an EPM collaborator that is an ACO, 50 percent of the EPM participant's repayment amount.

(14) The methodology for determining alignment payments must not directly account for the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent.

(15) All gainsharing payments and any alignment payments must be administered by the EPM participant in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(16) All gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(d) *Documentation requirements.* (1) The EPM participant must do all of the following:

(i) Document the sharing arrangement contemporaneously with the establishment of the arrangement.

(ii) Maintain accurate current and historical lists of all EPM collaborators, including EPM collaborator names and addresses.

(A) Update such lists on at least a quarterly basis.

(B) Publicly report the current and historical lists of EPM collaborators on a Web page on the EPM participant's Web site.

(iii) Maintain and require each EPM collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum all of the following:

(A) Nature of the payment (gainsharing payment or alignment payment).

(B) Identity of the parties making and receiving the payment.

(C) Date of the payment.

(D) Amount of the payment.

(E) Date and amount of any recoupment of all or a portion of an EPM collaborator's gainsharing payment.

(F) Explanation for each recoupment, such as whether the EPM collaborator received a gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation report, or was based on the submission of false or fraudulent data.

(2) The EPM participant must keep records of the following:

(i) Its process for determining and verifying its potential and current EPM collaborators' eligibility to participate in Medicare.

(ii) Its plan to track internal cost savings.

(iii) Information on the accounting systems used to track internal cost savings.

(iv) A description of current health information technology, including

systems to track reconciliation payments and internal cost savings.

(v) Its plan to track gainsharing payments and alignment payments.

(3) The EPM participant must retain and provide access to, and must require each EPM collaborator to retain and provide access to, the required documentation in accordance with § 512.110.

§ 512.505 Distribution arrangements under the EPM.

(a) *General.* (1) A PGP or ACO that has entered into a sharing arrangement with an EPM participant may distribute all or a portion of any gainsharing payment it receives from the EPM participant only in accordance with a distribution arrangement.

(2) All distribution arrangements must comply with the provisions of this section and all other applicable laws and regulations, including the fraud and abuse laws.

(b) *Requirements.* (1) All distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to EPM beneficiaries under the distribution arrangement.

(2) Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any distribution payments from an ACO must be determined in accordance with a methodology that is substantially based on quality of care and the provision EPM activities and that may take into account the amount of such EPM activities provided by a collaboration agent relative to other collaboration agents.

(6) The amount of any distribution payments from a PGP to a member must be determined either in a manner that complies with § 411.352(g) of this chapter or in accordance with a methodology that is substantially based on quality of care and the provision EPM activities and that may take into account the amount of such EPM activities provided by a collaboration agent relative to other collaboration agents.

(7) Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g), a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to an EPM beneficiary during an EPM episode that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

(8) Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g), the total amount of distribution payments for a performance year paid to a collaboration agent must not exceed the following:

(i) In the case of a collaboration agent that is physician or nonphysician practitioner, 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the collaboration agent to the EPM participant's EPM beneficiaries during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

(ii) In the case of a collaboration agent that is a PGP, 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by the PGP for items and services furnished by members of the PGP to the EPM participant's EPM beneficiaries during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

(9) With respect to the distribution of any gainsharing payment received by a PGP or ACO, the total amount of all distribution payments must not exceed the amount of the gainsharing payment received by the EPM collaborator from the EPM participant.

(10) All distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(11) The collaboration agent must retain the 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 the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(13) The EPM collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.110, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any distribution payment(s);

(iii) The identity of each collaboration agent that received a distribution payment; and

(iv) A description of the methodology and accounting formula for determining the amount of any distribution payment.

(14) The EPM collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same EPM participant.

(15) The EPM collaborator must retain and provide access to, and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 512.110.

§ 512.510 Downstream distribution arrangements under the EPM.

(a) *General.* (1) An ACO participant that is a PGP and that has entered into a distribution arrangement with an EPM collaborator that is an ACO may distribute all or a portion of any distribution payment it receives from the EPM collaborator only in accordance with a downstream distribution arrangement.

(2) All downstream distribution arrangements must comply with the provisions of this section and all applicable laws and regulations, including the fraud and abuse laws.

(b) *Requirements.* (1) All downstream distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to EPM beneficiaries under the downstream distribution arrangement.

(2) Participation in a downstream distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a downstream distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or

business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any downstream distribution payment must be determined either in a manner that complies with § 411.352(g) of this chapter or in accordance with a methodology that is substantially based on the quality of care and the provision of EPM activities and that may take into account the amount of such EPM activities provided by a downstream collaboration agent relative to other downstream collaboration agents.

(6) Except for a downstream distribution payment that complies with § 411.352(g), a downstream collaboration agent is eligible to receive a downstream distribution payment only if the PGP billed for an item or service furnished by the downstream collaboration agent to an EPM beneficiary during an EPM episode that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprise the gainsharing payment from which the ACO made the distribution payment to the PGP that is an ACO participant.

(7) Except for a downstream distribution payment that complies with § 411.352(g), the total amount of downstream distribution payments for a performance year paid to a downstream collaboration agent must not exceed 50 percent of the total Medicare-approved amounts under the PFS for services billed by the PGP and furnished by the downstream collaboration agent to the EPM participant's EPM beneficiaries during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment from which the ACO made the distribution payment to the PGP that is an ACO participant.

(8) The total amount of all downstream distribution payments made to downstream collaboration agents must not exceed the amount of the distribution payment received by the PGP from the ACO.

(9) All downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(10) The downstream collaboration agent must retain his or her ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(11) The downstream distribution arrangement must not—

(i) Induce the downstream 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.

(12) The PGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 512.110, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any downstream distribution payment.

(iii) The identity of each downstream collaboration agent that received a downstream distribution payment;.

(iv) A description of the methodology and accounting formula for determining the amount of any downstream distribution payment.

(13) The PGP may not enter into a downstream distribution arrangement with any PGP member who has—

(i) A sharing arrangement with an EPM participant; or

(ii) A distribution arrangement with the ACO the PGP is a participant in.

(14) The PGP must retain and provide access to, and must require downstream collaboration agents to retain and provide access to, the required documentation in accordance with § 512.110.

§ 512.520 Enforcement authority under the EPM.

(a) *OIG authority.* OIG authority is not limited or restricted by the provisions of the EPM, including the authority to audit, evaluate, investigate, or inspect the EPM participant, EPM collaborators, or any other person or entity or their records, data, or information, without limitation.

(b) *Other authorities.* None of the provisions of the EPM limits or restricts the authority of any other government agency permitted by law to audit, evaluate, investigate, or inspect the EPM participant, EPM collaborators, or any other person or entity or their records, data, or information, without limitation.

§ 512.525 Beneficiary engagement incentives under the EPM.

(a) *General.* EPM participants may choose to provide in-kind patient engagement incentives to beneficiaries in an EPM episode, subject to the following conditions:

(1) The incentive must be provided directly by the EPM participant or by an agent of the EPM participant under the EPM participant's direction and control to the EPM beneficiary during an EPM episode.

(2) The item or service provided must be reasonably connected to medical care provided to an EPM beneficiary during an EPM 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 (c) of this section, for a beneficiary in an EPM 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 EPM episode.

(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) *Technology provided to an EPM beneficiary.* Beneficiary engagement incentives involving technology are subject to the following additional conditions:

(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 EPM 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 (c) of this section, for a beneficiary in an EPM episode.

(3) Items of technology exceeding $100 in retail value must—

(i) Remain the property of the EPM participant; and

(ii) Be retrieved from the beneficiary at the end of the EPM episode. The EPM participant 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.

(c) *Clinical goals of the EPM.* The following are the clinical goals of the EPM, 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 treatment for the EPM clinical condition.

(4) Management of chronic diseases and conditions that may be affected by treatment for the EPM clinical condition.

(d) *Documentation of beneficiary engagement incentives.* (1) EPM participants must maintain documentation of items and services furnished as beneficiary engagement incentives that exceed $25 in retail value.

(2) The documentation established contemporaneously with the provision of the items and services 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 documentation regarding items of technology exceeding $100 in retail must also include contemporaneous documentation of any attempt to retrieve technology at the end of an EPM episode as described in paragraph (b)(3) of this section.

(4) The EPM participant must retain and provide access to the required documentation in accordance with § 512.110.

Subpart G—Waivers

§ 512.600 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) The number of visits that are furnished to the beneficiary during—

(i) An AMI episode, is up to 13 post-discharge home visits;

(ii) A CABG episode, is up to 9 post-discharge home visits; and

(iii) A SHFFT episode, is up to 9 post-discharge home visits.

(c) *Payment.* Up to the maximum post-discharge home visits for a specific EPM episode, as described in paragraph (b)(5) of this section, may be billed under Part B by the physician or non-physician 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.

§ 512.605 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 an EPM, but only for services that—

(1) May be furnished via telehealth under existing requirements; and

(2) Are included in the episode in accordance with § 512.210.

(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 an EPM 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 an EPM episode in accordance with § 512.210.

(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.

§ 512.610 Waiver of SNF 3-day rule.

(a) *Applicability of the SNF 3-day rule waiver.* CMS determines that the SNF 3-day rule is—

(1) Waived for the AMI model,

(2) Not waived for the CABG model, and

(3) Not waived for the SHFFT model.

(b) *Waiver of the SNF 3-day rule.* For episodes being tested in those EPMs where the SNF 3-day rule is waived under paragraph (a) of this section, CMS waives the SNF 3-day rule for coverage of a SNF stay for episodes that begin on or after April 1, 2018, for an EPM 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 EPM 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.

(c) *Financial liability for uncovered SNF services.* CMS will determine the financial liability for uncovered SNF services if, subsequent to an EPM hospital applying the SNF 3-day rule waiver under this section, an EPM hospital incorrectly applies the SNF 3-day rule waiver.

(1) If the EPM hospital discharges a beneficiary to a SNF that is not a qualified SNF under paragraph (b) of this section and provides the beneficiary with a discharge planning notice, as described at § 512.450(b)(6), to the

beneficiary at the time of discharge to a SNF then the SNF coverage requirements apply and the beneficiary may be financially liable for uncovered SNF services.

(2) The EPM hospital will be financially liable for the SNF stay and the SNF must not bill the beneficiary for the costs of the uncovered SNF services furnished during the SNF stay if, subsequent to an EPM hospital applying the SNF 3-day rule waiver under this section, CMS determines the EPM hospital discharges a beneficiary—

(i) To a SNF that is not a qualified SNF under paragraph (b) of this section and the EPM hospital does not provide the beneficiary with a discharge planning notice, as described at § 512.450(b)(6)

(ii) That is in an EPM where the SNF 3-day rule waiver is not applicable under paragraph (a) of this section; or

(iii) During an episode that begins prior to April 1, 2018, where the SNF 3-day rule waiver is not applicable under paragraph (b) of this section.

(d) *Other requirements.* All other Medicare rules for coverage and payment of Part A-covered SNF services continue to apply.

§ 512.615 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 § 512.600, including those related to recovery from the surgery, as described in paragraph (b) of this section, for episodes being tested in an EPM.

(b) *Services to which the waiver applies.* Up to the maximum post-discharge home visits for a specific EPM episode, as described in § 512.600(b)(5), including those related to recovery from the surgery, per EPM episode may be billed separately under Medicare Part B by the physician or non-physician practitioner, or by the participant hospital to which the physician or non-physician 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.

§ 512.620 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 1833(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 EPM participant hospitals.

(b) *Reconciliation payments or repayments.* Reconciliation payments or repayments do not affect the beneficiary cost-sharing amounts for the Medicare Part A and Part B services provided under an EPM.

§ 512.630 Waiver of physician definition for furnishing cardiac rehabilitation and intensive cardiac rehabilitation services to an EPM beneficiary.

(a) *General.* Section 410.49 of this chapter requires cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) services to be furnished under the direction of a physician as defined in § 410.49(a) of this chapter.

(b) *Waiver of the physician definition.* For a provider or supplier of CR and ICR services to an EPM beneficiary during an AMI and CABG episode, as defined in § 512.2, CMS waives the physician definition to allow the functions of supervising physician, prescribing exercise, and establishing, reviewing, and signing an individualized treatment plan for CR and ICR services to be furnished under the direction of—

(1) A physician, as defined in section 1861(r)(1) of the Act, or

(2) A qualified nonphysician practitioner, as defined by CMS.

(c) *Other definitions and requirements.* All other definitions and requirements in § 410.49 of this chapter related to a physician or supervising physician continue to apply.

Subpart H—CR Incentive Payment Model for EPM and Medicare Fee-for-Service Participants

§ 512.700 Basis and scope.

(a) *Basis.* This subpart implements the cardiac rehabilitation and intensive cardiac rehabilitation (CR) incentive payment model under section 1115A of the Act.

(b) *Scope.* This subpart sets forth:

(1) The participants in the CR incentive payment model;

(2) The CR/ICR services that count toward CR incentive payments;

(3) The methodology for determining CR incentive payments;

(4) Provisions for FFS–CR participants that are not EPM participants.

§ 512.703 CR incentive payment model participants.

(a) *Selection of CR MSAs.* The MSAs eligible for selection for AMI and CABG models will be classified into one of up to ten groups based on their historic utilization of CR/ICR services. Within each group, EPM–CR and FFS–CR MSAs will be randomly selected. The number of EPM–CRs to be selected within each group will be distributed proportionately between the groups based on the assignment of the 98 EPM MSAs. The same number of FFS–MSAs will then be drawn from each group.

(b) *Hospitals eligible for CR incentive payments.* (1) Hospitals that are AMI and CABG model participants located in the EPM–CR MSAs.

(2) *FFS–CR Participants.* Hospitals located in the FFS–CR MSAs that would meet all requirements in § 512.100(b) to be an AMI or CABG model participant if the hospital were located in an MSA selected for the AMI and CABG models.

§ 512.705 CR/ICR services that count towards CR incentive payments.

(a) *Identification of CR/ICR services.* CR/ICR services are identified by the HCPCS codes for CR/ICR services included in the CMS change request that implements the National Coverage Determination in the CR performance year.

(b) *CR participant eligibility for CR incentive payment.* (1) For EPM–CR participants, CR/ICR services paid by Medicare to any provider or supplier for AMI and CABG model beneficiaries during AMI and CABG model episodes result in eligibility for CR incentive payments.

(2) For FFS–CR participants, CR/ICR services paid by Medicare to any provider or supplier for beneficiaries during AMI care periods and CABG care periods that would meet the requirements to be AMI and CABG model episodes in accordance with all provisions in subpart B if the FFS–CR participant were an EPM participant result in eligibility for CR incentive payments.

(c) *Overlap between AMI care periods and CABG care periods with AMI and CABG model episodes.* (1) An AMI care period or CABG care period does not begin if the beneficiary is in an AMI or CABG model episode when the AMI care period or CABG care period would otherwise begin.

(2) An AMI care period or CABG care period is canceled if at any time during the AMI care period or CABG care period the beneficiary initiates an AMI or CABG model episode.

(d) *CR incentive payment time period.* All AMI and CABG model episodes and AMI care periods and CABG care periods begin on or after July 1, 2017 and end on or before December 31, 2021.

§ 512.710 Determination of CR incentive payments.

(a) *General.* CMS provides a CR incentive payment for each CR performance year to each EPM–CR participant and FFS–CR participant based on CR/ICR services paid by Medicare to any provider or supplier for beneficiaries in AMI and CABG model episodes or AMI and CABG care periods, respectively. CMS makes CR incentive payments from the Medicare Part B Trust Fund to CR participants, and also submits beneficiary-specific CR amounts to the CMS Master Database Management System. The initial level of the per-service CR incentive amount is $25 per CR/ICR service for each of up to 11 CR/ICR services paid for by Medicare. For those CR/ICR services in an AMI or CABG model episode or AMI care period or CABG care period that exceed 11, the per-service CR incentive amount increases to $175 per CR/ICR service for each additional CR/ICR service paid for by Medicare.

(b) *Determination of CR incentive payment.* At the same time that CMS carries out the determination of NPRA and reconciliation process for an EPM performance year as specified in § 512.305 for EPM participants, CMS also determines each CR participant's CR incentive payment for the CR performance year according to the following:

(1*) CR amount when the CR service count is less than 12.* CMS determines the CR amount for a beneficiary in an AMI or CABG model episode or AMI care period or CABG care period with a CR service count less than 12 by multiplying the CR service count by $25.

(2) *CR amount when the CR service count is 12 or more.* CMS determines the CR amount for a beneficiary in an AMI or CABG model episode or AMI care period or CABG care period with a CR service count of 12 or more as the sum of $275 ($25 multiplied by 11 for the first 11 CR/ICR services paid for by Medicare) and $175 multiplied by the difference between the CR service count and 11.

(3) *CR incentive payment.* CMS sums the CR amounts determined in paragraphs (b)(1) and (2) of this section across the CR participant's beneficiaries in AMI and CABG model episodes or AMI care periods and CABG care periods for a given CR performance year to determine the CR incentive payment for the CR performance year.

(c) *Relation of CR incentive payments to reconciliation and Medicare repayments under EPMs.* CR incentive payments to EPM–CR participants determined under § 512.710(b) are exclusive of reconciliation payments and Medicare repayment amounts determined under § 512.305(d).

(d) *Relation of CR incentive payments to sharing arrangements for EPM–CR participants.* CR incentive payments under § 512.710(b) are not eligible for and may not be distributed under sharing arrangements specified in § 512.500.

(e) *Exclusion of CR incentive payments when updating quality-adjusted target prices for EPM–CR participants.* CR incentive payments under § 512.710(b) are excluded when updating quality-adjusted target prices for EPM performance years 3 through 5.

(f) *CR incentive payment report.* At the same time CMS issues the reconciliation report as specified in § 512.305(f) to EPM participants, CMS issues each EPM–CR participant and each FFS–CR participant a CR incentive payment report for the CR performance year. Each report contains the following:

(1) The number of AMI and CABG model episodes or AMI care periods and CABG care periods attributed to the CR participant in which Medicare paid for 11 or fewer CR/ICR services for a beneficiary during the CR performance year, if any.

(2) The total number of CR/ICR services Medicare paid for during AMI and CABG model episodes or AMI care periods and CABG care periods identified in paragraph (f)(1) of this section.

(3) The amount of the CR incentive payment attributable to the AMI and CABG model episodes or AMI care periods and CABG care periods identified in paragraph (f)(1) of this section.

(4) The number of AMI and CABG model episodes or AMI care periods and CABG care periods attributed to the CR participant in which Medicare paid for 12 or more CR/ICR services for a beneficiary during the CR performance year, if any.

(5) The total number of CR/ICR services Medicare paid for during AMI and CABG model episodes or AMI care periods and CABG care periods identified in paragraph (f)(4) of this section.

(6) The amount of the CR incentive payment attributable to the AMI and CABG model episodes or AMI care periods and CABG care periods identified in paragraph (f)(4) of this section.

(7) The total amount of the CR incentive payment.

(g) *Timing of CR incentive payments.* CMS makes CR incentive payments on a retrospective basis subject to the following:

(1) For EPM–CR participants, CMS makes the CR incentive payment, if any, concurrently with EPM reconciliation payments or repayment amounts assessed for a specific EPM and CR performance year, subject to the appeals process for EPM participants in § 512.310.

(2) For FFS–CR participants, CMS makes the CR incentive payments, if any, at the same time as for EPM–CR participants, subject to the provisions in § 512.720.

Provisions for FFS–CR Participants

§ 512.715 Access to records and retention for FFS–CR participants.

FFS–CR participants and any other individuals or entities providing items or services to a FFS–CR beneficiary must do all of the following:

(a) Allow the Government, including CMS, OIG, HHS and the Comptroller General or their designees, scheduled and unscheduled access to all books, contracts, records, documents, and other evidence (including data related to CR/ICR service utilization and payments, billings, and the documentation required under § 512.740(b)) sufficient to enable the audit, evaluation, inspection, or investigation of the following:

(1) The individual's or entity's compliance with CR incentive payment model requirements.

(2) The obligation to repay any CR incentive payments owed to CMS.

(b) Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the FFS–CR participant's participation in the CR incentive payment model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(1) CMS determines a particular record or group of records should be retained for a longer period and notifies the FFS–CR participant at least 30 calendar days before the disposition date; or

(2) There has been a dispute or allegation of fraud or similar fault against the FFS–CR participant or any other individual or entity providing items or services to a FFS–CR beneficiary, in which case the records must be maintained for 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

§ 512.720 Appeals process for FFS–CR participants.

(a) *Notice of calculation error (first level of appeal).* Subject to the limitations on review in subpart H of

this part, if a FFS–CR participant wishes to dispute calculations involving a matter related to a CR incentive payment, the FFS–CR participant is required to provide written notice of the error, in a form and manner specified by CMS.

(1) Unless the FFS–CR participant provides such notice, CMS deems final the applicable CR incentive payment report 45 calendar days after the applicable CR incentive payment report is issued and proceeds with the payment as applicable.

(2) If CMS receives a notice of a calculation error within 45 calendar days of the issuance of the applicable CR incentive payment report, 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 FFS–CR participant.

(3) Only FFS–CR participants may use notice of calculation error process described in this part.

(b) *Dispute resolution process (second level of appeal).* (1) If the FFS–CR participant is dissatisfied with CMS's response to the notice of a calculation error, the FFS–CR participant may request a reconsideration review in a form and manner as specified by CMS.

(2) The reconsideration request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the FFS–CR participant's assertion that CMS or its representatives did not accurately calculate the CR incentive payment in accordance with subpart H of this part.

(3) If CMS does not receive a request for reconsideration from the FFS–CR participant within 10 calendar days of the issue date of CMS's response to the FFS–CR participant's notice of calculation error, then CMS's response to the calculation error is deemed final and CMS proceeds with the applicable processes, as described in subpart H of this part.

(4) The CMS reconsideration official notifies the FFS–CR participant in writing within 15 calendar days of receiving the FFS–CR participant'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 the FFS–CR participant.

(7) The CMS reconsideration official issues a written determination within 30 days of the review. The determination is final and binding.

(8) Only FFS–CR participants may use the dispute resolution process described in this part.

(c) *Exception to the notice of calculation error process.* If the FFS–CR participant contests a matter that does not involve an issue contained in, or a calculation which contributes to a CR incentive payment report a notice of calculation error is not required. In these instances, if CMS does not receive a request for reconsideration from the FFS–CR participant within 10 calendar days of the notice of the initial determination, the initial determination is deemed final and CMS proceeds with the action indicated in the initial determination.

(d) *Notice of FFS–CR participant termination from the CR incentive payment model.* If an FFS–CR participant receives notification that it has been terminated from the CR incentive payment model, it must provide a written request for reconsideration to CMS requesting review of the termination within 10 calendar days of the notice. CMS has 30 days to respond to the FFS–CR participant's request for review. If the FFS–CR participant fails to notify CMS, the termination is deemed final.

(e) *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 to expand 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 (e)(1) or (2) of this section.

§ 512.725 Data sharing for FFS–CR participants.

(a) *General.* CMS makes available to FFS–CR participants, through the most appropriate means, data that CMS determines may be useful to FFS–CR participants to do the following:

(1) Determine appropriate ways to increase the coordination of care.

(2) Improve quality.

(3) Enhance efficiencies in the delivery of care.

(4) Otherwise achieve the goals of the model described in this section.

(b) *Beneficiary-identifiable data.* (1) CMS makes beneficiary-identifiable data available to a FFS–CR participant in accordance with applicable privacy laws and only in response to the FFS–CR participant's request for such data for a beneficiary who has been furnished a billable service by the FFS–CR participant corresponding to the AMI care period or CABG care period definitions.

(2) The minimum data necessary to achieve the goals of the CR incentive payment test, as determined by CMS, may be provided under this section as frequently as on a quarterly basis throughout the FFS–CR participant's participation in the CR incentive payment test.

§ 512.730 Compliance enforcement for FFS–CR participants.

(a) *General.* FFS–CR participants must comply with all of the requirements outlined in this subpart. Except as specifically noted in this subpart, the regulations under this subpart 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 FFS–CR participant does any of the following:

(i) Fails to comply with any requirements of this subpart or is identified as noncompliant through monitoring by HHS (including CMS and OIG) of the CR incentive payment model, including but not limited to the following:

(A) Avoiding potentially high severity patients.

(B) Targeting potentially low severity 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.

(ii) Takes any action that threatens the health or safety of patients.

(iii) Avoids at risk Medicare beneficiaries, as this term is defined in § 425.20.

(iv) Avoids patients on the basis of payer status.

(v) 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 subpart.

(vi) Takes any action that CMS determines for program integrity reasons is not in the best interests of the CR incentive payment model, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of CR incentive payment 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.

(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 CR incentive payment model.

(2) Remedial actions include the following:

(i) Issuing a warning letter to the FFS–CR participant.

(ii) Requiring the FFS–CR participant to develop a corrective action plan, commonly referred to as a CAP.

(iii) Reducing or eliminating the FFS–CR participant's CR incentive payment.

(iv) Terminating the FFS–CR participant from the CR incentive payment model.

§ 512.735 Enforcement authority for FFS–CR participants.

(a) *OIG authority.* OIG authority is not limited or restricted by the provisions of the CR incentive payment model, including the authority to audit, evaluate, investigate, or inspect the FFS–CR participant, or any other person or entity or their records, data, or information, without limitation.

(b) *Other authorities.* None of the provisions of the CR incentive payment model limits or restricts the authority of any other government agency permitted by law to audit, evaluate, investigate, or inspect the FFS–CR participant or any other person or entity or their records, data, or information, without limitation.

§ 512.740 Beneficiary engagement incentives for FFS–CR participant use.

(a) *General.* FFS–CR participants may choose to provide transportation to CR/ICR services as in-kind patient engagement incentives under the CR incentive payment model, subject to the following conditions:

(1) The incentive must be provided directly by the FFS–CR participant or by an agent of the FFS–CR participant under the FFS–CR participant's direction and control to the FFS–CR beneficiary during an AMI care period or CABG care period.

(2) Transportation must not be tied to the receipt of items or services other than CR/ICR services during AMI care periods or CABG care periods.

(3) Transportation must not be tied to the receipt of items or services from a particular provider or supplier.

(5) The availability of transportation must not be advertised or promoted except that a beneficiary may be made aware of the availability of transportation at the time the beneficiary could reasonably benefit from it.

(6) The cost of transportation must not be shifted to another federal health care program, as defined at section 1128B(f) of the Act.

(b) *Documentation of beneficiary engagement incentives.* (1) FFS–CR participants must maintain documentation of transportation furnished as a beneficiary engagement incentive that exceeds $25 in retail value.

(2) The documentation established contemporaneously with the provision of transportation must include at least the following:

(i) The date the incentive is provided.

(ii) The identity of the beneficiary to whom the transportation was provided.

(3) The FFS–CR participant must retain and provide access to the required documentation in accordance with § 512.715.

§ 512.745 Waiver of physician definition for furnishing CR and ICR services to a FFS–CR beneficiary.

(a) *General.* Section 410.49 of this chapter requires cardiac rehabilitation and intensive cardiac rehabilitation services to be furnished under the direction of a physician as defined in § 410.49(a) of this chapter.

(b) *Waiver of the physician definition.* For a provider or supplier of CR or ICR services to a FFS–CR beneficiary during an AMI care period or CABG care period, as defined in § 512.2. CMS waives the physician definition to allow the functions of supervising physician, prescribing exercise, and establishing, reviewing, and signing an individualized treatment plan for CR or ICR services to be furnished under the direction of—

(1) A physician, as defined in section 1861(r)(1) of the Act; or

(2) A qualified nonphysician practitioner, as defined by CMS.

(c) *Other definitions and requirements.* All other definitions and requirements in § 410.49 of this chapter related to a physician or supervising physician continue to apply.

Subparts I–J [Reserved]

Subpart K—Model Termination

§ 512.900 Termination of an episode payment model.

CMS may terminate any episode payment model for reasons including but not limited to:

(a) CMS no longer has the funds to support the applicable model; or

(b) CMS terminates the applicable 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.

§ 512.905 Termination of the CR Incentive Payment Model.

CMS may terminate the CR incentive payment model for reasons including but not limited to:

(a) CMS no longer has the funds to support the CR incentive payment model; or

(b) CMS terminates the applicable 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: July 19, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: July 20, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–17733 Filed 7–26–16; 4:15 pm]

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Part III

Department of Commerce

International Trade Administration
Privacy Shield Framework; Notice

DEPARTMENT OF COMMERCE

International Trade Administration

[Docket No. 160721646–6646–01]

RIN 0625–XC022

Privacy Shield Framework

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice of Availability of Privacy Shield Framework Documents.

SUMMARY: The International Trade Administration (ITA) is publishing this notice to announce the availability of the Privacy Shield Framework documents. The EU-U.S. Privacy Shield Framework was designed by the U.S. Department of Commerce and European Commission to provide companies on both sides of the Atlantic with a mechanism to comply with European Union data protection requirements when transferring personal data from the European Union to the United States in support of transatlantic commerce. The Privacy Shield Framework documents published in this notice include the Privacy Shield Principles and Annex I describing the new arbitral model available under the Privacy Shield, letters from the Secretary of Commerce and Acting Under Secretary for International Trade describing the Department of Commerce's administration of the Privacy Shield, letters from the Chairwoman of the Federal Trade Commission and Secretary of Transportation describing their enforcement of the Privacy Shield, a letter from the Secretary of State regarding the Privacy Shield Ombudsperson, two letters from the Office of the Director of National Intelligence regarding safeguards and limitations applicable to U.S. national security authorities, and a letter from the Department of Justice regarding safeguards and limitations on U.S. Government access for law enforcement and public interest purposes.

DATES: The Department of Commerce will begin accepting self-certifications to the Privacy Shield on August 1, 2016.

FOR FURTHER INFORMATION CONTACT: Shannon Coe, International Trade Administration, 202–482–6013 or *Shannon.Coe@trade.gov*.

SUPPLEMENTARY INFORMATION:

July 7, 2016
Ms. Věra Jourová
Commissioner for Justice, Consumers and Gender Equality
European Commission
Rue de la Loi/Westraat 200
1049 Brussels
Belgium

Dear Commissioner Jourová:

On behalf of the United States, I am pleased to transmit herewith a package of EU-U.S. Privacy Shield materials that is the product of two years of productive discussions among our teams. This package, along with other materials available to the Commission from public sources, provides a very strong basis for a new adequacy finding by the European Commission.[1]

We should both be proud of the improvements to the Framework. The Privacy Shield is based on Principles that have strong consensus support on both sides of the Atlantic, and we have strengthened their operation. Through our work together, we have the real opportunity to improve the protection of privacy around the world.

The Privacy Shield Package includes the Privacy Shield Principles, along with a letter, attached as Annex 1, from the International Trade Administration (ITA) of the Department of Commerce, which administers the program, describing the commitments that our Department has made to ensure that the Privacy Shield operates effectively. The Package also includes Annex 2, which includes other Department of Commerce commitments relating to the new arbitral model available under the Privacy Shield.

I have directed my staff to devote all necessary resources to implement the Privacy Shield Framework expeditiously and fully and to ensure the commitments in Annex 1 and Annex 2 are met in a timely fashion.

The Privacy Shield Package also includes other documents from other United States agencies, namely:

- A letter from the Federal Trade Commission (FTC) describing its enforcement of the Privacy Shield;
- A letter from the Department of Transportation describing its enforcement of the Privacy Shield;
- Two letters prepared by the Office of the Director of National Intelligence (ODNI) regarding safeguards and limitations applicable to U.S. national security authorities;
- A letter from the Department of State and accompanying memorandum describing the State Department's commitment to establish a new Privacy Shield Ombudsperson for submission of inquiries regarding the United States' signals intelligence practices; and
- A letter prepared by the Department of Justice regarding safeguards and limitations on U.S. Government access for law enforcement and public interest purposes.

You can be assured that the United States takes these commitments seriously.

Within 30 days of final approval of the adequacy determination, the full Privacy Shield Package will be delivered to the **Federal Register** for publication.

We look forward to working with you as the Privacy Shield is implemented and as we embark on the next phase of this process together.

[1] Provided that the Commission Decision on the adequacy of the protection provided by the EU-U.S. Privacy Shield applies to Iceland, Liechtenstein and Norway, the Privacy Shield Package will cover both the European Union, as well as these three countries.

Sincerely,
Penny Pritzker

Annex 1: Letter From Acting Under Secretary for International Trade Ken Hyatt

The Honorable Věra Jourová
Commissioner for Justice, Consumers and Gender Equality
European Commission
Rue de la Loi/Westraat 200
1049 Brussels
Belgium

Dear Commissioner Jourová:

On behalf of the International Trade Administration, I am pleased to describe the enhanced protection of personal data that the EU-U.S. Privacy Shield Framework (''Privacy Shield'' or ''Framework'') provides and the commitments the Department of Commerce (''Department'') has made to ensure that the Privacy Shield operates effectively. Finalizing this historic arrangement is a major achievement for privacy and for businesses on both sides of the Atlantic. It offers confidence to EU individuals that their data will be protected and that they will have legal remedies to address any concerns. It offers certainty that will help grow the transatlantic economy by ensuring that thousands of European and American businesses can continue to invest and do business across our borders. The Privacy Shield is the result of over two years of hard work and collaboration with you, our colleagues in the European Commission (''Commission''). We look forward to continuing to work with the Commission to ensure that the Privacy Shield functions as intended.

We have worked with the Commission to develop the Privacy Shield to allow organizations established in the United States to meet the adequacy requirements for data protection under EU law. The new Framework will yield several significant benefits for both individuals and businesses. First, it provides an important set of privacy protections for the data of EU individuals. It requires participating U.S. organizations to develop a conforming privacy policy, publicly commit to comply with the Privacy Shield Principles so that the commitment becomes enforceable under U.S. law, annually re-certify their compliance to the Department, provide free independent dispute resolution to EU individuals, and be subject to the authority of the U.S. Federal Trade Commission (''FTC''), Department of Transportation (''DOT''), or another enforcement agency. Second, the Privacy Shield will enable thousands of companies in the United States and subsidiaries of European companies in the United States to receive personal data from the European Union to facilitate data flows that support transatlantic trade. The transatlantic economic relationship is already the world's largest, accounting for half of global economic output and nearly one trillion dollars in goods and services trade, supporting millions of jobs on both sides of the Atlantic. Businesses that rely on transatlantic data flows come from all industry sectors and include major Fortune 500 firms as well as many small and

medium-sized enterprises (SMEs). Transatlantic data flows allow U.S. organizations to process data required to offer goods, services, and employment opportunities to European individuals. The Privacy Shield supports shared privacy principles, bridging the differences in our legal approaches, while furthering trade and economic objectives of both Europe and the United States.

While a company's decision to self-certify to this new Framework will be voluntary, once a company publicly commits to the Privacy Shield, its commitment is enforceable under U.S. law by either the Federal Trade Commission or Department of Transportation, depending on which authority has jurisdiction over the Privacy Shield organization.

Enhancements Under the Privacy Shield Principles

The resulting Privacy Shield strengthens the protection of privacy by:

• Requiring additional information be provided to individuals in the Notice Principle, including a declaration of the organization's participation in the Privacy Shield, a statement of the individual's right to access personal data, and the identification of the relevant independent dispute resolution body;

• strengthening protection of personal data that is transferred from a Privacy Shield organization to a third party controller by requiring the parties to enter into a contract that provides that such data may only be processed for limited and specified purposes consistent with the consent provided by the individual and that the recipient will provide the same level of protection as the Principles;

• strengthening protection of personal data that is transferred from a Privacy Shield organization to a third party agent, including by requiring a Privacy Shield organization to: take reasonable and appropriate steps to ensure that the agent effectively processes the personal information transferred in a manner consistent with the organization's obligations under the Principles; upon notice, take reasonable and appropriate steps to stop and remediate unauthorized processing; and provide a summary or a representative copy of the relevant privacy provisions of its contract with that agent to the Department upon request;

• providing that a Privacy Shield organization is responsible for the processing of personal information it receives under the Privacy Shield and subsequently transfers to a third party acting as an agent on its behalf, and that the Privacy Shield organization shall remain liable under the Principles if its agent processes such personal information in a manner inconsistent with the Principles, unless the organization proves that it is not responsible for the event giving rise to the damage;

• clarifying that Privacy Shield organizations must limit personal information to the information that is relevant for the purposes of processing;

• requiring an organization to annually certify with the Department its commitment to apply the Principles to information it received while it participated in the Privacy Shield if it leaves the Privacy Shield and chooses to keep such data;

• requiring that independent recourse mechanisms be provided at no cost to the individual;

• requiring organizations and their selected independent recourse mechanisms to respond promptly to inquiries and requests by the Department for information relating to the Privacy Shield;

• requiring organizations to respond expeditiously to complaints regarding compliance with the Principles referred by EU Member State authorities through the Department; and

• requiring a Privacy Shield organization to make public any relevant Privacy Shield-related sections of any compliance or assessment report submitted to the FTC if it becomes subject to an FTC or court order based on non-compliance.

Administration and Supervision of the Privacy Shield Program by the Department of Commerce

The Department reiterates its commitment to maintain and make available to the public an authoritative list of U.S. organizations that have self-certified to the Department and declared their commitment to adhere to the Principles (the ''Privacy Shield List''). The Department will keep the Privacy Shield List up to date by removing organizations when they voluntarily withdraw, fail to complete the annual re-certification in accordance with the Department's procedures, or are found to persistently fail to comply. The Department will also maintain and make available to the public an authoritative record of U.S. organizations that had previously self-certified to the Department, but that have been removed from the Privacy Shield List, including those that were removed for persistent failure to comply with the Principles. The Department will identify the reason each organization was removed.

In addition, the Department commits to strengthening the administration and supervision of the Privacy Shield. Specifically, the Department will:

Provide Additional Information on the Privacy Shield Web Site

• Maintain the Privacy Shield List, as well as a record of those organizations that previously self-certified their adherence to the Principles, but which are no longer assured of the benefits of the Privacy Shield;

• include a prominently placed explanation clarifying that all organizations removed from the Privacy Shield List are no longer assured of the benefits of the Privacy Shield, but must nevertheless continue to apply the Principles to the personal information that they received while they participated in the Privacy Shield for as long as they retain such information; and

• provide a link to the list of Privacy Shield-related FTC cases maintained on the FTC Web site.

Verify Self-Certification Requirements

• Prior to finalizing an organization's self-certification (or annual re-certification) and placing an organization on the Privacy Shield List, verify that the organization has:

○ Provided required organization contact information;

○ described the activities of the organization with respect to personal information received from the EU;

○ indicated what personal information is covered by its self-certification;

○ if the organization has a public Web site, provided the web address where the privacy policy is available and the privacy policy is accessible at the web address provided, or if an organization does not have a public Web site, provided where the privacy policy is available for viewing by the public;

○ included in its relevant privacy policy a statement that it adheres to the Principles and if the privacy policy is available online, a hyperlink to the Department's Privacy Shield Web site;

○ identified the specific statutory body that has jurisdiction to hear any claims against the organization regarding possible unfair or deceptive practices and violations of laws or regulations governing privacy (and that is listed in the Principles or a future annex to the Principles);

○ if the organization elects to satisfy the requirements in points (a)(i) and (a)(iii) of the Recourse, Enforcement and Liability Principle by committing to cooperate with the appropriate EU data protection authorities (''DPAs''), indicated its intention to cooperate with DPAs in the investigation and resolution of complaints brought under the Privacy Shield, notably to respond to their inquiries when EU data subjects have brought their complaints directly to their national DPAs;

○ identified any privacy program in which the organization is a member;

○ identified the method of verification of assuring compliance with the Principles (*e.g.,* in-house, third party);

○ identified, both in its self-certification submission and in its privacy policy, the independent recourse mechanism that is available to investigate and resolve complaints;

○ included in its relevant privacy policy, if the policy is available online, a hyperlink to the Web site or complaint submission form of the independent recourse mechanism that is available to investigate unresolved complaints; and

○ if the organization has indicated that it intends to receive human resources information transferred from the EU for use in the context of the employment relationship, declared its commitment to cooperate and comply with DPAs to resolve complaints concerning its activities with regard to such data, provided the Department with a copy of its human resources privacy policy, and provided where the privacy policy is available for viewing by its affected employees.

• work with independent recourse mechanisms to verify that the organizations have in fact registered with the relevant mechanism indicated in their self-certification submissions, where such registration is required.

Expand Efforts To Follow Up With Organizations That Have Been Removed From the Privacy Shield List

• notify organizations that are removed from the Privacy Shield List for ''persistent failure to comply'' that they are not entitled

to retain information collected under the Privacy Shield; and

• send questionnaires to organizations whose self-certifications lapse or who have voluntarily withdrawn from the Privacy Shield to verify whether the organization will return, delete, or continue to apply the Principles to the personal information that they received while they participated in the Privacy Shield, and if personal information will be retained, verify who within the organization will serve as an ongoing point of contact for Privacy Shield-related questions.

Search for and Address False Claims of Participation

• Review the privacy policies of organizations that have previously participated in the Privacy Shield program, but that have been removed from the Privacy Shield List to identify any false claims of Privacy Shield participation;

• on an ongoing basis, when an organization: (a) Withdraws from participation in the Privacy Shield, (b) fails to recertify its adherence to the Principles, or (c) is removed as a participant in the Privacy Shield notably for ''persistent failure to comply,'' undertake, on an *ex officio* basis, to verify that the organization has removed from any relevant published privacy policy any references to the Privacy Shield that imply that the organization continues to actively participate in the Privacy Shield and is entitled to its benefits. Where the Department finds that such references have not been removed, the Department will warn the organization that the Department will, as appropriate, refer matters to the relevant agency for potential enforcement action if it continues to make the claim of Privacy Shield certification. If the organization neither removes the references nor self-certifies its compliance under the Privacy Shield, the Department will *ex officio* refer the matter to the FTC, DOT, or other appropriate enforcement agency or, in appropriate cases, take action to enforce the Privacy Shield certification mark;

• undertake other efforts to identify false claims of Privacy Shield participation and improper use of the Privacy Shield certification mark, including by conducting Internet searches to identify where images of the Privacy Shield certification mark are being displayed and references to Privacy Shield in organizations' privacy policies;

• promptly address any issues that we identify during our *ex officio* monitoring of false claims of participation and misuse of the certification mark, including warning organizations misrepresenting their participation in the Privacy Shield program as described above;

• take other appropriate corrective action, including pursuing any legal recourse the Department is authorized to take and referring matters to the FTC, DOT, or another appropriate enforcement agency; and

• promptly review and address complaints about false claims of participation that we receive.

The Department will undertake reviews of privacy policies of organizations to more effectively identify and address false claims of Privacy Shield participation. Specifically, the Department will review the privacy policies of organizations whose self-certification has lapsed due to their failure to re-certify adherence to the Principles. The Department will conduct this type of review to verify that such organizations have removed from any relevant published privacy policy any references that imply that the organizations continue to actively participate in the Privacy Shield. As a result of these types of reviews, we will identify organizations that have not removed such references and send those organizations a letter from the Department's Office of General Counsel warning of potential enforcement action if the references are not removed. The Department will take follow-up action to ensure that the organizations either remove the inappropriate references or re-certify their adherence to the Principles. In addition, the Department will undertake efforts to identify false claims of Privacy Shield participation by organizations that have never participated in the Privacy Shield program, and will take similar corrective action with respect to such organizations.

Conduct Periodic *ex officio* Compliance Reviews and Assessments of the Program

• On an ongoing basis, monitor effective compliance, including through sending detailed questionnaires to participating organizations, to identify issues that may warrant further follow-up action. In particular, such compliance reviews shall take place when: (a) The Department has received specific non-frivolous complaints about an organization's compliance with the Principles, (b) an organization does not respond satisfactorily to inquiries by the Department for information relating to the Privacy Shield, or (c) there is credible evidence that an organization does not comply with its commitments under the Privacy Shield. The Department shall, when appropriate, consult with the competent data protection authorities about such compliance reviews; and

• assess periodically the administration and supervision of the Privacy Shield program to ensure that monitoring efforts are appropriate to address new issues as they arise.

The Department has increased the resources that will be devoted to the administration and supervision of the Privacy Shield program, including doubling the number of staff responsible for the administration and supervision of the program. We will continue to dedicate appropriate resources to such efforts to ensure effective monitoring and administration of the program.

Tailor the Privacy Shield Web Site to Targeted Audiences

The Department will tailor the Privacy Shield Web site to focus on three target audiences: EU individuals, EU businesses, and U.S. businesses. The inclusion of material targeted directly to EU individuals and EU businesses will facilitate transparency in a number of ways. With regard to EU individuals, it will clearly explain: (1) The rights the Privacy Shield provides to EU individuals; (2) the recourse mechanisms available to EU individuals when they believe an organization has breached its commitment to comply with the Principles; and (3) how to find information pertaining to an organization's Privacy Shield self-certification. With regard to EU businesses, it will facilitate verification of: (1) Whether an organization is assured of the benefits of the Privacy Shield; (2) the type of information covered by an organization's Privacy Shield self-certification; (3) the privacy policy that applies to the covered information; and (4) the method the organization uses to verify its adherence to the Principles.

Increase Cooperation With DPAs

To increase opportunities for cooperation with DPAs, the Department will establish a dedicated contact at the Department to act as a liaison with DPAs. In instances where a DPA believes that an organization is not complying with the Principles, including following a complaint from an EU individual, the DPA can reach out to the dedicated contact at the Department to refer the organization for further review. The contact will also receive referrals regarding organizations that falsely claim to participate in the Privacy Shield, despite never having self-certified their adherence to the Principles. The contact will assist DPAs seeking information related to a specific organization's self-certification or previous participation in the program, and the contact will respond to DPA inquiries regarding the implementation of specific Privacy Shield requirements. Second, the Department will provide DPAs with material regarding the Privacy Shield for inclusion on their own Web sites to increase transparency for EU individuals and EU businesses. Increased awareness regarding the Privacy Shield and the rights and responsibilities it creates should facilitate the identification of issues as they arise, so that these can be appropriately addressed.

Facilitate Resolution of Complaints About Non-Compliance

The Department, through the dedicated contact, will receive complaints referred to the Department by a DPA that a Privacy Shield organization is not complying with the Principles. The Department will make its best effort to facilitate resolution of the complaint with the Privacy Shield organization. Within 90 days after receipt of the complaint, the Department will provide an update to the DPA. To facilitate the submission of such complaints, the Department will create a standard form for DPAs to submit to the Department's dedicated contact. The dedicated contact will track all referrals from DPAs received by the Department, and the Department will provide in the annual review described below a report analyzing in aggregate the complaints it receives each year.

Adopt Arbitral Procedures and Select Arbitrators in Consultation With the Commission

The Department will fulfill its commitments under Annex I and publish the procedures after agreement has been reached.

Joint Review Mechanism of the Functioning of the Privacy Shield

The Department of Commerce, the FTC, and other agencies, as appropriate, will hold annual meetings with the Commission, interested DPAs, and appropriate representatives from the Article 29 Working Party, where the Department will provide updates on the Privacy Shield program. The annual meetings will include discussion of current issues related to the functioning, implementation, supervision, and enforcement of the Privacy Shield, including referrals received by the Department from DPAs, the results of *ex officio* compliance reviews, and may also include discussion of relevant changes of law. The first annual review and subsequent reviews as appropriate will include a dialogue on other topics, such as in the area of automated decision-making, including aspects relating to similarities and differences in approaches in the EU and the US.

Update of Laws

The Department will make reasonable efforts to inform the Commission of material developments in the law in the United States so far as they are relevant to the Privacy Shield in the field of data privacy protection and the limitations and safeguards applicable to access to personal data by U.S. authorities and its subsequent use.

National Security Exception

With respect to the limitations to the adherence to the Privacy Shield Principles for national security purposes, the General Counsel of the Office of the Director of National Intelligence, Robert Litt, has also sent two letters addressed to Justin Antonipillai and Ted Dean of the Department of Commerce, and these have been forwarded to you. These letters extensively discuss, among other things, the policies, safeguards, and limitations that apply to signals intelligence activities conducted by the U.S. In addition, these letters describe the transparency provided by the Intelligence Community about these matters. As the Commission is assessing the Privacy Shield Framework, the information in these letters provides assurance to conclude that the Privacy Shield will operate appropriately, in accordance with the Principles therein. We understand that you may raise information that has been released publicly by the Intelligence Community, along with other information, in the future to inform the annual review of the Privacy Shield Framework.

On the basis of the Privacy Shield Principles and the accompanying letters and materials, including the Department's commitments regarding the administration and supervision of the Privacy Shield Framework, our expectation is that the Commission will determine that the EU-U.S. Privacy Shield Framework provides adequate protection for the purposes of EU law and data transfers from the European Union will continue to organizations that participate in the Privacy Shield.

Sincerely,
Ken Hyatt

Annex 2: Arbitral Model

Annex I

This Annex I provides the terms under which Privacy Shield organizations are obligated to arbitrate claims, pursuant to the Recourse, Enforcement and Liability Principle. The binding arbitration option described below applies to certain ''residual'' claims as to data covered by the EU-U.S. Privacy Shield. The purpose of this option is to provide a prompt, independent, and fair mechanism, at the option of individuals, for resolution of claimed violations of the Principles not resolved by any of the other Privacy Shield mechanisms, if any.

A. Scope

This arbitration option is available to an individual to determine, for residual claims, whether a Privacy Shield organization has violated its obligations under the Principles as to that individual, and whether any such violation remains fully or partially unremedied. This option is available only for these purposes. This option is not available, for example, with respect to the exceptions to the Principles [1] or with respect to an allegation about the adequacy of the Privacy Shield.

B. Available Remedies

Under this arbitration option, the Privacy Shield Panel (consisting of one or three arbitrators, as agreed by the parties) has the authority to impose individual-specific, non-monetary equitable relief (such as access, correction, deletion, or return of the individual's data in question) necessary to remedy the violation of the Principles only with respect to the individual. These are the only powers of the arbitration panel with respect to remedies. In considering remedies, the arbitration panel is required to consider other remedies that already have been imposed by other mechanisms under the Privacy Shield. No damages, costs, fees, or other remedies are available. Each party bears its own attorney's fees.

C. Pre-Arbitration Requirements

An individual who decides to invoke this arbitration option must take the following steps prior to initiating an arbitration claim: (1) Raise the claimed violation directly with the organization and afford the organization an opportunity to resolve the issue within the timeframe set forth in Section III.11(d)(i) of the Principles; (2) make use of the independent recourse mechanism under the Principles, which is at no cost to the individual; and (3) raise the issue through their Data Protection Authority to the Department of Commerce and afford the Department of Commerce an opportunity to use best efforts to resolve the issue within the timeframes set forth in the Letter from the International Trade Administration of the Department of Commerce, at no cost to the individual.

This arbitration option may not be invoked if the individual's same claimed violation of the Principles (1) has previously been subject to binding arbitration; (2) was the subject of a final judgment entered in a court action to which the individual was a party; or (3) was previously settled by the parties. In addition, this option may not be invoked if an EU Data Protection Authority (1) has authority under Sections III.5 or III.9 of the Principles; or (2) has the authority to resolve the claimed violation directly with the organization. A DPA's authority to resolve the same claim against an EU data controller does not alone preclude invocation of this arbitration option against a different legal entity not bound by the DPA authority.

D. Binding Nature of Decisions

An individual's decision to invoke this binding arbitration option is entirely voluntary. Arbitral decisions will be binding on all parties to the arbitration. Once invoked, the individual forgoes the option to seek relief for the same claimed violation in another forum, except that if non-monetary equitable relief does not fully remedy the claimed violation, the individual's invocation of arbitration will not preclude a claim for damages that is otherwise available in the courts.

E. Review and Enforcement

Individuals and Privacy Shield organizations will be able to seek judicial review and enforcement of the arbitral decisions pursuant to U.S. law under the Federal Arbitration Act.[2] Any such cases

[1] Section I.5 of the Principles.

[2] Chapter 2 of the Federal Arbitration Act (''FAA'') provides that ''[a]n arbitration agreement or arbitral award arising out of a legal relationship, whether contractual or not, which is considered as commercial, including a transaction, contract, or agreement described in [section 2 of the FAA], falls under the Convention [on the Recognition and Enforcement of Foreign Arbitral Awards of June 10, 1958, 21 U.S.T. 2519, T.I.A.S. No. 6997 (''New York Convention'')].'' 9 U.S.C. 202. The FAA further provides that ''[a]n agreement or award arising out of such a relationship which is entirely between citizens of the United States shall be deemed not to fall under the [New York] Convention unless that relationship involves property located abroad, envisages performance or enforcement abroad, or has some other reasonable relation with one or more foreign states.'' *Id.* Under Chapter 2, ''any party to the arbitration may apply to any court having jurisdiction under this chapter for an order confirming the award as against any other party to the arbitration. The court shall confirm the award unless it finds one of the grounds for refusal or deferral of recognition or enforcement of the award specified in the said [New York] Convention.'' *Id.* § 207. Chapter 2 further provides that ''[t]he district courts of the United States . . . shall have original jurisdiction over . . . an action or proceeding [under the New York Convention], regardless of the amount in controversy.'' *Id.* section 203.

Chapter 2 also provides that ''Chapter 1 applies to actions and proceedings brought under this chapter to the extent that chapter is not in conflict with this chapter or the [New York] Convention as ratified by the United States.'' *Id.* section 208. Chapter 1, in turn, provides that ''[a] written provision in . . . a contract evidencing a transaction involving commerce to settle by arbitration a controversy thereafter arising out of such contract or transaction, or the refusal to perform the whole or any part thereof, or an agreement in writing to submit to arbitration an existing controversy arising out of such a contract, transaction, or refusal, shall be valid, irrevocable, and enforceable, save upon such grounds as exist at law or in equity for the revocation of any

Continued

must be brought in the federal district court whose territorial coverage includes the primary place of business of the Privacy Shield organization. This arbitration option is intended to resolve individual disputes, and arbitral decisions are not intended to function as persuasive or binding precedent in matters involving other parties, including in future arbitrations or in EU or U.S. courts, or FTC proceedings.

F. The Arbitration Panel

The parties will select the arbitrators from the list of arbitrators discussed below.

Consistent with applicable law, the U.S. Department of Commerce and the European Commission will develop a list of at least 20 arbitrators, chosen on the basis of independence, integrity, and expertise. The following shall apply in connection with this process:

Arbitrators:

(1) Will remain on the list for a period of 3 years, absent exceptional circumstances or for cause, renewable for one additional period of 3 years;

(2) shall not be subject to any instructions from, or be affiliated with, either party, or any Privacy Shield organization, or the U.S., EU, or any EU Member State or any other governmental authority, public authority, or enforcement authority; and

(3) must be admitted to practice law in the U.S. and be experts in U.S. privacy law, with expertise in EU data protection law.

G. Arbitration Procedures

Consistent with applicable law, within 6 months from the adoption of the adequacy decision, the Department of Commerce and the European Commission will agree to adopt an existing, well-established set of U.S. arbitral procedures (such as AAA or JAMS) to govern proceedings before the Privacy Shield Panel, subject to each of the following considerations:

1. An individual may initiate binding arbitration, subject to the pre-arbitration requirements provision above, by delivering a ''Notice'' to the organization. The Notice shall contain a summary of steps taken under Paragraph C to resolve the claim, a description of the alleged violation, and, at the choice of the individual, any supporting documents and materials and/or a discussion of law relating to the alleged claim.

2. Procedures will be developed to ensure that an individual's same claimed violation does not receive duplicative remedies or procedures.

3. FTC action may proceed in parallel with arbitration.

4. No representative of the U.S., EU, or any EU Member State or any other governmental authority, public authority, or enforcement authority may participate in these arbitrations, provided, that at the request of an EU individual, EU DPAs may provide assistance in the preparation only of the Notice but EU DPAs may not have access to discovery or any other materials related to these arbitrations.

5. The location of the arbitration will be the United States, and the individual may choose video or telephone participation, which will be provided at no cost to the individual. In-person participation will not be required.

6. The language of the arbitration will be English unless otherwise agreed by the parties. Upon a reasoned request, and taking into account whether the individual is represented by an attorney, interpretation at the arbitral hearing as well as translation of arbitral materials will be provided at no cost to the individual, unless the panel finds that, under the circumstances of the specific arbitration, this would lead to unjustified or disproportionate costs.

7. Materials submitted to arbitrators will be treated confidentially and will only be used in connection with the arbitration.

8. Individual-specific discovery may be permitted if necessary, and such discovery will be treated confidentially by the parties and will only be used in connection with the arbitration.

9. Arbitrations should be completed within 90 days of the delivery of the Notice to the organization at issue, unless otherwise agreed to by the parties.

H. Costs

Arbitrators should take reasonable steps to minimize the costs or fees of the arbitrations.

Subject to applicable law, the Department of Commerce will facilitate the establishment of a fund, into which Privacy Shield organizations will be required to pay an annual contribution, based in part on the size of the organization, which will cover the arbitral cost, including arbitrator fees, up to maximum amounts (''caps''), in consultation with the European Commission. The fund will be managed by a third party, which will report regularly on the operations of the fund. At the annual review, the Department of Commerce and European Commission will review the operation of the fund, including the need to adjust the amount of the contributions or of the caps, and will consider, among other things, the number of arbitrations and the costs and timing of the arbitrations, with the mutual understanding that there will be no excessive financial burden imposed on Privacy Shield organizations. Attorney's fees are not covered by this provision or any fund under this provision.

EU-U.S. Privacy Shield Principles

EU-U.S. Privacy Shield Framework Principles Issued by the U.S. Department of Commerce

I. Overview

1. While the United States and the European Union share the goal of enhancing privacy protection, the United States takes a different approach to privacy from that taken by the European Union. The United States uses a sectoral approach that relies on a mix of legislation, regulation, and self-regulation. Given those differences and to provide organizations in the United States with a reliable mechanism for personal data transfers to the United States from the European Union while ensuring that EU data subjects continue to benefit from effective safeguards and protection as required by European legislation with respect to the processing of their personal data when they have been transferred to non-EU countries, the Department of Commerce is issuing these Privacy Shield Principles, including the Supplemental Principles (collectively ''the Principles'') under its statutory authority to foster, promote, and develop international commerce (15 U.S.C. 1512). The Principles were developed in consultation with the European Commission, and with industry and other stakeholders, to facilitate trade and commerce between the United States and European Union. They are intended for use solely by organizations in the United States receiving personal data from the European Union for the purpose of qualifying for the Privacy Shield and thus benefitting from the European Commission's adequacy decision.[1] The Principles do not affect the application of national provisions implementing Directive 95/46/EC (''the Directive'') that apply to the processing of personal data in the Member States. Nor do the Principles limit privacy obligations that otherwise apply under U.S. law.

2. In order to rely on the Privacy Shield to effectuate transfers of personal data from the EU, an organization must self-certify its adherence to the Principles to the Department of Commerce (or its designee) (''the Department''). While decisions by organizations to thus enter the Privacy Shield are entirely voluntary, effective compliance is compulsory: Organizations that self-certify to the Department and publicly declare their commitment to adhere to the Principles must comply fully with the Principles. In order to enter the Privacy Shield, an organization must (a) be subject to the investigatory and enforcement powers of the Federal Trade Commission (the ''FTC''), the Department of Transportation or another statutory body that will effectively ensure compliance with the Principles *(other U.S. statutory bodies recognized by the EU may be included as an annex in the future)*; (b) publicly declare its commitment to comply with the Principles; (c) publicly disclose its privacy policies in line with these Principles; and (d) fully implement them. An organization's failure to comply is enforceable under Section 5 of the Federal Trade Commission Act prohibiting unfair and deceptive acts in or affecting commerce (15 U.S.C. 45(a)) or other laws or regulations prohibiting such acts.

3. The Department of Commerce will maintain and make available to the public an authoritative list of U.S. organizations that have self-certified to the Department and declared their commitment to adhere to the Principles (''the Privacy Shield List''). Privacy Shield benefits are assured from the

contract.'' *Id.* section 2. Chapter 1 further provides that ''any party to the arbitration may apply to the court so specified for an order confirming the award, and thereupon the court must grant such an order unless the award is vacated, modified, or corrected as prescribed in sections 10 and 11 of [the FAA].'' *Id.* section 9.

[1] Provided that the Commission Decision on the adequacy of the protection provided by the EU-U.S. Privacy Shield applies to Iceland, Liechtenstein and Norway, the Privacy Shield Package will cover both the European Union, as well as these three countries. Consequently, references to the EU and its Member States will be read as including Iceland, Liechtenstein and Norway.

date that the Department places the organization on the Privacy Shield List. The Department will remove an organization from the Privacy Shield List if it voluntarily withdraws from the Privacy Shield or if it fails to complete its annual re-certification to the Department. An organization's removal from the Privacy Shield List means it may no longer benefit from the European Commission's adequacy decision to receive personal information from the EU. The organization must continue to apply the Principles to the personal information it received while it participated in the Privacy Shield, and affirm to the Department on an annual basis its commitment to do so, for as long as it retains such information; otherwise, the organization must return or delete the information or provide ''adequate'' protection for the information by another authorized means. The Department will also remove from the Privacy Shield List those organizations that have persistently failed to comply with the Principles; these organizations do not qualify for Privacy Shield benefits and must return or delete the personal information they received under the Privacy Shield.

4. The Department will also maintain and make available to the public an authoritative record of U.S. organizations that had previously self-certified to the Department, but that have been removed from the Privacy Shield List. The Department will provide a clear warning that these organizations are not participants in the Privacy Shield; that removal from the Privacy Shield List means that such organizations cannot claim to be Privacy Shield compliant and must avoid any statements or misleading practices implying that they participate in the Privacy Shield; and that such organizations are no longer entitled to benefit from the European Commission's adequacy decision that would enable those organizations to receive personal information from the EU. An organization that continues to claim participation in the Privacy Shield or makes other Privacy Shield-related misrepresentations after it has been removed from the Privacy Shield List may be subject to enforcement action by the FTC, the Department of Transportation, or other enforcement authorities.

5. Adherence to these Principles may be limited: (a) To the extent necessary to meet national security, public interest, or law enforcement requirements; (b) by statute, government regulation, or case law that creates conflicting obligations or explicit authorizations, provided that, in exercising any such authorization, an organization can demonstrate that its non-compliance with the Principles is limited to the extent necessary to meet the overriding legitimate interests furthered by such authorization; or (c) if the effect of the Directive or Member State law is to allow exceptions or derogations, provided such exceptions or derogations are applied in comparable contexts. Consistent with the goal of enhancing privacy protection, organizations should strive to implement these Principles fully and transparently, including indicating in their privacy policies where exceptions to the Principles permitted by (b) above will apply on a regular basis. For the same reason, where the option is allowable under the Principles and/or U.S. law, organizations are expected to opt for the higher protection where possible.

6. Organizations are obligated to apply the Principles to all personal data transferred in reliance on the Privacy Shield after they enter the Privacy Shield. An organization that chooses to extend Privacy Shield benefits to human resources personal information transferred from the EU for use in the context of an employment relationship must indicate this when it self-certifies to the Department and conform to the requirements set forth in the Supplemental Principle on Self-Certification.

7. U.S. law will apply to questions of interpretation and compliance with the Principles and relevant privacy policies by Privacy Shield organizations, except where such organizations have committed to cooperate with European data protection authorities (''DPAs''). Unless otherwise stated, all provisions of the Principles apply where they are relevant.

8. Definitions:

a. ''Personal data'' and ''personal information'' are data about an identified or identifiable individual that are within the scope of the Directive, received by an organization in the United States from the European Union, and recorded in any form.

b. ''Processing'' of personal data means any operation or set of operations which is performed upon personal data, whether or not by automated means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure or dissemination, and erasure or destruction.

c. ''Controller'' means a person or organization which, alone or jointly with others, determines the purposes and means of the processing of personal data.

9. The effective date of the Principles is the date of final approval of the European Commission's adequacy determination.

II. Principles

1. Notice

a. An organization must inform individuals about:

i. Its participation in the Privacy Shield and provide a link to, or the web address for, the Privacy Shield List,

ii. the types of personal data collected and, where applicable, the entities or subsidiaries of the organization also adhering to the Principles,

iii. its commitment to subject to the Principles all personal data received from the EU in reliance on the Privacy Shield,

iv. the purposes for which it collects and uses personal information about them,

v. how to contact the organization with any inquiries or complaints, including any relevant establishment in the EU that can respond to such inquiries or complaints,

vi. the type or identity of third parties to which it discloses personal information, and the purposes for which it does so,

vii. the right of individuals to access their personal data,

viii. the choices and means the organization offers individuals for limiting the use and disclosure of their personal data,

ix. the independent dispute resolution body designated to address complaints and provide appropriate recourse free of charge to the individual, and whether it is: (1) The panel established by DPAs, (2) an alternative dispute resolution provider based in the EU, or (3) an alternative dispute resolution provider based in the United States,

x. being subject to the investigatory and enforcement powers of the FTC, the Department of Transportation or any other U.S. authorized statutory body,

xi. the possibility, under certain conditions, for the individual to invoke binding arbitration,

xii. the requirement to disclose personal information in response to lawful requests by public authorities, including to meet national security or law enforcement requirements, and

xiii. its liability in cases of onward transfers to third parties.

b. This notice must be provided in clear and conspicuous language when individuals are first asked to provide personal information to the organization or as soon thereafter as is practicable, but in any event before the organization uses such information for a purpose other than that for which it was originally collected or processed by the transferring organization or discloses it for the first time to a third party.

2. Choice

a. An organization must offer individuals the opportunity to choose (opt out) whether their personal information is (i) to be disclosed to a third party or (ii) to be used for a purpose that is materially different from the purpose(s) for which it was originally collected or subsequently authorized by the individuals. Individuals must be provided with clear, conspicuous, and readily available mechanisms to exercise choice.

b. By derogation to the previous paragraph, it is not necessary to provide choice when disclosure is made to a third party that is acting as an agent to perform task(s) on behalf of and under the instructions of the organization. However, an organization shall always enter into a contract with the agent.

c. For sensitive information (*i.e.,* personal information specifying medical or health conditions, racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership or information specifying the sex life of the individual), organizations must obtain affirmative express consent (opt in) from individuals if such information is to be (i) disclosed to a third party or (ii) used for a purpose other than those for which it was originally collected or subsequently authorized by the individuals through the exercise of opt-in choice. In addition, an organization should treat as sensitive any personal information received from a third party where the third party identifies and treats it as sensitive.

3. Accountability for Onward Transfer

a. To transfer personal information to a third party acting as a controller, organizations must comply with the Notice and Choice Principles. Organizations must also enter into a contract with the third-party controller that provides that such data may

only be processed for limited and specified purposes consistent with the consent provided by the individual and that the recipient will provide the same level of protection as the Principles and will notify the organization if it makes a determination that it can no longer meet this obligation. The contract shall provide that when such a determination is made the third party controller ceases processing or takes other reasonable and appropriate steps to remediate.

b. To transfer personal data to a third party acting as an agent, organizations must: (i) Transfer such data only for limited and specified purposes; (ii) ascertain that the agent is obligated to provide at least the same level of privacy protection as is required by the Principles; (iii) take reasonable and appropriate steps to ensure that the agent effectively processes the personal information transferred in a manner consistent with the organization's obligations under the Principles; (iv) require the agent to notify the organization if it makes a determination that it can no longer meet its obligation to provide the same level of protection as is required by the Principles; (v) upon notice, including under (iv), take reasonable and appropriate steps to stop and remediate unauthorized processing; and (vi) provide a summary or a representative copy of the relevant privacy provisions of its contract with that agent to the Department upon request.

4. Security

a. Organizations creating, maintaining, using or disseminating personal information must take reasonable and appropriate measures to protect it from loss, misuse and unauthorized access, disclosure, alteration and destruction, taking into due account the risks involved in the processing and the nature of the personal data.

5. Data Integrity and Purpose Limitation

a. Consistent with the Principles, personal information must be limited to the information that is relevant for the purposes of processing.[2] An organization may not process personal information in a way that is incompatible with the purposes for which it has been collected or subsequently authorized by the individual. To the extent necessary for those purposes, an organization must take reasonable steps to ensure that personal data is reliable for its intended use, accurate, complete, and current. An organization must adhere to the Principles for as long as it retains such information.

b. Information may be retained in a form identifying or making identifiable[3] the individual only for as long as it serves a purpose of processing within the meaning of 5a. This obligation does not prevent organizations from processing personal information for longer periods for the time and to the extent such processing reasonably serves the purposes of archiving in the public interest, journalism, literature and art, scientific or historical research, and statistical analysis. In these cases, such processing shall be subject to the other Principles and provisions of the Framework. Organizations should take reasonable and appropriate measures in complying with this provision.

6. Access

a. Individuals must have access to personal information about them that an organization holds and be able to correct, amend, or delete that information where it is inaccurate, or has been processed in violation of the Principles, except where the burden or expense of providing access would be disproportionate to the risks to the individual's privacy in the case in question, or where the rights of persons other than the individual would be violated.

7. Recourse, Enforcement and Liability

a. Effective privacy protection must include robust mechanisms for assuring compliance with the Principles, recourse for individuals who are affected by non-compliance with the Principles, and consequences for the organization when the Principles are not followed. At a minimum such mechanisms must include:

i. Readily available independent recourse mechanisms by which each individual's complaints and disputes are investigated and expeditiously resolved at no cost to the individual and by reference to the Principles, and damages awarded where the applicable law or private-sector initiatives so provide;

ii. follow-up procedures for verifying that the attestations and assertions organizations make about their privacy practices are true and that privacy practices have been implemented as presented and, in particular, with regard to cases of non-compliance; and

iii. obligations to remedy problems arising out of failure to comply with the Principles by organizations announcing their adherence to them and consequences for such organizations. Sanctions must be sufficiently rigorous to ensure compliance by organizations.

b. Organizations and their selected independent recourse mechanisms will respond promptly to inquiries and requests by the Department for information relating to the Privacy Shield. All organizations must respond expeditiously to complaints regarding compliance with the Principles referred by EU Member State authorities through the Department. Organizations that have chosen to cooperate with DPAs, including organizations that process human resources data, must respond directly to such authorities with regard to the investigation and resolution of complaints.

c. Organizations are obligated to arbitrate claims and follow the terms as set forth in Annex I, provided that an individual has invoked binding arbitration by delivering notice to the organization at issue and following the procedures and subject to conditions set forth in Annex I.

d. In the context of an onward transfer, a Privacy Shield organization has responsibility for the processing of personal information it receives under the Privacy Shield and subsequently transfers to a third party acting as an agent on its behalf. The Privacy Shield organization shall remain liable under the Principles if its agent processes such personal information in a manner inconsistent with the Principles, unless the organization proves that it is not responsible for the event giving rise to the damage.

e. When an organization becomes subject to an FTC or court order based on non-compliance, the organization shall make public any relevant Privacy Shield-related sections of any compliance or assessment report submitted to the FTC, to the extent consistent with confidentiality requirements. The Department has established a dedicated point of contact for DPAs for any problems of compliance by Privacy Shield organizations. The FTC will give priority consideration to referrals of non-compliance with the Principles from the Department and EU Member State authorities, and will exchange information regarding referrals with the referring state authorities on a timely basis, subject to existing confidentiality restrictions.

III. Supplemental Principles

1. Sensitive Data

a. An organization is not required to obtain affirmative express consent (opt in) with respect to sensitive data where the processing is:

i. In the vital interests of the data subject or another person;

ii. necessary for the establishment of legal claims or defenses;

iii. required to provide medical care or diagnosis;

iv. carried out in the course of legitimate activities by a foundation, association or any other non-profit body with a political, philosophical, religious or trade-union aim and on condition that the processing relates solely to the members of the body or to the persons who have regular contact with it in connection with its purposes and that the data are not disclosed to a third party without the consent of the data subjects;

v. necessary to carry out the organization's obligations in the field of employment law; or

vi. related to data that are manifestly made public by the individual.

2. Journalistic Exceptions

a. Given U.S. constitutional protections for freedom of the press and the Directive's exemption for journalistic material, where the rights of a free press embodied in the First Amendment of the U.S. Constitution intersect with privacy protection interests, the First Amendment must govern the balancing of these interests with regard to the activities of U.S. persons or organizations.

[2] Depending on the circumstances, examples of compatible processing purposes may include those that reasonably serve customer relations, compliance and legal considerations, auditing, security and fraud prevention, preserving or defending the organization's legal rights, or other purposes consistent with the expectations of a reasonable person given the context of the collection.

[3] In this context, if, given the means of identification reasonably likely to be used (considering, among other things, the costs of and the amount of time required for identification and the available technology at the time of the processing) and the form in which the data is retained, an individual could reasonably be identified by the organization, or a third party if it would have access to the data, then the individual is ''identifiable.''

b. Personal information that is gathered for publication, broadcast, or other forms of public communication of journalistic material, whether used or not, as well as information found in previously published material disseminated from media archives, is not subject to the requirements of the Privacy Shield Principles.

3. Secondary Liability

a. Internet Service Providers (''ISPs''), telecommunications carriers, and other organizations are not liable under the Privacy Shield Principles when on behalf of another organization they merely transmit, route, switch, or cache information. As is the case with the Directive itself, the Privacy Shield does not create secondary liability. To the extent that an organization is acting as a mere conduit for data transmitted by third parties and does not determine the purposes and means of processing those personal data, it would not be liable.

4. Performing Due Diligence and Conducting Audits

a. The activities of auditors and investment bankers may involve processing personal data without the consent or knowledge of the individual. This is permitted by the Notice, Choice, and Access Principles under the circumstances described below.

b. Public stock corporations and closely held companies, including Privacy Shield organizations, are regularly subject to audits. Such audits, particularly those looking into potential wrongdoing, may be jeopardized if disclosed prematurely. Similarly, a Privacy Shield organization involved in a potential merger or takeover will need to perform, or be the subject of, a ''due diligence'' review. This will often entail the collection and processing of personal data, such as information on senior executives and other key personnel. Premature disclosure could impede the transaction or even violate applicable securities regulation. Investment bankers and attorneys engaged in due diligence, or auditors conducting an audit, may process information without knowledge of the individual only to the extent and for the period necessary to meet statutory or public interest requirements and in other circumstances in which the application of these Principles would prejudice the legitimate interests of the organization. These legitimate interests include the monitoring of organizations' compliance with their legal obligations and legitimate accounting activities, and the need for confidentiality connected with possible acquisitions, mergers, joint ventures, or other similar transactions carried out by investment bankers or auditors.

5. The Role of the Data Protection Authorities

a. Organizations will implement their commitment to cooperate with European Union data protection authorities (''DPAs'') as described below. Under the Privacy Shield, U.S. organizations receiving personal data from the EU must commit to employ effective mechanisms for assuring compliance with the Privacy Shield Principles. More specifically as set out in the Recourse, Enforcement and Liability Principle, participating organizations must provide: (a)(i) Recourse for individuals to whom the data relate; (a)(ii) follow up procedures for verifying that the attestations and assertions they have made about their privacy practices are true; and (a)(iii) obligations to remedy problems arising out of failure to comply with the Principles and consequences for such organizations. An organization may satisfy points (a)(i) and (a)(iii) of the Recourse, Enforcement and Liability Principle if it adheres to the requirements set forth here for cooperating with the DPAs.

b. An organization commits to cooperate with the DPAs by declaring in its Privacy Shield self-certification submission to the Department of Commerce (*see* Supplemental Principle on Self-Certification) that the organization:

i. Elects to satisfy the requirement in points (a)(i) and (a)(iii) of the Privacy Shield Recourse, Enforcement and Liability Principle by committing to cooperate with the DPAs;

ii. will cooperate with the DPAs in the investigation and resolution of complaints brought under the Privacy Shield; and

iii. will comply with any advice given by the DPAs where the DPAs take the view that the organization needs to take specific action to comply with the Privacy Shield Principles, including remedial or compensatory measures for the benefit of individuals affected by any non-compliance with the Principles, and will provide the DPAs with written confirmation that such action has been taken.

c. *Operation of DPA Panels*

i. The cooperation of the DPAs will be provided in the form of information and advice in the following way:

1. The advice of the DPAs will be delivered through an informal panel of DPAs established at the European Union level, which will *inter alia* help ensure a harmonized and coherent approach.

2. The panel will provide advice to the U.S. organizations concerned on unresolved complaints from individuals about the handling of personal information that has been transferred from the EU under the Privacy Shield. This advice will be designed to ensure that the Privacy Shield Principles are being correctly applied and will include any remedies for the individual(s) concerned that the DPAs consider appropriate.

3. The panel will provide such advice in response to referrals from the organizations concerned and/or to complaints received directly from individuals against organizations which have committed to cooperate with DPAs for Privacy Shield purposes, while encouraging and if necessary helping such individuals in the first instance to use the in-house complaint handling arrangements that the organization may offer.

4. Advice will be issued only after both sides in a dispute have had a reasonable opportunity to comment and to provide any evidence they wish. The panel will seek to deliver advice as quickly as this requirement for due process allows. As a general rule, the panel will aim to provide advice within 60 days after receiving a complaint or referral and more quickly where possible.

5. The panel will make public the results of its consideration of complaints submitted to it, if it sees fit.

6. The delivery of advice through the panel will not give rise to any liability for the panel or for individual DPAs.

ii. As noted above, organizations choosing this option for dispute resolution must undertake to comply with the advice of the DPAs. If an organization fails to comply within 25 days of the delivery of the advice and has offered no satisfactory explanation for the delay, the panel will give notice of its intention either to refer the matter to the Federal Trade Commission, the Department of Transportation, or other U.S. federal or state body with statutory powers to take enforcement action in cases of deception or misrepresentation, or to conclude that the agreement to cooperate has been seriously breached and must therefore be considered null and void. In the latter case, the panel will inform the Department of Commerce so that the Privacy Shield List can be duly amended. Any failure to fulfill the undertaking to cooperate with the DPAs, as well as failures to comply with the Privacy Shield Principles, will be actionable as a deceptive practice under Section 5 of the FTC Act or other similar statute.

d. An organization that wishes its Privacy Shield benefits to cover human resources data transferred from the EU in the context of the employment relationship must commit to cooperate with the DPAs with regard to such data (*see* Supplemental Principle on Human Resources Data).

e. Organizations choosing this option will be required to pay an annual fee which will be designed to cover the operating costs of the panel, and they may additionally be asked to meet any necessary translation expenses arising out of the panel's consideration of referrals or complaints against them. The annual fee will not exceed USD 500 and will be less for smaller companies.

6. Self-Certification

a. Privacy Shield benefits are assured from the date on which the Department has placed the organization's self-certification submission on the Privacy Shield List after having determined that the submission is complete.

b. To self-certify for the Privacy Shield, an organization must provide to the Department a self-certification submission, signed by a corporate officer on behalf of the organization that is joining the Privacy Shield, that contains at least the following information:

i. Name of organization, mailing address, email address, telephone, and fax numbers;

ii. description of the activities of the organization with respect to personal information received from the EU; and

iii. description of the organization's privacy policy for such personal information, including:

1. If the organization has a public Web site, the relevant web address where the privacy policy is available, or if the organization does not have a public Web site, where the privacy policy is available for viewing by the public;

2. its effective date of implementation;

3. a contact office for the handling of complaints, access requests, and any other issues arising under the Privacy Shield;

4. the specific statutory body that has jurisdiction to hear any claims against the organization regarding possible unfair or deceptive practices and violations of laws or regulations governing privacy (and that is listed in the Principles or a future annex to the Principles);

5. name of any privacy program in which the organization is a member;

6. method of verification (*e.g.,* in-house, third party) (*see* Supplemental Principle on Verification; and

7. the independent recourse mechanism that is available to investigate unresolved complaints.

c. Where the organization wishes its Privacy Shield benefits to cover human resources information transferred from the EU for use in the context of the employment relationship, it may do so where a statutory body listed in the Principles or a future annex to the Principles has jurisdiction to hear claims against the organization arising out of the processing of human resources information. In addition, the organization must indicate this in its self-certification submission and declare its commitment to cooperate with the EU authority or authorities concerned in conformity with the Supplemental Principles on Human Resources Data and the Role of the Data Protection Authorities as applicable and that it will comply with the advice given by such authorities. The organization must also provide the Department with a copy of its human resources privacy policy and provide information where the privacy policy is available for viewing by its affected employees.

d. The Department will maintain the Privacy Shield List of organizations that file completed self-certification submissions, thereby assuring the availability of Privacy Shield benefits, and will update such list on the basis of annual self-recertification submissions and notifications received pursuant to the Supplemental Principle on Dispute Resolution and Enforcement. Such self-certification submissions must be provided not less than annually; otherwise the organization will be removed from the Privacy Shield List and Privacy Shield benefits will no longer be assured. Both the Privacy Shield List and the self-certification submissions by the organizations will be made publicly available. All organizations that are placed on the Privacy Shield List by the Department must also state in their relevant published privacy policy statements that they adhere to the Privacy Shield Principles. If available online, an organization's privacy policy must include a hyperlink to the Department's Privacy Shield Web site and a hyperlink to the Web site or complaint submission form of the independent recourse mechanism that is available to investigate unresolved complaints.

e. The Privacy Principles apply immediately upon certification. Recognizing that the Principles will impact commercial relationships with third parties, organizations that certify to the Privacy Shield Framework in the first two months following the Framework's effective date shall bring existing commercial relationships with third parties into conformity with the Accountability for Onward Transfer Principle as soon as possible, and in any event no later than nine months from the date upon which they certify to the Privacy Shield. During that interim period, where organizations transfer data to a third party, they shall (i) apply the Notice and Choice Principles, and (ii) where personal data is transferred to a third party acting as an agent, ascertain that the agent is obligated to provide at least the same level of protection as is required by the Principles.

f. An organization must subject to the Privacy Shield Principles all personal data received from the EU in reliance upon the Privacy Shield. The undertaking to adhere to the Privacy Shield Principles is not time-limited in respect of personal data received during the period in which the organization enjoys the benefits of the Privacy Shield. Its undertaking means that it will continue to apply the Principles to such data for as long as the organization stores, uses or discloses them, even if it subsequently leaves the Privacy Shield for any reason. An organization that withdraws from the Privacy Shield but wants to retain such data must affirm to the Department on an annual basis its commitment to continue to apply the Principles or provide ''adequate'' protection for the information by another authorized means (for example, using a contract that fully reflects the requirements of the relevant standard contractual clauses adopted by the European Commission); otherwise, the organization must return or delete the information. An organization that withdraws from the Privacy Shield must remove from any relevant privacy policy any references to the Privacy Shield that imply that the organization continues to actively participate in the Privacy Shield and is entitled to its benefits.

g. An organization that will cease to exist as a separate legal entity as a result of a merger or a takeover must notify the Department of this in advance. The notification should also indicate whether the acquiring entity or the entity resulting from the merger will (i) continue to be bound by the Privacy Shield Principles by the operation of law governing the takeover or merger or (ii) elect to self-certify its adherence to the Privacy Shield Principles or put in place other safeguards, such as a written agreement that will ensure adherence to the Privacy Shield Principles. Where neither (i) nor (ii) applies, any personal data that has been acquired under the Privacy Shield must be promptly deleted.

h. When an organization leaves the Privacy Shield for any reason, it must remove all statements implying that the organization continues to participate in the Privacy Shield or is entitled to the benefits of the Privacy Shield. The EU-U.S. Privacy Shield certification mark, if used, must also be removed. Any misrepresentation to the general public concerning an organization's adherence to the Privacy Shield Principles may be actionable by the FTC or other relevant government body. Misrepresentations to the Department may be actionable under the False Statements Act (18 U.S.C. 1001).

7. Verification

a. Organizations must provide follow up procedures for verifying that the attestations and assertions they make about their Privacy Shield privacy practices are true and those privacy practices have been implemented as represented and in accordance with the Privacy Shield Principles.

b. To meet the verification requirements of the Recourse, Enforcement and Liability Principle, an organization must verify such attestations and assertions either through self-assessment or outside compliance reviews.

c. Under the self-assessment approach, such verification must indicate that an organization's published privacy policy regarding personal information received from the EU is accurate, comprehensive, prominently displayed, completely implemented and accessible. It must also indicate that its privacy policy conforms to the Privacy Shield Principles; that individuals are informed of any in-house arrangements for handling complaints and of the independent mechanisms through which they may pursue complaints; that it has in place procedures for training employees in its implementation, and disciplining them for failure to follow it; and that it has in place internal procedures for periodically conducting objective reviews of compliance with the above. A statement verifying the self-assessment must be signed by a corporate officer or other authorized representative of the organization at least once a year and made available upon request by individuals or in the context of an investigation or a complaint about non-compliance.

d. Where the organization has chosen outside compliance review, such a review must demonstrate that its privacy policy regarding personal information received from the EU conforms to the Privacy Shield Principles, that it is being complied with, and that individuals are informed of the mechanisms through which they may pursue complaints. The methods of review may include, without limitation, auditing, random reviews, use of ''decoys'', or use of technology tools as appropriate. A statement verifying that an outside compliance review has been successfully completed must be signed either by the reviewer or by the corporate officer or other authorized representative of the organization at least once a year and made available upon request by individuals or in the context of an investigation or a complaint about compliance.

e. Organizations must retain their records on the implementation of their Privacy Shield privacy practices and make them available upon request in the context of an investigation or a complaint about non-compliance to the independent body responsible for investigating complaints or to the agency with unfair and deceptive practices jurisdiction. Organizations must also respond promptly to inquiries and other requests for information from the Department relating to the organization's adherence to the Principles.

8. Access

a. *The Access Principle in Practice*

i. Under the Privacy Shield Principles, the right of access is fundamental to privacy protection. In particular, it allows individuals to verify the accuracy of information held about them. The Access Principle means that individuals have the right to:

1. Obtain from an organization confirmation of whether or not the organization is processing personal data relating to them; [4]

2. have communicated to them such data so that they could verify its accuracy and the lawfulness of the processing; and

3. have the data corrected, amended or deleted where it is inaccurate or processed in violation of the Principles.

ii. Individuals do not have to justify requests for access to their personal data. In responding to individuals' access requests, organizations should first be guided by the concern(s) that led to the requests in the first place. For example, if an access request is vague or broad in scope, an organization may engage the individual in a dialogue so as to better understand the motivation for the request and to locate responsive information. The organization might inquire about which part(s) of the organization the individual interacted with or about the nature of the information or its use that is the subject of the access request.

iii. Consistent with the fundamental nature of access, organizations should always make good faith efforts to provide access. For example, where certain information needs to be protected and can be readily separated from other personal information subject to an access request, the organization should redact the protected information and make available the other information. If an organization determines that access should be restricted in any particular instance, it should provide the individual requesting access with an explanation of why it has made that determination and a contact point for any further inquiries.

b. *Burden or Expense of Providing Access*

i. The right of access to personal data may be restricted in exceptional circumstances where the legitimate rights of persons other than the individual would be violated or where the burden or expense of providing access would be disproportionate to the risks to the individual's privacy in the case in question. Expense and burden are important factors and should be taken into account but they are not controlling factors in determining whether providing access is reasonable.

ii. For example, if the personal information is used for decisions that will significantly affect the individual (*e.g.,* the denial or grant of important benefits, such as insurance, a mortgage, or a job), then consistent with the other provisions of these Supplemental Principles, the organization would have to disclose that information even if it is relatively difficult or expensive to provide. If the personal information requested is not sensitive or not used for decisions that will significantly affect the individual, but is readily available and inexpensive to provide, an organization would have to provide access to such information.

c. *Confidential Commercial Information*

i. Confidential commercial information is information that an organization has taken steps to protect from disclosure, where disclosure would help a competitor in the market. Organizations may deny or limit access to the extent that granting full access would reveal its own confidential commercial information, such as marketing inferences or classifications generated by the organization, or the confidential commercial information of another that is subject to a contractual obligation of confidentiality.

ii. Where confidential commercial information can be readily separated from other personal information subject to an access request, the organization should redact the confidential commercial information and make available the non-confidential information.

d. *Organization of Data Bases*

i. Access can be provided in the form of disclosure of the relevant personal information by an organization to the individual and does not require access by the individual to an organization's data base.

ii. Access needs to be provided only to the extent that an organization stores the personal information. The Access Principle does not itself create any obligation to retain, maintain, reorganize, or restructure personal information files.

e. *When Access May be Restricted*

i. As organizations must always make good faith efforts to provide individuals with access to their personal data, the circumstances in which organizations may restrict such access are limited, and any reasons for restricting access must be specific. As under the Directive, an organization can restrict access to information to the extent that disclosure is likely to interfere with the safeguarding of important countervailing public interests, such as national security; defense; or public security. In addition, where personal information is processed solely for research or statistical purposes, access may be denied. Other reasons for denying or limiting access are:

1. Interference with the execution or enforcement of the law or with private causes of action, including the prevention, investigation or detection of offenses or the right to a fair trial;

2. disclosure where the legitimate rights or important interests of others would be violated;

3. breaching a legal or other professional privilege or obligation;

4. prejudicing employee security investigations or grievance proceedings or in connection with employee succession planning and corporate re-organizations; or

5. prejudicing the confidentiality necessary in monitoring, inspection or regulatory functions connected with sound management, or in future or ongoing negotiations involving the organization.

ii. An organization which claims an exception has the burden of demonstrating its necessity, and the reasons for restricting access and a contact point for further inquiries should be given to individuals.

f. *Right to Obtain Confirmation and Charging a Fee to Cover the Costs for Providing Access*

i. An individual has the right to obtain confirmation of whether or not this organization has personal data relating to him or her. An individual also has the right to have communicated to him or her personal data relating to him or her. An organization may charge a fee that is not excessive.

ii. Charging a fee may be justified, for example, where requests for access are manifestly excessive, in particular because of their repetitive character.

iii. Access may not be refused on cost grounds if the individual offers to pay the costs.

g. *Repetitious or Vexatious Requests for Access*

i. An organization may set reasonable limits on the number of times within a given period that access requests from a particular individual will be met. In setting such limitations, an organization should consider such factors as the frequency with which information is updated, the purpose for which the data are used, and the nature of the information.

h. *Fraudulent Requests for Access*

i. An organization is not required to provide access unless it is supplied with sufficient information to allow it to confirm the identity of the person making the request.

i. *Timeframe for Responses*

i. Organizations should respond to access requests within a reasonable time period, in a reasonable manner, and in a form that is readily intelligible to the individual. An organization that provides information to data subjects at regular intervals may satisfy an individual access request with its regular disclosure if it would not constitute an excessive delay.

9. Human Resources Data

a. *Coverage by the Privacy Shield*

i. Where an organization in the EU transfers personal information about its employees (past or present) collected in the context of the employment relationship, to a parent, affiliate, or unaffiliated service provider in the United States participating in the Privacy Shield, the transfer enjoys the benefits of the Privacy Shield. In such cases, the collection of the information and its processing prior to transfer will have been subject to the national laws of the EU country where it was collected, and any conditions for or restrictions on its transfer according to those laws will have to be respected.

ii. The Privacy Shield Principles are relevant only when individually identified or identifiable records are transferred or accessed. Statistical reporting relying on aggregate employment data and containing no personal data or the use of anonymized data does not raise privacy concerns.

b. *Application of the Notice and Choice Principles*

i. A U.S. organization that has received employee information from the EU under the

[4] The organization should answer requests from an individual concerning the purposes of the processing, the categories of personal data concerned, and the recipients or categories of recipients to whom the personal data is disclosed.

Privacy Shield may disclose it to third parties or use it for different purposes only in accordance with the Notice and Choice Principles. For example, where an organization intends to use personal information collected through the employment relationship for non-employment-related purposes, such as marketing communications, the U.S. organization must provide the affected individuals with the requisite choice before doing so, unless they have already authorized the use of the information for such purposes. Such use must not be incompatible with the purposes for which the personal information has been collected or subsequently authorised by the individual. Moreover, such choices must not be used to restrict employment opportunities or take any punitive action against such employees.

ii. It should be noted that certain generally applicable conditions for transfer from some EU Member States may preclude other uses of such information even after transfer outside the EU and such conditions will have to be respected.

iii. In addition, employers should make reasonable efforts to accommodate employee privacy preferences. This could include, for example, restricting access to the personal data, anonymizing certain data, or assigning codes or pseudonyms when the actual names are not required for the management purpose at hand.

iv. To the extent and for the period necessary to avoid prejudicing the ability of the organization in making promotions, appointments, or other similar employment decisions, an organization does not need to offer notice and choice.

c. *Application of the Access Principle*

i. The Supplemental Principle on Access provides guidance on reasons which may justify denying or limiting access on request in the human resources context. Of course, employers in the European Union must comply with local regulations and ensure that European Union employees have access to such information as is required by law in their home countries, regardless of the location of data processing and storage. The Privacy Shield requires that an organization processing such data in the United States will cooperate in providing such access either directly or through the EU employer.

d. *Enforcement*

i. In so far as personal information is used only in the context of the employment relationship, primary responsibility for the data vis-à-vis the employee remains with the organization in the EU. It follows that, where European employees make complaints about violations of their data protection rights and are not satisfied with the results of internal review, complaint, and appeal procedures (or any applicable grievance procedures under a contract with a trade union), they should be directed to the state or national data protection or labor authority in the jurisdiction where the employees work. This includes cases where the alleged mishandling of their personal information is the responsibility of the U.S. organization that has received the information from the employer and thus involves an alleged breach of the Privacy Shield Principles. This will be the most efficient way to address the often overlapping rights and obligations imposed by local labor law and labor agreements as well as data protection law.

ii. A U.S. organization participating in the Privacy Shield that uses EU human resources data transferred from the European Union in the context of the employment relationship and that wishes such transfers to be covered by the Privacy Shield must therefore commit to cooperate in investigations by and to comply with the advice of competent EU authorities in such cases.

e. *Application of the Accountability for Onward Transfer Principle*

i. For occasional employment-related operational needs of the Privacy Shield organization with respect to personal data transferred under the Privacy Shield, such as the booking of a flight, hotel room, or insurance coverage, transfers of personal data of a small number of employees can take place to controllers without application of the Access Principle or entering into a contract with the third-party controller, as otherwise required under the Accountability for Onward Transfer Principle, provided that the Privacy Shield organization has complied with the Notice and Choice Principles.

10. Obligatory Contracts for Onward Transfers

a. *Data Processing Contracts*

i. When personal data is transferred from the EU to the United States only for processing purposes, a contract will be required, regardless of participation by the processor in the Privacy Shield.

ii. Data controllers in the European Union are always required to enter into a contract when a transfer for mere processing is made, whether the processing operation is carried out inside or outside the EU, and whether or not the processor participates in the Privacy Shield. The purpose of the contract is to make sure that the processor:

1. Acts only on instructions from the controller;

2. provides appropriate technical and organizational measures to protect personal data against accidental or unlawful destruction or accidental loss, alternation, unauthorized disclosure or access, and understands whether onward transfer is allowed; and

3. taking into account the nature of the processing, assists the controller in responding to individuals exercising their rights under the Principles.

iii. Because adequate protection is provided by Privacy Shield participants, contracts with Privacy Shield participants for mere processing do not require prior authorization (or such authorization will be granted automatically by the EU Member States), as would be required for contracts with recipients not participating in the Privacy Shield or otherwise not providing adequate protection.

b. *Transfers within a Controlled Group of Corporations or Entities*

i. When personal information is transferred between two controllers within a controlled group of corporations or entities, a contract is not always required under the Accountability for Onward Transfer Principle. Data controllers within a controlled group of corporations or entities may base such transfers on other instruments, such as EU Binding Corporate Rules or other intra-group instruments (*e.g.,* compliance and control programs), ensuring the continuity of protection of personal information under the Principles. In case of such transfers, the Privacy Shield organization remains responsible for compliance with the Principles.

c. *Transfers between Controllers*

i. For transfers between controllers, the recipient controller need not be a Privacy Shield organization or have an independent recourse mechanism. The Privacy Shield organization must enter into a contract with the recipient third-party controller that provides for the same level of protection as is available under the Privacy Shield, not including the requirement that the third party controller be a Privacy Shield organization or have an independent recourse mechanism, provided it makes available an equivalent mechanism.

11. Dispute Resolution and Enforcement

a. The Recourse, Enforcement and Liability Principle sets out the requirements for Privacy Shield enforcement. How to meet the requirements of point (a)(ii) of the Principle is set out in the Supplemental Principle on Verification. This Supplemental Principle addresses points (a)(i) and (a)(iii), both of which require independent recourse mechanisms. These mechanisms may take different forms, but they must meet the Recourse, Enforcement and Liability Principle's requirements. Organizations satisfy the requirements through the following: (i) Compliance with private sector developed privacy programs that incorporate the Privacy Shield Principles into their rules and that include effective enforcement mechanisms of the type described in the Recourse, Enforcement and Liability Principle; (ii) compliance with legal or regulatory supervisory authorities that provide for handling of individual complaints and dispute resolution; or (iii) commitment to cooperate with data protection authorities located in the European Union or their authorized representatives.

b. This list is intended to be illustrative and not limiting. The private sector may design additional mechanisms to provide enforcement, so long as they meet the requirements of the Recourse, Enforcement and Liability Principle and the Supplemental Principles. Please note that the Recourse, Enforcement and Liability Principle's requirements are additional to the requirement that self-regulatory efforts must be enforceable under Section 5 of the Federal Trade Commission Act, which prohibits unfair and deceptive acts, or another law or regulation prohibiting such acts.

c. In order to help ensure compliance with their Privacy Shield commitments and to support the administration of the program, organizations, as well as their independent recourse mechanisms, must provide information relating to the Privacy Shield when requested by the Department. In addition, organizations must respond

expeditiously to complaints regarding their compliance with the Principles referred through the Department by DPAs. The response should address whether the complaint has merit and, if so, how the organization will rectify the problem. The Department will protect the confidentiality of information it receives in accordance with U.S. law.

d. *Recourse Mechanisms*

i. Consumers should be encouraged to raise any complaints they may have with the relevant organization before proceeding to independent recourse mechanisms. Organizations must respond to a consumer within 45 days of receiving a complaint. Whether a recourse mechanism is independent is a factual question that can be demonstrated notably by impartiality, transparent composition and financing, and a proven track record. As required by the Recourse, Enforcement and Liability Principle, the recourse available to individuals must be readily available and free of charge to individuals. Dispute resolution bodies should look into each complaint received from individuals unless they are obviously unfounded or frivolous. This does not preclude the establishment of eligibility requirements by the organization operating the recourse mechanism, but such requirements should be transparent and justified (for example, to exclude complaints that fall outside the scope of the program or are for consideration in another forum), and should not have the effect of undermining the commitment to look into legitimate complaints. In addition, recourse mechanisms should provide individuals with full and readily available information about how the dispute resolution procedure works when they file a complaint. Such information should include notice about the mechanism's privacy practices, in conformity with the Privacy Shield Principles. They should also cooperate in the development of tools such as standard complaint forms to facilitate the complaint resolution process.

ii. Independent recourse mechanisms must include on their public Web sites information regarding the Privacy Shield Principles and the services that they provide under the Privacy Shield. This information must include: (1) Information on or a link to the Privacy Shield Principles' requirements for independent recourse mechanisms; (2) a link to the Department's Privacy Shield Web site; (3) an explanation that their dispute resolution services under the Privacy Shield are free of charge to individuals; (4) a description of how a Privacy Shield-related complaint can be filed; (5) the timeframe in which Privacy Shield-related complaints are processed; and (6) a description of the range of potential remedies.

iii. Independent recourse mechanisms must publish an annual report providing aggregate statistics regarding their dispute resolution services. The annual report must include: (1) The total number of Privacy Shield-related complaints received during the reporting year; (2) the types of complaints received; (3) dispute resolution quality measures, such as the length of time taken to process complaints; and (4) the outcomes of the complaints received, notably the number and types of remedies or sanctions imposed.

iv. As set forth in Annex I, an arbitration option is available to an individual to determine, for residual claims, whether a Privacy Shield organization has violated its obligations under the Principles as to that individual, and whether any such violation remains fully or partially unremedied. This option is available only for these purposes. This option is not available, for example, with respect to the exceptions to the Principles [5] or with respect to an allegation about the adequacy of the Privacy Shield. Under this arbitration option, the Privacy Shield Panel (consisting of one or three arbitrators, as agreed by the parties) has the authority to impose individual-specific, non-monetary equitable relief (such as access, correction, deletion, or return of the individual's data in question) necessary to remedy the violation of the Principles only with respect to the individual. Individuals and Privacy Shield organizations will be able to seek judicial review and enforcement of the arbitral decisions pursuant to U.S. law under the Federal Arbitration Act.

e. *Remedies and Sanctions*

i. The result of any remedies provided by the dispute resolution body should be that the effects of non-compliance are reversed or corrected by the organization, insofar as feasible, and that future processing by the organization will be in conformity with the Principles and, where appropriate, that processing of the personal data of the individual who brought the complaint will cease. Sanctions need to be rigorous enough to ensure compliance by the organization with the Principles. A range of sanctions of varying degrees of severity will allow dispute resolution bodies to respond appropriately to varying degrees of non-compliance. Sanctions should include both publicity for findings of non-compliance and the requirement to delete data in certain circumstances.[6] Other sanctions could include suspension and removal of a seal, compensation for individuals for losses incurred as a result of non-compliance and injunctive awards. Private sector dispute resolution bodies and self-regulatory bodies must notify failures of Privacy Shield organizations to comply with their rulings to the governmental body with applicable jurisdiction or to the courts, as appropriate, and to notify the Department.

f. *FTC Action*

ii. The FTC has committed to reviewing on a priority basis referrals alleging non-compliance with the Principles received from: (i) Privacy self-regulatory organizations and other independent dispute resolution bodies; (ii) EU Member States; and (iii) the Department, to determine whether Section 5 of the FTC Act prohibiting unfair or deceptive acts or practices in commerce has been violated. If the FTC concludes that it has reason to believe Section 5 has been violated, it may resolve the matter by seeking an administrative cease and desist order prohibiting the challenged practices or by filing a complaint in a federal district court, which if successful could result in a federal court order to same effect. This includes false claims of adherence to the Privacy Shield Principles or participation in the Privacy Shield by organizations, which either are no longer on the Privacy Shield List or have never self-certified to the Department. The FTC may obtain civil penalties for violations of an administrative cease and desist order and may pursue civil or criminal contempt for violation of a federal court order. The FTC will notify the Department of any such actions it takes. The Department encourages other government bodies to notify it of the final disposition of any such referrals or other rulings determining adherence to the Privacy Shield Principles.

g. *Persistent Failure to Comply*

i. If an organization persistently fails to comply with the Principles, it is no longer entitled to benefit from the Privacy Shield. Organizations that have persistently failed to comply with the Principles will be removed from the Privacy Shield List by the Department and must return or delete the personal information they received under the Privacy Shield.

ii. Persistent failure to comply arises where an organization that has self-certified to the Department refuses to comply with a final determination by any privacy self-regulatory, independent dispute resolution, or government body, or where such a body determines that an organization frequently fails to comply with the Principles to the point where its claim to comply is no longer credible. In these cases, the organization must promptly notify the Department of such facts. Failure to do so may be actionable under the False Statements Act (18 U.S.C. 1001). An organization's withdrawal from a private-sector privacy self-regulatory program or independent dispute resolution mechanism does not relieve it of its obligation to comply with the Principles and would constitute a persistent failure to comply.

iii. The Department will remove an organization from the Privacy Shield List in response to any notification it receives of persistent failure to comply, whether it is received from the organization itself, from a privacy self-regulatory body or another independent dispute resolution body, or from a government body, but only after first providing 30 days' notice and an opportunity to respond to the organization that has failed to comply. Accordingly, the Privacy Shield List maintained by the Department will make clear which organizations are assured and which organizations are no longer assured of Privacy Shield benefits.

iv. An organization applying to participate in a self-regulatory body for the purposes of requalifying for the Privacy Shield must provide that body with full information about its prior participation in the Privacy Shield.

12. Choice—Timing of Opt Out

a. Generally, the purpose of the Choice Principle is to ensure that personal information is used and disclosed in ways

[5] Section I.5 of the Principles.

[6] Dispute resolution bodies have discretion about the circumstances in which they use these sanctions. The sensitivity of the data concerned is one factor to be taken into consideration in deciding whether deletion of data should be required, as is whether an organization has collected, used, or disclosed information in blatant contravention of the Privacy Shield Principles.

that are consistent with the individual's expectations and choices. Accordingly, an individual should be able to exercise ''opt out'' choice of having personal information used for direct marketing at any time subject to reasonable limits established by the organization, such as giving the organization time to make the opt out effective. An organization may also require sufficient information to confirm the identity of the individual requesting the ''opt out.'' In the United States, individuals may be able to exercise this option through the use of a central ''opt out'' program such as the Direct Marketing Association's Mail Preference Service. Organizations that participate in the Direct Marketing Association's Mail Preference Service should promote its availability to consumers who do not wish to receive commercial information. In any event, an individual should be given a readily available and affordable mechanism to exercise this option.

b. Similarly, an organization may use information for certain direct marketing purposes when it is impracticable to provide the individual with an opportunity to opt out before using the information, if the organization promptly gives the individual such opportunity at the same time (and upon request at any time) to decline (at no cost to the individual) to receive any further direct marketing communications and the organization complies with the individual's wishes.

13. Travel Information

a. Airline passenger reservation and other travel information, such as frequent flyer or hotel reservation information and special handling needs, such as meals to meet religious requirements or physical assistance, may be transferred to organizations located outside the EU in several different circumstances. Under Article 26 of the Directive, personal data may be transferred ''to a third country which does not ensure an adequate level of protection within the meaning of Article 25(2)'' on the condition that it (i) is necessary to provide the services requested by the consumer or to fulfill the terms of an agreement, such as a ''frequent flyer'' agreement; or (ii) has been unambiguously consented to by the consumer. U.S. organizations subscribing to the Privacy Shield provide adequate protection for personal data and may therefore receive data transfers from the EU without meeting these conditions or other conditions set out in Article 26 of the Directive. Since the Privacy Shield includes specific rules for sensitive information, such information (which may need to be collected, for example, in connection with customers' needs for physical assistance) may be included in transfers to Privacy Shield participants. In all cases, however, the organization transferring the information has to respect the law in the EU Member State in which it is operating, which may inter alia impose special conditions for the handling of sensitive data.

14. Pharmaceutical and Medical Products

a. *Application of EU Member State Laws or the Privacy Shield Principles*

i. EU Member State law applies to the collection of the personal data and to any processing that takes place prior to the transfer to the United States. The Privacy Shield Principles apply to the data once they have been transferred to the United States. Data used for pharmaceutical research and other purposes should be anonymized when appropriate.

b. *Future Scientific Research*

i. Personal data developed in specific medical or pharmaceutical research studies often play a valuable role in future scientific research. Where personal data collected for one research study are transferred to a U.S. organization in the Privacy Shield, the organization may use the data for a new scientific research activity if appropriate notice and choice have been provided in the first instance. Such notice should provide information about any future specific uses of the data, such as periodic follow-up, related studies, or marketing.

ii. It is understood that not all future uses of the data can be specified, since a new research use could arise from new insights on the original data, new medical discoveries and advances, and public health and regulatory developments. Where appropriate, the notice should therefore include an explanation that personal data may be used in future medical and pharmaceutical research activities that are unanticipated. If the use is not consistent with the general research purpose(s) for which the personal data were originally collected, or to which the individual has consented subsequently, new consent must be obtained.

c. *Withdrawal from a Clinical Trial*

i. Participants may decide or be asked to withdraw from a clinical trial at any time. Any personal data collected previous to withdrawal may still be processed along with other data collected as part of the clinical trial, however, if this was made clear to the participant in the notice at the time he or she agreed to participate.

d. *Transfers for Regulatory and Supervision Purposes*

i. Pharmaceutical and medical device companies are allowed to provide personal data from clinical trials conducted in the EU to regulators in the United States for regulatory and supervision purposes. Similar transfers are allowed to parties other than regulators, such as company locations and other researchers, consistent with the Principles of Notice and Choice.

e. *''Blinded'' Studies*

i. To ensure objectivity in many clinical trials, participants, and often investigators as well, cannot be given access to information about which treatment each participant may be receiving. Doing so would jeopardize the validity of the research study and results. Participants in such clinical trials (referred to as ''blinded'' studies) do not have to be provided access to the data on their treatment during the trial if this restriction has been explained when the participant entered the trial and the disclosure of such information would jeopardize the integrity of the research effort.

ii. Agreement to participate in the trial under these conditions is a reasonable forgoing of the right of access. Following the conclusion of the trial and analysis of the results, participants should have access to their data if they request it. They should seek it primarily from the physician or other health care provider from whom they received treatment within the clinical trial, or secondarily from the sponsoring organization.

f. *Product Safety and Efficacy Monitoring*

i. A pharmaceutical or medical device company does not have to apply the Privacy Shield Principles with respect to the Notice, Choice, Accountability for Onward Transfer, and Access Principles in its product safety and efficacy monitoring activities, including the reporting of adverse events and the tracking of patients/subjects using certain medicines or medical devices, to the extent that adherence to the Principles interferes with compliance with regulatory requirements. This is true both with respect to reports by, for example, health care providers to pharmaceutical and medical device companies, and with respect to reports by pharmaceutical and medical device companies to government agencies like the Food and Drug Administration.

g. *Key-coded Data*

i. Invariably, research data are uniquely key-coded at their origin by the principal investigator so as not to reveal the identity of individual data subjects. Pharmaceutical companies sponsoring such research do not receive the key. The unique key code is held only by the researcher, so that he or she can identify the research subject under special circumstances (*e.g.,* if follow-up medical attention is required). A transfer from the EU to the United States of data coded in this way would not constitute a transfer of personal data that would be subject to the Privacy Shield Principles.

15. Public Record and Publicly Available Information

a. An organization must apply the Privacy Shield Principles of Security, Data Integrity and Purpose Limitation, and Recourse, Enforcement and Liability to personal data from publicly available sources. These Principles shall apply also to personal data collected from public records, *i.e.,* those records kept by government agencies or entities at any level that are open to consultation by the public in general.

b. It is not necessary to apply the Notice, Choice, or Accountability for Onward Transfer Principles to public record information, as long as it is not combined with non-public record information, and any conditions for consultation established by the relevant jurisdiction are respected. Also, it is generally not necessary to apply the Notice, Choice, or Accountability for Onward Transfer Principles to publicly available information unless the European transferor indicates that such information is subject to restrictions that require application of those Principles by the organization for the uses it intends. Organizations will have no liability for how such information is used by those obtaining such information from published materials.

c. Where an organization is found to have intentionally made personal information public in contravention of the Principles so

that it or others may benefit from these exceptions, it will cease to qualify for the benefits of the Privacy Shield.

d. It is not necessary to apply the Access Principle to public record information as long as it is not combined with other personal information (apart from small amounts used to index or organize the public record information); however, any conditions for consultation established by the relevant jurisdiction are to be respected. In contrast, where public record information is combined with other non-public record information (other than as specifically noted above), an organization must provide access to all such information, assuming it is not subject to other permitted exceptions.

e. As with public record information, it is not necessary to provide access to information that is already publicly available to the public at large, as long as it is not combined with non-publicly available information. Organizations that are in the business of selling publicly available information may charge the organization's customary fee in responding to requests for access. Alternatively, individuals may seek access to their information from the organization that originally compiled the data.

16. Access Requests by Public Authorities

a. In order to provide transparency in respect of lawful requests by public authorities to access personal information, Privacy Shield organizations may voluntarily issue periodic transparency reports on the number of requests for personal information they receive by public authorities for law enforcement or national security reasons, to the extent such disclosures are permissible under applicable law.

b. The information provided by the Privacy Shield organizations in these reports together with information that has been released by the intelligence community, along with other information, can be used to inform the annual joint review of the functioning of the Privacy Shield in accordance with the Principles.

c. Absence of notice in accordance with point (a)(xii) of the Notice Principle shall not prevent or impair an organization's ability to respond to any lawful request.

Annex I: Arbitral Model

Annex I

This Annex I provides the terms under which Privacy Shield organizations are obligated to arbitrate claims, pursuant to the Recourse, Enforcement and Liability Principle. The binding arbitration option described below applies to certain ''residual'' claims as to data covered by the EU-U.S. Privacy Shield. The purpose of this option is to provide a prompt, independent, and fair mechanism, at the option of individuals, for resolution of claimed violations of the Principles not resolved by any of the other Privacy Shield mechanisms, if any.

A. Scope

This arbitration option is available to an individual to determine, for residual claims, whether a Privacy Shield organization has violated its obligations under the Principles as to that individual, and whether any such violation remains fully or partially unremedied. This option is available only for these purposes. This option is not available, for example, with respect to the exceptions to the Principles [7] or with respect to an allegation about the adequacy of the Privacy Shield.

B. Available Remedies

Under this arbitration option, the Privacy Shield Panel (consisting of one or three arbitrators, as agreed by the parties) has the authority to impose individual-specific, non-monetary equitable relief (such as access, correction, deletion, or return of the individual's data in question) necessary to remedy the violation of the Principles only with respect to the individual. These are the only powers of the arbitration panel with respect to remedies. In considering remedies, the arbitration panel is required to consider other remedies that already have been imposed by other mechanisms under the Privacy Shield. No damages, costs, fees, or other remedies are available. Each party bears its own attorney's fees.

C. Pre-Arbitration Requirements

An individual who decides to invoke this arbitration option must take the following steps prior to initiating an arbitration claim: (1) Raise the claimed violation directly with the organization and afford the organization an opportunity to resolve the issue within the timeframe set forth in Section III.11(d)(i) of the Principles; (2) make use of the independent recourse mechanism under the Principles, which is at no cost to the individual; and (3) raise the issue through their Data Protection Authority to the Department of Commerce and afford the Department of Commerce an opportunity to use best efforts to resolve the issue within the timeframes set forth in the Letter from the International Trade Administration of the Department of Commerce, at no cost to the individual.

This arbitration option may not be invoked if the individual's same claimed violation of the Principles (1) has previously been subject to binding arbitration; (2) was the subject of a final judgment entered in a court action to which the individual was a party; or (3) was previously settled by the parties. In addition, this option may not be invoked if an EU Data Protection Authority (1) has authority under Sections III.5 or III.9 of the Principles; or (2) has the authority to resolve the claimed violation directly with the organization. A DPA's authority to resolve the same claim against an EU data controller does not alone preclude invocation of this arbitration option against a different legal entity not bound by the DPA authority.

D. Binding Nature of Decisions

An individual's decision to invoke this binding arbitration option is entirely voluntary. Arbitral decisions will be binding on all parties to the arbitration. Once invoked, the individual forgoes the option to seek relief for the same claimed violation in another forum, except that if non-monetary equitable relief does not fully remedy the claimed violation, the individual's invocation of arbitration will not preclude a claim for damages that is otherwise available in the courts.

E. Review and Enforcement

Individuals and Privacy Shield organizations will be able to seek judicial review and enforcement of the arbitral decisions pursuant to U.S. law under the Federal Arbitration Act.[8] Any such cases must be brought in the federal district court whose territorial coverage includes the primary place of business of the Privacy Shield organization. This arbitration option is intended to resolve individual disputes, and arbitral decisions are not intended to function as persuasive or binding precedent in matters involving other parties, including in future arbitrations or in EU or U.S. courts, or FTC proceedings.

F. The Arbitration Panel

The parties will select the arbitrators from the list of arbitrators discussed below.

Consistent with applicable law, the U.S. Department of Commerce and the European

[7] Section I.5 of the Principles.

[8] Chapter 2 of the Federal Arbitration Act (''FAA'') provides that ''[a]n arbitration agreement or arbitral award arising out of a legal relationship, whether contractual or not, which is considered as commercial, including a transaction, contract, or agreement described in [section 2 of the FAA], falls under the Convention [on the Recognition and Enforcement of Foreign Arbitral Awards of June 10, 1958, 21 U.S.T. 2519, T.I.A.S. No. 6997 (''New York Convention'')].'' 9 U.S.C. 202. The FAA further provides that ''[a]n agreement or award arising out of such a relationship which is entirely between citizens of the United States shall be deemed not to fall under the [New York] Convention unless that relationship involves property located abroad, envisages performance or enforcement abroad, or has some other reasonable relation with one or more foreign states.'' *Id.* Under Chapter 2, ''any party to the arbitration may apply to any court having jurisdiction under this chapter for an order confirming the award as against any other party to the arbitration. The court shall confirm the award unless it finds one of the grounds for refusal or deferral of recognition or enforcement of the award specified in the said [New York] Convention.'' *Id.* section 207. Chapter 2 further provides that ''[t]he district courts of the United States . . . shall have original jurisdiction over . . . an action or proceeding [under the New York Convention], regardless of the amount in controversy.'' *Id.* section 203.

Chapter 2 also provides that ''Chapter 1 applies to actions and proceedings brought under this chapter to the extent that chapter is not in conflict with this chapter or the [New York] Convention as ratified by the United States.'' *Id.* section 208. Chapter 1, in turn, provides that ''[a] written provision in . . . a contract evidencing a transaction involving commerce to settle by arbitration a controversy thereafter arising out of such contract or transaction, or the refusal to perform the whole or any part thereof, or an agreement in writing to submit to arbitration an existing controversy arising out of such a contract, transaction, or refusal, shall be valid, irrevocable, and enforceable, save upon such grounds as exist at law or in equity for the revocation of any contract.'' *Id.* section 2. Chapter 1 further provides that ''any party to the arbitration may apply to the court so specified for an order confirming the award, and thereupon the court must grant such an order unless the award is vacated, modified, or corrected as prescribed in sections 10 and 11 of [the FAA].'' *Id.* section 9.

Commission will develop a list of at least 20 arbitrators, chosen on the basis of independence, integrity, and expertise. The following shall apply in connection with this process:

Arbitrators:

(1) Will remain on the list for a period of 3 years, absent exceptional circumstances or for cause, renewable for one additional period of 3 years;

(2) shall not be subject to any instructions from, or be affiliated with, either party, or any Privacy Shield organization, or the U.S., EU, or any EU Member State or any other governmental authority, public authority, or enforcement authority; and

(3) must be admitted to practice law in the U.S. and be experts in U.S. privacy law, with expertise in EU data protection law.

G. Arbitration Procedures

Consistent with applicable law, within 6 months from the adoption of the adequacy decision, the Department of Commerce and the European Commission will agree to adopt an existing, well-established set of U.S. arbitral procedures (such as AAA or JAMS) to govern proceedings before the Privacy Shield Panel, subject to each of the following considerations:

1. An individual may initiate binding arbitration, subject to the pre-arbitration requirements provision above, by delivering a ''Notice'' to the organization. The Notice shall contain a summary of steps taken under Paragraph C to resolve the claim, a description of the alleged violation, and, at the choice of the individual, any supporting documents and materials and/or a discussion of law relating to the alleged claim.

2. Procedures will be developed to ensure that an individual's same claimed violation does not receive duplicative remedies or procedures.

3. FTC action may proceed in parallel with arbitration.

4. No representative of the U.S., EU, or any EU Member State or any other governmental authority, public authority, or enforcement authority may participate in these arbitrations, provided, that at the request of an EU individual, EU DPAs may provide assistance in the preparation only of the Notice but EU DPAs may not have access to discovery or any other materials related to these arbitrations.

5. The location of the arbitration will be the United States, and the individual may choose video or telephone participation, which will be provided at no cost to the individual. In-person participation will not be required.

6. The language of the arbitration will be English unless otherwise agreed by the parties. Upon a reasoned request, and taking into account whether the individual is represented by an attorney, interpretation at the arbitral hearing as well as translation of arbitral materials will be provided at no cost to the individual, unless the panel finds that, under the circumstances of the specific arbitration, this would lead to unjustified or disproportionate costs.

7. Materials submitted to arbitrators will be treated confidentially and will only be used in connection with the arbitration.

8. Individual-specific discovery may be permitted if necessary, and such discovery will be treated confidentially by the parties and will only be used in connection with the arbitration.

9. Arbitrations should be completed within 90 days of the delivery of the Notice to the organization at issue, unless otherwise agreed to by the parties.

H. Costs

Arbitrators should take reasonable steps to minimize the costs or fees of the arbitrations. Subject to applicable law, the Department of Commerce will facilitate the establishment of a fund, into which Privacy Shield organizations will be required to pay an annual contribution, based in part on the size of the organization, which will cover the arbitral cost, including arbitrator fees, up to maximum amounts (''caps''), in consultation with the European Commission. The fund will be managed by a third party, which will report regularly on the operations of the fund. At the annual review, the Department of Commerce and European Commission will review the operation of the fund, including the need to adjust the amount of the contributions or of the caps, and will consider, among other things, the number of arbitrations and the costs and timing of the arbitrations, with the mutual understanding that there will be no excessive financial burden imposed on Privacy Shield organizations. Attorney's fees are not covered by this provision or any fund under this provision.

Letter From U.S. Secretary of State John Kerry

July 7, 2016

Dear Commissioner Jourová,

I am pleased we have reached an understanding on the European Union-United States Privacy Shield that will include an Ombudsperson mechanism through which authorities in the EU will be able to submit requests on behalf of EU individuals regarding U.S. signals intelligence practices.

On January 17, 2014, President Barack Obama announced important intelligence reforms included in Presidential Policy Directive 28 (PPD–28). Under PPD–28, I designated Under Secretary of State Catherine A. Novelli, who also serves as Senior Coordinator for International Information Technology Diplomacy, as our point of contact for foreign governments that wish to raise concerns regarding U.S. signals intelligence activities. Building on this role, I have established a Privacy Shield Ombudsperson mechanism in accordance with the terms set out in Annex A, which have been updated since my letter of February 22, 2016. I have directed Under Secretary Novelli to perform this function. Under Secretary Novelli is independent from the U.S. intelligence community, and reports directly to me.

I have directed my staff to devote the necessary resources to implement this new Ombudsperson mechanism, and am confident it will be an effective means to address EU individuals' concerns.

Sincerely,

John F. Kerry

Annex A: EU-U.S. Privacy Shield Ombudsperson Mechanism

EU-U.S. Privacy Shield Ombudsperson Mechanism Regarding Signals Intelligence

In recognition of the importance of the EU-U.S. Privacy Shield Framework, this Memorandum sets forth the process for implementing a new mechanism, consistent with Presidential Policy Directive 28 (PPD–28), regarding signals intelligence.[9]

On January 17, 2014, President Obama gave a speech announcing important intelligence reforms. In that speech, he pointed out that ''[o]ur efforts help protect not only our nation, but our friends and allies as well. Our efforts will only be effective if ordinary citizens in other countries have confidence that the United States respects their privacy too.'' President Obama announced the issuance of a new presidential directive—PPD–28—to ''clearly prescribe what we do, and do not do, when it comes to our overseas surveillance.''

Section 4(d) of PPD–28 directs the Secretary of State to designate a ''Senior Coordinator for International Information Technology Diplomacy'' (Senior Coordinator) ''to . . . serve as a point of contact for foreign governments who wish to raise concerns regarding signals intelligence activities conducted by the United States.'' As of January 2015, Under Secretary C. Novelli has served as the Senior Coordinator.

This Memorandum describes a new mechanism that the Senior Coordinator will follow to facilitate the processing of requests relating to national security access to data transmitted from the EU to the United States pursuant to the Privacy Shield, standard contractual clauses (SCCs), binding corporate rules (BCRs), ''Derogations,'' [10] or ''Possible Future Derogations,'' [11] through established

[9] Provided that the Commission Decision on the adequacy of the protection provided by the EU-U.S. Privacy Shield applies to Iceland, Liechtenstein and Norway, the Privacy Shield Package will cover both the European Union, as well as these three countries. Consequently, references to the EU and its Member States will be read as including Iceland, Liechtenstein and Norway.

[10] ''Derogations'' in this context mean a commercial transfer or transfers that take place on the condition that: (a) the data subject has given his consent unambiguously to the proposed transfer; or (b) the transfer is necessary for the performance of a contract between the data subject and the controller or the implementation of precontractual measures taken in response to the data subject's request; or (c) the transfer is necessary for the conclusion or performance of a contract concluded in the interest of the data subject between the controller and a third party; or (d) the transfer is necessary or legally required on important public interest grounds, or for the establishment, exercise or defense of legal claims; or (e) the transfer is necessary in order to protect the vital interests of the data subject; or (f) the transfer is made from a register which according to laws or regulations is intended to provide information to the public and which is open to consultation either by the public in general or by any person who can demonstrate legitimate interest, to the extent that the conditions laid down in law for consultation are fulfilled in the particular case.

[11] ''Possible Future Derogations'' in this context mean a commercial transfer or transfers that take

avenues under applicable United States laws and policy, and the response to those requests.

1. The Privacy Shield Ombudsperson. The Senior Coordinator will serve as the Privacy Shield Ombudsperson and designate additional State Department officials, as appropriate to assist in her performance of the responsibilities detailed in this memorandum. (Hereinafter, the Coordinator and any officials performing such duties will be referred to as ''Privacy Shield Ombudsperson.'') The Privacy Shield Ombudsperson will work closely with appropriate officials from other departments and agencies who are responsible for processing requests in accordance with applicable United States law and policy. The Ombudsperson is independent from the Intelligence Community. The Ombudsperson reports directly to the Secretary of State who will ensure that the Ombudsperson carries out its function objectively and free from improper influence that is liable to have an effect on the response to be provided.

2. Effective Coordination. The Privacy Shield Ombudsperson will be able to effectively use and coordinate with the oversight bodies, described below, in order to ensure that the Ombudsperson's response to requests from the submitting EU individual complaint handing body is based on the necessary information. When the request relates to the compatibility of surveillance with U.S. law, the Privacy Shield Ombudsperson will be able to cooperate with one of the independent oversight bodies with investigatory powers.

a. The Privacy Shield Ombudsperson will work closely with other United States Government officials, including appropriate independent oversight bodies, to ensure that completed requests are processed and resolved in accordance with applicable laws and policies. In particular, the Privacy Shield Ombudsperson will be able to coordinate closely with the Office of the Director of National Intelligence, the Department of Justice, and other departments and agencies involved in United States national security as appropriate, and Inspectors General, Freedom of Information Act Officers, and Civil Liberties and Privacy Officers.

b. The United States Government will rely on mechanisms for coordinating and overseeing national security matters across departments and agencies to help ensure that the Privacy Shield Ombudsperson is able to respond within the meaning of Section 4(e) to completed requests under Section 3(b).

c. The Privacy Shield Ombudsperson may refer matters related to requests to the Privacy and Civil Liberties Oversight Board for its consideration.

3. Submitting Requests.

a. A request will initially be submitted to the supervisory authorities in the Member States competent for the oversight of national security services and/or the processing of personal data by public authorities. The request will be submitted to the Ombudsperson by a EU centralized body (hereafter together: The ''EU individual complaint handling body'').

b. The EU individual complaint handling body will ensure, in compliance with the following actions, that the request is complete:

(i) Verifying the identity of the individual, and that the individual is acting on his/her own behalf, and not as a representative of a governmental or intergovernmental organization.

(ii) Ensuring the request is made in writing, and that it contains the following basic information:

- Any information that forms the basis for the request,
- the nature of information or relief sought,
- the United States Government entities believed to be involved, if any, and
- the other measures pursued to obtain the information or relief requested and the response received through those other measures.

(iii) Verifying that the request pertains to data reasonably believed to have been transferred from the EU to the United States pursuant to the Privacy Shield, SCCs, BCRs, Derogations, or Possible Future Derogations.

(iv) Making an initial determination that the request is not frivolous, vexatious, or made in bad faith.

c. To be completed for purposes of further handling by the Privacy Shield Ombudsperson under this memorandum, the request need not demonstrate that the requester's data has in fact been accessed by the United States Government through signal intelligence activities.

4. Commitments to Communicate with Submitting EU Individual Complaint Handling Body.

a. The Privacy Shield Ombudsperson will acknowledge receipt of the request to the submitting EU individual complaint handling body.

b. The Privacy Shield Ombudsperson will conduct an initial review to verify that the request has been completed in conformance with Section 3(b). If the Privacy Shield Ombudsperson notes any deficiencies or has any questions regarding the completion of the request, the Privacy Shield Ombudsperson will seek to address and resolve those concerns with the submitting EU individual complaint handling body.

c. If, to facilitate appropriate processing of the request, the Privacy Shield Ombudsperson needs more information about the request, or if specific action is needed to be taken by the individual who originally submitted the request, the Privacy Shield Ombudsperson will so inform the submitting EU individual complaint handling body.

d. The Privacy Shield Ombudsperson will track the status of requests and provide updates as appropriate to the submitting EU individual complaint handling body.

e. Once a request has been completed as described in Section 3 of this Memorandum, the Privacy Shield Ombudsperson will provide in a timely manner an appropriate response to the submitting EU individual complaint handling body, subject to the continuing obligation to protect information under applicable laws and policies. The Privacy Shield Ombudsperson will provide a response to the submitting EU individual complaint handling body confirming (i) that the complaint has been properly investigated, and (ii) that the U.S. law, statutes, executives orders, presidential directives, and agency policies, providing the limitations and safeguards described in the ODNI letter, have been complied with, or, in the event of non-compliance, such non-compliance has been remedied. The Privacy Shield Ombudsperson will neither confirm nor deny whether the individual has been the target of surveillance nor will the Privacy Shield Ombudsperson confirm the specific remedy that was applied. As further explained in Section 5, FOIA requests will be processed as provided under that statute and applicable regulations.

f. The Privacy Shield Ombudsperson will communicate directly with the EU individual complaint handling body, who will in turn be responsible for communicating with the individual submitting the request. If direct communications are part of one of the underlying processes described below, then those communications will take place in accordance with existing procedures.

g. Commitments in this Memorandum will not apply to general claims that the EU-U.S. Privacy Shield is inconsistent with European Union data protection requirements. The commitments in this Memorandum are made based on the common understanding by the European Commission and the U.S. government that given the scope of commitments under this mechanism, there may be resource constraints that arise, including with respect to Freedom of Information Act (FOIA) requests. Should the carrying-out of the Privacy Shield Ombudsperson's functions exceed reasonable resource constraints and impede the fulfillment of these commitments, the U.S. government will discuss with the European Commission any adjustments that may be appropriate to address the situation.

5. Requests for Information. Requests for access to United States Government records may be made and processed under the Freedom of Information Act (FOIA).

a. FOIA provides a means for any person to seek access to existing federal agency records, regardless of the nationality of the requester. This statute is codified in the United States Code at 5 U.S.C. 552. The statute, together with additional information about FOIA, is available at *www.FOIA.gov*

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place on one of the following conditions, to the extent the condition constitutes lawful grounds for transfers of personal data from the EU to the U.S.: (a) The data subject has explicitly consented to the proposed transfer, after having been informed of the possible risks of such transfers for the data subject due to the absence of an adequacy decision and appropriate safeguards; or (b) the transfer is necessary in order to protect the vital interests of the data subject or of other persons, where the data subject is physically or legally incapable of giving consent; or (c) in case of a transfer to a third country or an international organization and none of the other derogations or possible future derogations is applicable, only if the transfer is not repetitive, concerns only a limited number of data subjects, is necessary for the purposes of compelling legitimate interests pursued by the controller which are not overridden by the interests or rights and freedoms of the data subject, and the controller has assessed all the circumstances surrounding the data transfer and has on the basis of that assessment provided suitable safeguards with regard to the protection of personal data.

and *http://www.justice.gov/oip/foia-resources*. Each agency has a Chief FOIA Officer, and has provided information on its public Web site about how to submit a FOIA request to the agency. Agencies have processes for consulting with one another on FOIA requests that involve records held by another agency.

b. By way of example:

(i) The Office of the Director of National Intelligence (ODNI) has established the ODNI FOIA Portal for the ODNI: *http://www.dni.gov/index.php/about-this-site/foia*. This portal provides information on submitting a request, checking on the status of an existing request, and accessing information that has been released and published by the ODNI under FOIA. The ODNI FOIA Portal includes links to other FOIA Web sites for IC elements: *http://www.dni.gov/index.php/about-this-site/foia/other-ic-foia-sites*.

(ii) The Department of Justice's Office of Information Policy provides comprehensive information about FOIA: *http://www.justice.gov/oip*. This includes not only information about submitting a FOIA request to the Department of Justice, but also provides guidance to the United States government on interpreting and applying FOIA requirements.

c. Under FOIA, access to government records is subject to certain enumerated exemptions. These include limits on access to classified national security information, personal information of third parties, and information concerning law enforcement investigations, and are comparable to the limitations imposed by each EU Member State with its own information access law. These limitations apply equally to Americans and non-Americans.

d. Disputes over the release of records requested pursuant to FOIA can be appealed administratively and then in federal court. The court is required to make a *de novo* determination of whether records are properly withheld, 5 U.S.C. 552(a)(4)(B), and can compel the government to provide access to records. In some cases courts have overturned government assertions that information should be withheld as classified. Although no monetary damages are available, courts can award attorney's fees.

6. Requests for Further Action. A request alleging violation of law or other misconduct will be referred to the appropriate United States Government body, including independent oversight bodies, with the power to investigate the respective request and address non-compliance as described below.

a. Inspectors General are statutorily independent; have broad power to conduct investigations, audits and reviews of programs, including of fraud and abuse or violation of law; and can recommend corrective actions.

(i) The Inspector General Act of 1978, as amended, statutorily established the Federal Inspectors General (IG) as independent and objective units within most agencies whose duties are to combat waste, fraud, and abuse in the programs and operations of their respective agencies. To this end, each IG is responsible for conducting audits and investigations relating to the programs and operations of its agency. Additionally, IGs provide leadership and coordination and recommend policies for activities designed to promote economy, efficiency, and effectiveness, and prevent and detect fraud and abuse, in agency programs and operations.

(ii) Each element of the Intelligence Community has its own Office of the Inspector General with responsibility for oversight of foreign intelligence activities, among other matters. A number of Inspector General reports about intelligence programs have been publicly released.

(iii) By way of example:

- The Office of the Inspector General of the Intelligence Community (IC IG) was established pursuant to Section 405 of the Intelligence Authorization Act of Fiscal Year 2010. The IC IG is responsible for conducting IC-wide audits, investigations, inspections, and reviews that identify and address systemic risks, vulnerabilities, and deficiencies that cut across IC agency missions, in order to positively impact IC-wide economies and efficiencies. The IC IG is authorized to investigate complaints or information concerning allegations of a violation of law, rule, regulation, waste, fraud, abuse of authority, or a substantial or specific danger to public health and safety in connection with ODNI and/or IC intelligence programs and activities. The IC IG provides information on how to contact the IC IG directly to submit a report: *http://www.dni.gov/index.php/about-this-site/contact-the-ig*.
- The Office of the Inspector General (OIG) in the U.S. Department of Justice (DOJ) is a statutorily created independent entity whose mission is to detect and deter waste, fraud, abuse, and misconduct in DOJ programs and personnel, and to promote economy and efficiency in those programs. The OIG investigates alleged violations of criminal and civil laws by DOJ employees and also audits and inspects DOJ programs. The OIG has jurisdiction over all complaints of misconduct against Department of Justice employees, including the Federal Bureau of Investigation; Drug Enforcement Administration; Federal Bureau of Prisons; U.S. Marshals Service; Bureau of Alcohol, Tobacco, Firearms, and Explosives; United States Attorneys Offices; and employees who work in other Divisions or Offices in the Department of Justice. (The one exception is that allegations of misconduct by a Department attorney or law enforcement personnel that relate to the exercise of the Department attorney's authority to investigate, litigate, or provide legal advice are the responsibility of the Department's Office of Professional Responsibility.) In addition, section 1001 of the USA Patriot Act, signed into law on October 26, 2001, directs the Inspector General to review information and receive complaints alleging abuses of civil rights and civil liberties by Department of Justice employees. The OIG maintains a public Web site—*https://www.oig.justice.gov*—which includes a ''Hotline'' for submitting complaints—*https://www.oig.justice.gov/hotline/index.htm*.

b. Privacy and Civil Liberties offices and entities in the United States Government also have relevant responsibilities. By way of example:

(i) Section 803 of the Implementing Recommendations of the 9/11 Commission Act of 2007, codified in the United States Code at 42 U.S.C. 2000-ee1, establishes privacy and civil liberties officers at certain departments and agencies (including the Department of State, Department of Justice, and ODNI). Section 803 specifies that these privacy and civil liberties officers will serve as the principal advisor to, among other things, ensure that such department, agency, or element has adequate procedures to address complaints from individuals who allege such department, agency, or element has violated their privacy or civil liberties.

(ii) The ODNI's Civil Liberties and Privacy Office (ODNI CLPO) is led by the ODNI Civil Liberties Protection Officer, a position established by the National Security Act of 1948, as amended. The duties of the ODNI CLPO include ensuring that the policies and procedures of the elements of the Intelligence Community include adequate protections for privacy and civil liberties, and reviewing and investigating complaints alleging abuse or violation of civil liberties and privacy in ODNI programs and activities. The ODNI CLPO provides information to the public on its Web site, including instructions for how to submit a complaint: *www.dni.gov/clpo*. If the ODNI CLPO receives a privacy or civil liberties complaint involving IC programs and activities, it will coordinate with other IC elements on how that complaint should be further processed within the IC. Note that the National Security Agency (NSA) also has a Civil Liberties and Privacy Office, which provides information about its responsibilities on its Web site—*https://www.nsa.gov/civil_liberties/*. If information indicates that an agency is out of compliance with privacy requirements (*e.g.,* a requirement under Section 4 of PPD–28), then agencies have compliance mechanisms to review and remedy the incident. Agencies are required to report compliance incidents under PPD–28 to the ODNI.

(iii) The Office of Privacy and Civil Liberties (OPCL) at the Department of Justice supports the duties and responsibilities of the Department's Chief Privacy and Civil Liberties Officer (CPCLO). The principal mission of OPCL is to protect the privacy and civil liberties of the American people through review, oversight, and coordination of the Department's privacy operations. OPCL provides legal advice and guidance to Departmental components; ensures the Department's privacy compliance, including compliance with the Privacy Act of 1974, the privacy provisions of both the E-Government Act of 2002 and the Federal Information Security Management Act, as well as administration policy directives issued in furtherance of those Acts; develops and provides Departmental privacy training; assists the CPCLO in developing Departmental privacy policy; prepares privacy-related reporting to the President and Congress; and reviews the information handling practices of the Department to ensure that such practices are consistent with

the protection of privacy and civil liberties. OPCL provides information to the public about its responsibilities at *http://www.justice.gov/opcl*.

(iv) According to 42 U.S.C. 2000ee *et seq.,* the Privacy and Civil Liberties Oversight Board shall continually review (i) the policies and procedures, as well as their implementation, of the departments, agencies and elements of the executive branch relating to efforts to protect the Nation from terrorism to ensure that privacy and civil liberties are protected, and (ii) other actions by the executive branch relating to such efforts to determine whether such actions appropriately protect privacy and civil liberties and are consistent with governing laws, regulations, and policies regarding privacy and civil liberties. It shall receive and review reports and other information from privacy officers and civil liberties officers and, when appropriate, make recommendations to them regarding their activities. Section 803 of the Implementing Recommendations of the 9/11 Commission Act of 2007, codified at 42 U.S.C. 2000ee–1, directs the privacy and civil liberties officers of eight federal agencies (including the Secretary of Defense, Secretary of Homeland Security, Director of National Intelligence, and Director of the Central Intelligence Agency), and any additional agency designated by the Board, to submit periodic reports to the PCLOB, including the number, nature, and disposition of the complaints received by the respective agency for alleged violations. The PCLOB's enabling statute directs the Board to receive these reports and, when appropriate, make recommendations to the privacy and civil liberties officers regarding their activities.

Letter From Federal Trade Commission Chairwoman Edith Ramirez

July 7, 2016
VIA EMAIL

Věra Jourová, Commissioner for Justice, Consumers and Gender Equality, European Commission, Rue de la Loi/Wetstraat 200, 1049 Brussels, Belgium

Dear Commissioner Jourová:

The United States Federal Trade Commission (''FTC'') appreciates the opportunity to describe its enforcement of the new EU-U.S. Privacy Shield Framework (the ''Privacy Shield Framework'' or ''Framework''). We believe the Framework will play a critical role in facilitating privacy-protective commercial transactions in an increasingly interconnected world. It will enable businesses to conduct important operations in the global economy, while at the same time ensuring that EU consumers retain important privacy protections. The FTC has long committed to protecting privacy across borders and will make enforcement of the new Framework a high priority. Below, we explain the FTC's history of strong privacy enforcement generally, including our enforcement of the original Safe Harbor program, as well as the FTC's approach to enforcement of the new Framework.

The FTC first publicly expressed its commitment to enforce the Safe Harbor program in 2000. At that time, then-FTC Chairman Robert Pitofsky sent the European Commission a letter outlining the FTC's pledge to vigorously enforce the Safe Harbor Privacy Principles. The FTC has continued to uphold this commitment through nearly 40 enforcement actions, numerous additional investigations, and cooperation with individual European data protection authorities (''EU DPAs'') on matters of mutual interest.

After the European Commission raised concerns in November 2013 about the administration and enforcement of the Safe Harbor program, we and the U.S. Department of Commerce began consultations with officials from the European Commission to explore ways to strengthen it. While those consultations were proceeding, on October 6, 2015, the European Court of Justice issued a decision in the *Schrems* case that, among other things, invalidated the European Commission's decision on the adequacy of the Safe Harbor program. Following the decision, we continued to work closely with the Department of Commerce and the European Commission in an effort to strengthen the privacy protections provided to EU individuals. The Privacy Shield Framework is a result of these ongoing consultations. As was the case with the Safe Harbor program, the FTC hereby commits to vigorous enforcement of the new Framework. This letter memorializes that commitment.

Notably, we affirm our commitment in four key areas: (1) Referral prioritization and investigations; (2) addressing false or deceptive Privacy Shield membership claims; (3) continued order monitoring; and (4) enhanced engagement and enforcement cooperation with EU DPAs. We provide below detailed information about each of these commitments and relevant background about the FTC's role in protecting consumer privacy and enforcing Safe Harbor, as well as the broader privacy landscape in the United States.[12]

I. Background

A. FTC Privacy Enforcement and Policy Work

The FTC has broad civil enforcement authority to promote consumer protection and competition in the commercial sphere. As part of its consumer protection mandate, the FTC enforces a wide range of laws to protect the privacy and security of consumer data. The primary law enforced by the FTC, the FTC Act, prohibits ''unfair'' and ''deceptive'' acts or practices in or affecting commerce.[13] A representation, omission, or practice is deceptive if it is material and likely to mislead consumers acting reasonably under the circumstances.[14] An act or practice is unfair if it causes, or is likely to cause, substantial injury that is not reasonably avoidable by consumers or outweighed by countervailing benefits to consumers or competition.[15] The FTC also enforces targeted statutes that protect information relating to health, credit and other financial matters, as well as children's online information, and has issued regulations implementing each of these statutes.

The FTC's jurisdiction under the FTC Act applies to matters ''in or affecting commerce.'' The FTC does not have jurisdiction over criminal law enforcement or national security matters. Nor can the FTC reach most other governmental actions. In addition, there are exceptions to the FTC's jurisdiction over commercial activities, including with respect to banks, airlines, the business of insurance, and the common carrier activities of telecommunications service providers. The FTC also does not have jurisdiction over most non-profit organizations, but it does have jurisdiction over sham charities or other non-profits that in actuality operate for profit. The FTC also has jurisdiction over non-profit organizations that operate for the profit of their for-profit members, including by providing substantial economic benefits to those members.[16] In some instances, the FTC's jurisdiction is concurrent with that of other law enforcement agencies.

We have developed strong working relationships with federal and state authorities and work closely with them to coordinate investigations or make referrals where appropriate.

Enforcement is the lynchpin of the FTC's approach to privacy protection. To date, the FTC has brought over 500 cases protecting the privacy and security of consumer information. This body of cases covers both offline and online information and includes enforcement actions against companies large and small, alleging that they failed to properly dispose of sensitive consumer data, failed to secure consumers' personal information, deceptively tracked consumers online, spammed consumers, installed spyware or other malware on consumers' computers, violated Do Not Call and other telemarketing rules, and improperly collected and shared consumer information on mobile devices. The FTC's enforcement actions—in both the physical and digital worlds—send an important message to companies about the need to protect consumer privacy.

The FTC has also pursued numerous policy initiatives aimed at enhancing consumer privacy that inform its enforcement work. The FTC has hosted workshops and issued reports recommending best practices aimed at improving privacy in the mobile ecosystem; increasing transparency of the data broker industry; maximizing the benefits of big data while mitigating its risks, particularly for low-income and underserved consumers; and highlighting the privacy and security

[12] We provide additional information about U.S. federal and state privacy laws in Attachment A. In addition, a summary of our recent privacy and security enforcement actions is available on the FTC's Web site at *https://www.ftc.gov/reports/privacy-data-security-update-2015*.

[13] 15 U.S.C. 45(a).

[14] *See* FTC Policy Statement on Deception, *appended to Cliffdale Assocs., Inc.,* 103 F.T.C. 110, 174 (1984), *available at https://www.ftc.gov/public-statements/1983/10/ftc-policy-statement-deception.*

[15] *See* 15 U.S.C 45(n); FTC Policy Statement on Unfairness, *appended to Int'l Harvester Co.,* 104 F.T.C. 949, 1070 (1984), *available at https://www.ftc.gov/public-statements/1980/12/ftc-policy-statement-unfairness.*

[16] *See California Dental Ass'n* v. *FTC,* 526 U.S. 756 (1999).

implications of facial recognition and the Internet of Things, among other areas.

The FTC also engages in consumer and business education to enhance the impact of its enforcement and policy development initiatives. The FTC has used a variety of tools— publications, online resources, workshops, and social media—to provide educational materials on a wide range of topics, including mobile apps, children's privacy, and data security. Most recently, the Commission launched its ''Start With Security'' initiative, which includes new guidance for businesses drawing on lessons learned from the agency's data security cases, as well as a series of workshops across the country. In addition, the FTC has long been a leader in educating consumers about basic computer security. Last year, our OnGuard Online site and its Spanish language counterpart, Alerta en Línea, had more than 5 million page views.

B. U.S. Legal Protections Benefiting EU Consumers

The Framework will operate in the context of the larger U.S. privacy landscape, which protects EU consumers in a number of ways.

The FTC Act's prohibition on unfair or deceptive acts or practices is not limited to protecting U.S. consumers from U.S. companies, as it includes those practices that (1) cause or are likely to cause reasonably foreseeable injury in the United States, or (2) involve material conduct in the United States. Further, the FTC can use all remedies, including restitution, that are available to protect domestic consumers when protecting foreign consumers.

Indeed, the FTC's enforcement work significantly benefits both U.S. and foreign consumers. For example, our cases enforcing Section 5 of the FTC Act have protected the privacy of U.S. and foreign consumers alike. In a case against an information broker, Accusearch, the FTC alleged that the company's sale of confidential telephone records to third parties without consumers' knowledge or consent was an unfair practice in violation of Section 5 of the FTC Act. Accusearch sold information relating to both U.S. and foreign consumers.[17] The court granted injunctive relief against Accusearch prohibiting, among other things, the marketing or sale of consumers' personal information without written consent, unless it was lawfully obtained from publicly available information, and ordered disgorgement of almost $200,000.[18]

The FTC's settlement with TRUSTe is another example. It ensures that consumers, including those in the European Union, can rely on representations that a global self-regulatory organization makes about its review and certification of domestic and foreign online services.[19] Importantly, our action against TRUSTe also strengthens the privacy self-regulatory system more broadly by ensuring the accountability of entities that play an important role in self-regulatory schemes, including cross-border privacy frameworks.

The FTC also enforces other targeted laws whose protections extend to non-U.S. consumers, such as the Children's Online Privacy Protection Act (''COPPA''). Among other things, COPPA requires that operators of child-directed Web sites and online services, or general audience sites that knowingly collect personal information from children under the age of 13, provide parental notice and obtain verifiable parental consent. U.S.-based Web sites and services that are subject to COPPA and collect personal information from foreign children are required to comply with COPPA. Foreign-based Web sites and online services must also comply with COPPA if they are directed to children in the United States, or if they knowingly collect personal information from children in the United States. In addition to the U.S. federal laws enforced by the FTC, certain other federal and state consumer protection and privacy laws may provide additional benefits to EU consumers.

C. Safe Harbor Enforcement

As part of its privacy and security enforcement program, the FTC has also sought to protect EU consumers by bringing enforcement actions that involved Safe Harbor violations. The FTC has brought 39 Safe Harbor enforcement actions: 36 alleging false certification claims, and three cases—against Google, Facebook, and Myspace—involving alleged violations of Safe Harbor Privacy Principles.[20] These cases demonstrate the enforceability of certifications and the repercussions for non-compliance. Twenty-year consent orders require Google, Facebook, and Myspace to implement comprehensive privacy programs that must be reasonably designed to address privacy risks related to the development and management of new and existing products and services and to protect the privacy and confidentiality of personal information. The comprehensive privacy programs mandated under these orders must identify foreseeable material risks and have controls to address those risks. The companies must also submit to ongoing, independent assessments of their privacy programs, which must be provided to the FTC. The orders also prohibit these companies from misrepresenting their privacy practices and their participation in any privacy or security program. This prohibition would also apply to companies' acts and practices under the new Privacy Shield Framework. The FTC can enforce these orders by seeking civil penalties. In fact, Google paid a record $22.5 million civil penalty in 2012 to resolve allegations it had violated its order. Consequently, these FTC orders help protect over a billion consumers worldwide, hundreds of millions of whom reside in Europe.

The FTC's cases have also focused on false, deceptive, or misleading claims of Safe Harbor participation. The FTC takes these claims seriously. For example, in *FTC* v. *Karnani,* the FTC brought an action in 2011 against an Internet marketer in the United States alleging that he and his company tricked British consumers into believing that the company was based in the United Kingdom, including by using .uk web extensions and referencing British currency and the UK postal system.[21] However, when consumers received the products, they discovered unexpected import duties, warranties that were not valid in the United Kingdom, and charges associated with obtaining refunds. The FTC also charged that the defendants deceived consumers about their participation in the Safe Harbor program. Notably, all of the consumer victims were in the United Kingdom.

Many of our other Safe Harbor enforcement cases involved organizations that joined the Safe Harbor program but failed to renew their annual certification while they continued to represent themselves as current members. As discussed further below, the FTC also commits to addressing false claims of participation in the Privacy Shield Framework. This strategic enforcement activity will complement the Department of Commerce's increased actions to verify compliance with program requirements for certification and re-certification, its monitoring of effective compliance, including through the use of questionnaires to Framework participants, and its increased efforts to identify false Framework membership claims and misuse of any Framework certification mark.[22]

II. Referral Prioritization and Investigations

As we did under the Safe Harbor program, the FTC commits to give priority to Privacy Shield referrals from EU Member States. We will also prioritize referrals of non-compliance with self-regulatory guidelines relating to the Privacy Shield Framework from privacy self- regulatory organizations

[17] *See* Office of the Privacy Commissioner of Canada, Complaint under PIPEDA against Accusearch, Inc., doing business as Abika.com, *https://www.priv.gc.ca/cf-dc/2009/20090090731e.asp.* The Office of the Privacy Commissioner of Canada filed an *amicus curiae* brief in the appeal of the FTC action and conducted its own investigation, concluding that Accusearch's practices also violated Canadian law.

[18] *See FTC* v. *Accusearch, Inc.,* No. 06CV015D (D. Wyo. Dec. 20, 2007), *aff'd* 570 F.3d 1187 (10th Cir. 2009).

[19] *See In the Matter of True Ultimate Standards Everywhere, Inc.,* No. C–4512 (F.T.C. Mar. 12, 2015) (decision and order), *available at https://wwwftc.gov/system/files/documents/cases/150318trust-edo.pdf.*

[20] *See In the Matter of Google, Inc.,* No. C–4336 (F.T.C. Oct. 13 2011) (decision and order), *available at https://wwwftc.gov/news-events/press-releases/2011/03/ftc-charges-deceptive-privacy-practices-googles-rollout-its- buzz; In the Matter of Facebook, Inc.,* No. C–4365 (F.T.C. July 27, 2012) (decision and order), *available at https://wwwftc.gov/news-events/press-releases/2012/08/ftc-approves-final-settlement-facebook*; *In the Matter of Myspace LLC,* No. C–4369 (F.T.C. Aug. 30, 2012) (decision and order), *available at https://www.ftc.gov/news-events/press-releases/2012/09/ftc-finalizes-privacy-settlement-myspace.*

[21] *See FTC* v. *Karnani,* No. 2:09-cv-05276 (C.D. Cal. May 20, 2011) (stipulated final order), *available at https://www.ftc.gov/sites/default/files/documents/cases/2011/06/110609karnanistip.pdf; see also* Lesley Fair, FTC Business Center Blog, *Around the World in Shady Ways, http://www.business.ftc.gov/blog/2011/06/around-world-shady-ways* (June 9, 2011).

[22] Letter from Ken Hyatt, Acting Under Secretary of Commerce for International Trade, International Trade Administration, to Věra Jourová, Commissioner for Justice, Consumers and Gender Equality.

and other independent dispute resolution bodies.

To facilitate referrals under the Framework from EU Member States, the FTC is creating a standardized referral process and providing guidance to EU Member States on the type of information that would best assist the FTC in its inquiry into a referral. As part of this effort, the FTC will designate an agency point of contact for EU Member State referrals. It is most useful when the referring authority has conducted a preliminary inquiry into the alleged violation and can cooperate with the FTC in an investigation.

Upon receipt of a referral from an EU Member State or self-regulatory organization, the FTC can take a range of actions to address the issues raised. For example, we may review the company's privacy policies, obtain further information directly from the company or from third parties, follow up with the referring entity, assess whether there is a pattern of violations or significant number of consumers affected, determine whether the referral implicates issues within the purview of the Department of Commerce, assess whether consumer and business education would be helpful, and, as appropriate, initiate an enforcement proceeding.

The FTC also commits to exchange information on referrals with referring enforcement authorities, including the status of referrals, subject to confidentiality laws and restrictions. To the extent feasible given the number and type of referrals received, the information provided will include an evaluation of the referred matters, including a description of significant issues raised and any action taken to address law violations within the jurisdiction of the FTC. The FTC will also provide feedback to the referring authority on the types of referrals received in order to increase the effectiveness of efforts to address unlawful conduct. If a referring enforcement authority seeks information about the status of a particular referral for purposes of pursuing its own enforcement proceeding, the FTC will respond, taking into account the number of referrals under consideration and subject to confidentiality and other legal requirements.

The FTC will also work closely with EU DPAs to provide enforcement assistance. In appropriate cases, this could include information sharing and investigative assistance pursuant to the U.S. SAFE WEB Act, which authorizes FTC assistance to foreign law enforcement agencies when the foreign agency is enforcing laws prohibiting practices that are substantially similar to those prohibited by laws the FTC enforces.[23] As part of this assistance, the FTC can share information obtained in connection with an FTC investigation, issue compulsory process on behalf of the EU DPA conducting its own investigation, and seek oral testimony from witnesses or defendants in connection with the DPA's enforcement proceeding, subject to the requirements of the U.S. SAFE WEB Act. The FTC regularly uses this authority to assist other authorities around the world in privacy and consumer protection cases.[24]

In addition to prioritizing Privacy Shield referrals from EU Member States and privacy self-regulatory organizations,[25] the FTC commits to investigating possible Framework violations on its own initiative where appropriate using a range of tools.

For well over a decade, the FTC has maintained a robust program of investigating privacy and security issues involving commercial organizations. As part of these investigations, the FTC routinely examined whether the entity at issue was making Safe Harbor representations. If the entity was making such representations and the investigation revealed apparent violations of the Safe Harbor Privacy Principles, the FTC included allegations of Safe Harbor violations in its enforcement actions. We will continue this proactive approach under the new Framework. Importantly, the FTC conducts many more investigations than ultimately result in public enforcement actions. Many FTC investigations are closed because staff does not identify an apparent law violation. Because FTC investigations are non-public and confidential, the closing of an investigation is often not made public.

The nearly 40 enforcement actions initiated by the FTC involving the Safe Harbor program evidence the agency's commitment to proactive enforcement of cross-border privacy programs. The FTC will look for potential Framework violations as part of the privacy and security investigations we undertake on a regular basis.

III. Addressing False or Deceptive Privacy Shield Membership Claims

As referenced above, the FTC will take action against entities that misrepresent their participation in the Framework. The FTC will give priority consideration to referrals from the Department of Commerce regarding organizations that it identifies as improperly holding themselves out to be current members of the Framework or using any Framework certification mark without authorization.

In addition, we note that if an organization's privacy policy promises that it complies with the Privacy Shield Principles, its failure to make or maintain a registration with the Department of Commerce likely will not, by itself, excuse the organization from FTC enforcement of those Framework commitments.

IV. Order Monitoring

The FTC also affirms its commitment to monitor enforcement orders to ensure compliance with the Privacy Shield Framework.

We will require compliance with the Framework through a variety of appropriate injunctive provisions in future FTC Framework orders. This includes prohibiting misrepresentations regarding the Framework and other privacy programs when these are the basis for the underlying FTC action.

The FTC's cases enforcing the original Safe Harbor program are instructive. In the 36 cases involving false or deceptive claims of Safe Harbor certification, each order prohibits the defendant from misrepresenting its participation in Safe Harbor or any other privacy or security program and requires the company to make compliance reports available to the FTC. In cases that involved violations of Safe Harbor Privacy Principles, companies have been required to implement comprehensive privacy programs and obtain independent third-party assessments of those programs every other year for twenty years, which they must provide to the FTC.

Violations of the FTC's administrative orders can lead to civil penalties of up to $16,000 per violation, or $16,000 per day for a continuing violation,[26] which, in the case of practices affecting many consumers, can amount to millions of dollars. Each consent order also has reporting and compliance provisions. The entities under order must retain documents demonstrating their compliance for a specified number of years. The orders must also be disseminated to employees responsible for ensuring order compliance.

The FTC systematically monitors compliance with Safe Harbor orders, as it does with all of its orders. The FTC takes enforcement of its privacy and data security orders seriously and brings actions to enforce them when necessary. For example, as noted above, Google paid a $22.5 million civil penalty to resolve allegations it had violated its FTC order. Importantly, FTC orders will continue to protect all consumers worldwide who interact with a business, not just those consumers who have lodged complaints.

Finally, the FTC will continue to maintain an online list of companies subject to orders obtained in connection with enforcement of both the Safe Harbor program and the new Privacy Shield Framework.[27] In addition, the Privacy Shield Principles now require companies subject to an FTC or court order based on non-compliance with the Principles

[23] In determining whether to exercise its U.S. SAFE WEB Act authority, the FTC considers, inter alia: ''(A) whether the requesting agency has agreed to provide or will provide reciprocal assistance to the Commission; (B) whether compliance with the request would prejudice the public interest of the United States; and (C) whether the requesting agency's investigation or enforcement proceeding concerns acts or practices that cause or are likely to cause injury to a significant number of persons.'' 15 U.S.C. 46(j)(3). This authority does not apply to enforcement of competition laws.

[24] In fiscal years 2012–2015, for example, the FTC used its U.S. SAFE WEB Act authority to share information in response to almost 60 requests from foreign agencies and it issued nearly 60 civil investigative demands (equivalent to administrative subpoenas) to aid 25 foreign investigations.

[25] Although the FTC does not resolve or mediate individual consumer complaints, the FTC affirms that it will prioritize Privacy Shield referrals from EU DPAs. In addition, the FTC uses complaints in its Consumer Sentinel database, which is accessible by many other law enforcement agencies, to identify trends, determine enforcement priorities, and identify potential investigative targets. EU individuals can use the same complaint system available to U.S. citizens to submit a complaint to the FTC at *www.ftc.gov/complaint*. For individual Privacy Shield complaints, however, it may be most useful for EU individuals to submit complaints to their Member State DPA or alternative dispute resolution provider.

[26] 15 U.S.C. 45(m); 16 CFR 1.98.

[27] *See* FTC, Business Center, Legal Resources, *https://www.ftc.gov/tips-advice/business-center/legal- resources?type=case&field consumer protection topics tid=251.*

to make public any relevant Framework-related sections of any compliance or assessment report submitted to the FTC, to the extent consistent with confidentiality laws and rules.

V. Engagement With EU DPAs and Enforcement Cooperation

The FTC recognizes the important role that EU DPAs play with respect to Framework compliance and encourages increased consultation and enforcement cooperation. In addition to any consultation with referring DPAs on case-specific matters, the FTC commits to participate in periodic meetings with designated representatives of the Article 29 Working Party to discuss in general terms how to improve enforcement cooperation with respect to the Framework. The FTC will also participate, along with the Department of Commerce, the European Commission, and Article 29 Working Party representatives, in the annual review of the Framework to discuss its implementation.

The FTC also encourages the development of tools that will enhance enforcement cooperation with EU DPAs, as well as other privacy enforcement authorities around the world. In particular, the FTC, along with enforcement partners in the European Union and around the globe, last year launched an alert system within the Global Privacy Enforcement Network (''GPEN'') to share information about investigations and promote enforcement coordination. This GPEN Alert tool could be particularly useful in the context of the Privacy Shield Framework. The FTC and EU DPAs could use it to coordinate with respect to the Framework and other privacy investigations, including as a starting point for sharing information in order to deliver coordinated and more effective privacy protection for consumers. We look forward to continuing to work with participating EU authorities to deploy the GPEN Alert system more broadly and develop other tools to improve enforcement cooperation in privacy cases, including those involving the Framework.

* * *

The FTC is pleased to affirm its commitment to enforcing the new Privacy Shield Framework. We also look forward to continuing engagement with our EU colleagues as we work together to protect consumer privacy on both sides of the Atlantic.

Sincerely,

Edith Ramirez, Chairwoman

Attachment A

The EU-U.S. Privacy Shield Framework in Context: An Overview of the U.S. Privacy and Security Landscape

The protections provided by the EU-U.S. Privacy Shield Framework (the ''Framework'') exist in the context of the broader privacy protections afforded under the U.S. legal system as a whole. First, the U.S. Federal Trade Commission (''FTC'') has a robust privacy and data security program for U.S. commercial practices that protects consumers worldwide. Second, the landscape of consumer privacy and security protection in the United States has evolved substantially since 2000 when the original U.S.-EU Safe Harbor program was adopted. Since that time, many federal and state privacy and security laws have been enacted, and public and private litigation to enforce privacy rights has increased significantly. The broad scope of U.S. legal protections for consumer privacy and security applicable to commercial data practices complements the protections provided to EU individuals by the new Framework.

I. The FTC's General Privacy and Security Enforcement Program

The FTC is the leading U.S. consumer protection agency focused on commercial sector privacy. The FTC has authority to prosecute unfair and deceptive acts or practices that violate consumer privacy, as well as to enforce more targeted privacy laws that protect certain financial and health information, information about children, and information used to make certain eligibility decisions about consumers.

The FTC has unparalleled experience in consumer privacy enforcement. The FTC's enforcement actions have addressed unlawful practices in offline and online environments. For example, the FTC has brought enforcement actions against well-known companies, such as Google, Facebook, Twitter, Microsoft, Wyndham, Oracle, HTC, and Snapchat, as well as lesser-known companies. The FTC has sued businesses that allegedly spammed consumers, installed spyware on computers, failed to secure consumers' personal information, deceptively tracked consumers online, violated children's privacy, unlawfully collected information on consumers' mobile devices, and failed to secure Internet-connected devices used to store personal information. The resulting orders have typically provided for ongoing monitoring by the FTC for a period of twenty years, prohibited further law violations, and subjected the businesses to substantial financial penalties for order violations.[1] Importantly, FTC orders do not just protect the individuals who may have complained about a problem; rather, they protect all consumers dealing with the business going forward. In the cross-border context, the FTC has jurisdiction to protect consumers worldwide from practices taking place in the United States.[2]

To date, the FTC has brought over 130 spam and spyware cases, over 120 ''Do Not Call'' telemarketing cases, over 100 Fair Credit Reporting Act actions, almost 60 data security cases, more than 50 general privacy actions, almost 30 cases for violations of the Gramm-Leach-Bliley Act, and over 20 actions enforcing the Children's Online Privacy Protection Act (''COPPA'').[3] In addition to these cases, the FTC has also issued and publicized warning letters.[4]

As part of its history of strong privacy enforcement, the FTC has also regularly looked for potential violations of the Safe Harbor program. Since the Safe Harbor program was adopted, the FTC has undertaken numerous investigations into Safe Harbor compliance on its own initiative and has brought 39 cases against U.S. companies for Safe Harbor violations. The FTC will continue this proactive approach by making enforcement of the new Framework a priority.

II. Federal and State Protections for Consumer Privacy

The Safe Harbor Enforcement Overview, which appears as an annex to the European Commission's Safe Harbor adequacy decision, provides a summary of many of the federal and state privacy laws in place at the time the Safe Harbor program was adopted in 2000.[5] At that time, many federal statutes regulated the commercial collection and use of personal information, beyond Section 5 of the FTC Act, including: the Cable Communications Policy Act, the Driver's Privacy Protection Act, the Electronic Communications Privacy Act, the Electronic Funds Transfer Act, the Fair Credit Reporting Act, the Gramm-Leach-Bliley Act, the Right to Financial Privacy Act, the Telephone Consumer Protection Act, and the Video Privacy Protection Act. Many states had analogous laws in these areas as well.

Since 2000, there have been numerous developments at both the federal and state level that provide additional consumer privacy protections.[6] At the federal level, for example, the FTC amended the COPPA Rule in 2013 to provide a number of additional protections for children's personal information. The FTC also issued two rules implementing the Gramm-Leach-Bliley Act—the Privacy Rule and the Safeguards Rule—

[1] Any entity that fails to comply with an FTC order is subject to a civil penalty of up to $16,000 per violation, or $16,000 per day for a continuing violation. *See* 15 U.S.C. 45(l); 16 CFR 1.98(c).

[2] Congress has expressly affirmed the FTC's authority to seek legal remedies, including restitution, for any acts or practices involving foreign commerce that (1) cause or are likely to cause reasonably foreseeable injury in the United States, or (2) involve material conduct occurring within the United States. *See* 15 U.S.C. 45(a)(4).

[3] In some instances, the Commission's privacy and data security cases allege that a company engaged in both deceptive and unfair practices; these cases also sometimes involve alleged violations of multiple statues, such as the Fair Credit Reporting Act, the Gramm-Leach-Bliley Act, and COPPA.

[4] *See, e.g.,* Press Release, Fed. Trade Comm'n, FTC Warns Children's App Maker BabyBus About Potential COPPA Violations (Dec. 22, 2014), *https://www.ftc.gov/news-events/press-releases/2014/12/ftc-warns-childrens-app-maker-babybus-about-potential-coppa;* Press Release, Fed. Trade Comm'n, FTC Warns Data Broker Operations of Possible Privacy Violations (May 7, 2013), *https://www.ftc.gov/news-events/press-releases/2013/05/ftc-warns-data-broker-operations-possible-privacy-violations;* Press Release, Fed. Trade Comm'n, FTC Warns Data Brokers That Provide Tenant Rental Histories They May Be Subject to Fair Credit Reporting Act (Apr. 3, 2013), *https://www.ftc.gov/news-events/press-releases/2013/04/ftc-warns-data-brokers-provide-tenant-rental-histories-they-may.*

[5] *See* U.S. Dep't of Commerce, Safe Harbor Enforcement Overview, *https://build.export.gov/main/safeharbor/eu/eg main 018481.*

[6] For a more comprehensive summary of the legal protections in the United States, see Daniel J. Solove & Paul Schwartz, *Information Privacy Law* (5th ed. 2015).

which require financial institutions [7] to make disclosures about their information sharing practices and to implement a comprehensive information security program to protect consumer information.[8] Similarly, the Fair and Accurate Credit Transactions Act (''FACTA''), enacted in 2003, supplements longstanding U.S. credit laws to establish requirements for the masking, sharing, and disposal of certain sensitive financial data. The FTC promulgated a number of rules under FACTA regarding, among other things, consumers' right to a free annual credit report; secure disposal requirements for consumer report information; consumers' right to opt out of receiving certain offers of credit and insurance; consumers' right to opt out of the use of information provided by an affiliated company to market its products and services; and requirements for financial institutions and creditors to implement identity theft detection and prevention programs.[9] In addition, rules promulgated under the Health Insurance Portability and Accountability Act were revised in 2013, adding additional safeguards to protect the privacy and security of personal health information.[10] Rules protecting consumers from unwanted telemarketing calls, robocalls, and spam have also gone into effect. Congress has also enacted laws requiring certain companies that collect health information to provide consumers with notification in the event of a breach.[11]

States have also been very active in passing laws related to privacy and security. Since 2000, forty-seven states, the District of Columbia, Guam, Puerto Rico and the Virgin Islands have enacted laws requiring businesses to notify individuals of security breaches of personal information.[12] At least thirty-two states and Puerto Rico have data disposal laws, establishing requirements for the destruction or disposal of personal information.[13] A number of states also have enacted general data security laws. In addition, California has enacted various privacy laws, including a law requiring companies to have privacy policies and disclose their Do Not Track practices,[14] a ''Shine the Light'' law requiring greater transparency for data brokers,[15] and a law that mandates an ''eraser button'' allowing minors to request the deletion of certain social media information.[16] Using these laws and other authorities, federal and state governments have levied significant fines against companies that have failed to protect the privacy and security of consumers' personal information.[17]

Private lawsuits have also led to successful judgments and settlements that provide additional privacy and data security protection for consumers. For example, in 2015, Target agreed to pay $10 million as part of a settlement with customers who claimed their personal financial information was compromised by a widespread data breach. In 2013, AOL agreed to pay a $5 million settlement to resolve a class action involving alleged inadequate de-identification related to the release of search queries of hundreds of thousands of AOL members. Additionally, a federal court approved a $9 million payment by Netflix for allegedly keeping rental history records in violation of the Video Privacy Protection Act of 1988. Federal courts in California approved two separate settlements with Facebook, one for $20 million and another for $9.5 million, involving the company's collection, use, and sharing of its users' personal information. And, in 2008, a California state court approved a $20 million settlement with LensCrafters for unlawful disclosure of consumers' medical information.

In sum, as this summary illustrates, the United States provides significant legal protection for consumer privacy and security. The new Privacy Shield Framework, which ensures meaningful safeguards for EU individuals, will operate against this larger backdrop in which the protection of consumers' privacy and security continues to be an important priority.

Letter From U.S. Secretary of Transportation Anthony Foxx

February 19, 2016
Commissioner Vera Jourová
European Commission
Rue de la Loi*I* Wetstraat 200
1 049 l 049 Brussels
Belgium

Re: EU-U.S. Privacy Shield Framework

Dear Commissioner Jourová:

The United States Department of Transportation (''Department'' or ''DOT'') appreciates the opportunity to describe its role in enforcing the EU-U.S. Privacy Shield Framework. This Framework plays a critical role in protecting personal data provided during commercial transactions in an increasingly interconnected world. It enables businesses to conduct important operations in the global economy, while at the same time ensuring that EU consumers retain important privacy protections.

The DOT first publicly expressed its commitment to enforcement of the Safe Harbor Framework in a letter sent to the European Commission over 15 years ago. The DOT pledged to vigorously enforce the Safe Harbor Privacy Principles in that letter. The DOT continues to uphold this commitment and this letter memorializes that commitment.

Notably, the DOT renews its commitment in the following key areas: (1) Prioritization of investigation of alleged Privacy Shield violations; (2) appropriate enforcement action against entities making false or deceptive Privacy Shield certification claims; and (3) monitoring and making public enforcement orders concerning Privacy Shield violations. We provide information about each of these commitments and, for necessary context, pertinent background about the DOT's role in protecting consumer privacy and enforcing the Privacy Shield Framework.

I. Background

A. DOT's Privacy Authority

The Department is strongly committed to ensuring the privacy of information provided by consumers to airlines and ticket agents. The DOT's authority to take action in this area is found in 49 U.S.C. 41712, which prohibits a carrier or ticket agent from engaging in ''an unfair or deceptive practice or an unfair method of competition'' in the sale of air transportation that results or is likely to result in consumer harm. Section 41712 is patterned after Section 5 of the Federal Trade Commission (FTC) Act (15 U.S.C. 45). We interpret our unfair or deceptive practice statute as prohibiting an airline or ticket agent from: (1) Violating the terms of its privacy policy; or (2) gathering or disclosing private information in a way that violates public policy, is immoral, or causes substantial consumer injury not offset by any countervailing benefits. We also interpret section 41712 as prohibiting carriers and ticket agents from: (l) violating any rule issued by the Department that identifies specific privacy practices as unfair or deceptive; or (2) violating the Children's Online Privacy Protection Act (COPPA) or FTC rules implementing COPPA. Under federal law, the DOT has exclusive authority to regulate the privacy practices of airlines, and it shares jurisdiction with the FTC with respect to the privacy practices of ticket agents in the sale of air transportation.

As such, once a carrier or seller of air transportation publicly commits to the

[7] Financial institutions are defined very broadly under the Gramm-Leach-Bliley Act to include all businesses that are ''significantly engaged'' in providing financial products or services. This includes, for example, check-cashing businesses, payday lenders, mortgage brokers, nonbank lenders, personal property or real estate appraisers, and professional tax preparers.

[8] Under the Consumer Financial Protection Act of 2010 (''CFPA''), Title X of Pub. L. 111–203, 124 Stat. 1955 (July 21, 2010) (also known as the ''Dodd-Frank Wall Street Reform and Consumer Protection Act''), most of the FTC's Gramm-Leach-Bliley Act rulemaking authority was transferred to the Consumer Financial Protection Bureau (''CFPB''). The FTC retains enforcement authority under the Gramm-Leach-Bliley Act as well as rulemaking authority for the Safeguards Rule and limited rulemaking authority under the Privacy Rule with respect to auto dealers.

[9] Under the CFPA, the Commission shares its FCRA enforcement role with the CFPB, but rulemaking authority transferred in large part to the CFPB (with the exception of the Red Flags and Disposal Rules).

[10] *See* 45 CFR parts 160, 162, and 164.

[11] *See e.g.,* American Recovery & Reinvestment Act of 2009, Pub. L. No. 111–5, 123 Stat. 115 (2009) and relevant regulations, 45 CFR 16.404–164.414; 16 CFR part 318.

[12] *See, e.g.,* National Conference of State Legislatures (''NCSL''), *State Security Breach Notification Laws* (Jan. 4, 2016), *available at http://www.ncsl.org/research/telecommunications-and-information-technology/security-breach-notification-laws.aspx.*

[13] NCSL, *Data Disposal Laws* (Jan. 12, 2016), *available at http://www.ncsl.org/research/telecommunications-and-information-technology/data-disposal-laws.aspx.*

[14] Cal. Bus. & Professional Code sections 22575–22579.

[15] Cal. Civ. Code sections 1798.80–1798.84.

[16] Cal. Bus. & Professional Code sections 22580–22582.

[17] *See* Jay Cline, *U.S. Takes the Gold in Doling Out Privacy Fines,* Computerworld (Feb. 17, 2014), *available at http://www.computerworld.com/s/article/9246393/Jay Cline U.S. takes the gold in doling out privac y fines?taxonomyId=17&pageNumber=1.*

Privacy Shield Framework's privacy principles the Department is able to use the statutory powers of section 41712 to ensure compliance with those principles. Therefore, once a passenger provides information to a carrier or ticket agent that has committed to honoring the Privacy Shield Framework's privacy principles, any failure to do so by the carrier or ticket agent would be a violation of section 41712.

B. Enforcement Practices

The Department's Office of Aviation Enforcement and Proceedings (Aviation Enforcement Office) investigates and prosecutes cases under 49 U.S.C. 41712. It enforces the statutory prohibition in section 41712 against unfair and deceptive practices primarily through negotiation, preparing cease and desist orders, and drafting orders assessing civil penalties. The office learns of potential violations largely from complaints it receives from individuals, travel agents, airlines, and U.S. and foreign government agencies. Consumers may use the DOT's Web site to file privacy complaints against airlines and ticket agents.[1]

If a reasonable and appropriate settlement in a case is not reached, the Aviation Enforcement Office has the authority to institute an enforcement proceeding involving an evidentiary hearing before a DOT administrative law judge (ALJ). The ALJ has the authority to issue cease-and desist orders and civil penalties. Violations of section 41712 can result in the issuance of cease and desist orders and the imposition of civil penalties of up to $27,500 for each violation of section 41712.

The Department does not have the authority to award damages or provide pecuniary relief to individual complainants. However, the Department does have the authority to approve settlements resulting from investigations brought by its Aviation Enforcement Office that directly benefit consumers (*e.g.,* cash, vouchers) as an offset to monetary penalties otherwise payable to the U.S. Government. This has occurred in the past, and may also occur in the context of the Privacy Shield Framework principles when circumstances warrant. Repeated violations of section 41712 by an airline would also raise questions regarding the airline's compliance disposition which could, in egregious situations, result in an airline being found to be no longer fit to operate and, therefore, losing its economic operating authority.

To date, the DOT has received relatively few complaints involving alleged privacy violations by ticket agents or airlines. When they arise, they are investigated according to the principles set forth above.

C. DOT Legal Protections Benefiting EU Consumers

Under section 41712, the prohibition on unfair or deceptive practices in air transportation or the sale of air transportation applies to U.S. and foreign air carriers as well as ticket agents. The DOT frequently takes action against U.S. and foreign airlines for practices that affect both foreign and U.S. consumers on the basis that the airline's practices took place in the course of providing transportation to or from the United States. The DOT does and will continue to use all remedies that are available to protect both foreign and U.S. consumers from unfair or deceptive practices in air transportation by regulated entities.

The DOT also enforces, with respect to airlines, other targeted laws whose protections extend to non-U.S. consumers such as COPPA. Among other things, COPPA requires that operators of child-directed Web sites and online services, or general audience sites that knowingly collect personal information from children under 13 provide parental notice and obtain verifiable parental consent. U.S.-based Web sites and services that are subject to COPPA and collect personal information from foreign children are required to comply with COPPA. Foreign-based Web sites and online services must also comply with COPPA if they are directed to children in the United States, or if they knowingly collect personal information from children in the United States. To the extent that U.S. or foreign airlines doing business in the United States violate COPPA, the DOT would have jurisdiction to take enforcement action.

II. Privacy Shield Enforcement

If an airline or ticket agent chooses to participate in the Privacy Shield Framework and the Department receives a complaint that such an airline or ticket agent had allegedly violated the Framework, the Department would take the following steps to vigorously enforce the Framework.

A. Prioritizing Investigation of Alleged Violations

The Department's Aviation Enforcement Office will investigate each complaint alleging Privacy Shield violations (including complaints received from EU Data Protection Authorities) and take enforcement action where there is evidence of a violation. Further, the Aviation Enforcement Office will cooperate with the FTC and Department of Commerce and give priority consideration to allegations that the regulated entities are not complying with privacy commitments made as part of the Privacy Shield Framework.

Upon receipt of an allegation of a violation of the Privacy Shield Framework, the Department's Aviation Enforcement Office may take a range of actions as part of its investigation. For example, it may review the ticket agent or airline's privacy policies, obtain further information from the ticket agent or airline or from third parties, follow up with the referring entity, and assess whether there is a pattern of violations or significant number of consumers affected. In addition, it would determine whether the issue implicates matters within the purview of the Department of Commerce or FTC, assess whether consumer education and business education would be helpful, and as appropriate, initiate an enforcement proceeding.

If the Department becomes aware of potential Privacy Shield violations by ticket agents, it will coordinate with the FTC on the matter. We will also advise the FTC and the Department of Commerce of the outcome of any Privacy Shield enforcement action.

B. Addressing False or Deceptive Membership Claims

The Department remains committed to investigating Privacy Shield violations, including false or deceptive claims of membership in the Privacy Shield Program. We will give priority consideration to referrals from the Department of Commerce regarding organizations that it identifies as improperly holding themselves out to be current members of Privacy Shield or using the Privacy Shield Framework certification mark without authorization.

In addition, we note that if an organization's privacy policy promises that it complies with the substantive Privacy Shield principles, its failure to make or maintain a registration with the Department of Commerce likely will not, by itself, excuse the organization from DOT enforcement of those commitments.

C. Monitoring and Making Public Enforcement Orders Concerning Privacy Shield Violations

The Department's Aviation Enforcement Office also remains committed to monitoring enforcement orders as needed to ensure compliance with the Privacy Shield program. Specifically, if the office issues an order directing an airline or ticket agent to cease and desist from future violations of Privacy Shield and section 41712, it will monitor the entity's compliance with the cease-and-desist provision in the order. In addition, the office will ensure that orders resulting from Privacy Shield cases are available on its Web site.

We look forward to our continued work with our federal partners and EU stakeholders on Privacy Shield matters.

I hope that this information proves helpful. If you have any questions or need further information, please feel free to contact me.

Sincerely,
Anthony R. Foxx
Secretary of Transportation

Letter From General Counsel Robert Litt, Office of the Director of National Intelligence

Mr. Justin S. Antonipillai
Counselor
U.S. Department of Commerce
1401 Constitution Ave. NW.
Washington, DC 20230
Mr. Ted Dean
Deputy Assistant Secretary
International Trade Administration
1401 Constitution Ave. NW.
Washington, DC 20230
Dear Mr. Antonipillai and Mr. Dean:

Over the last two and a half years, in the context of negotiations for the EU-U.S. Privacy Shield, the United States has provided substantial information about the operation of U.S. Intelligence Community signals intelligence collection activity. This has included information about the governing legal framework, the multi-layered oversight of those activities, the extensive transparency about those activities, and the overall protections for privacy and civil liberties, in order to assist the European

[1] *http://www.transportation.gov/airconsumer/privacy-complaints.*

Commission in making a determination about the adequacy of those protections as they relate to the national security exception to the Privacy Shield principles. This document summarizes the information that has been provided.

I. PPD–28 and the Conduct of U.S. Signals Intelligence Activity

The U.S. Intelligence Community collects foreign intelligence in a carefully controlled manner, in strict accordance with U.S. laws and subject to multiple layers of oversight, focusing on important foreign intelligence and national security priorities. A mosaic of laws and policies governs U.S. signals intelligence collection, including the U.S. Constitution, the Foreign Intelligence Surveillance Act (50 U.S.C. 1801 *et seq.*) (FISA), Executive Order 12333 and its implementing procedures, Presidential guidance, and numerous procedures and guidelines, approved by the FISA Court and the Attorney General, that establish additional rules limiting the collection, retention, use, and dissemination of foreign intelligence information.[2]

a. PPD 28 Overview

In January 2014, President Obama gave a speech outlining various reforms to U.S. signals intelligence activities, and issued Presidential Policy Directive 28 (PPD–28) concerning those activities.[3] The President emphasized that U.S. signals intelligence activities help secure not only our country and our freedoms, but also the security and freedoms of other countries, including EU Member States, that rely on the information U.S. intelligence agencies obtain to protect their own citizens.

PPD–28 sets out a series of principles and requirements that apply to all U.S. signals intelligence activities and for all people, regardless of nationality or location. In particular, it sets certain requirements for procedures to address the collection, retention, and dissemination of personal information about non-U.S. persons acquired pursuant to U.S. signals intelligence. These requirements are set forth in more detail below, but in summary:

- The PPD reiterates that the United States collects signals intelligence only as authorized by statute, executive order, or other Presidential directive.
- The PPD establishes procedures to ensure that signals intelligence activity is conducted only in furtherance of legitimate and authorized national security purposes.
- The PPD also requires that privacy and civil liberties be integral concerns in the planning of signals intelligence collection activities. In particular, the United States does not collect intelligence to suppress or burden criticism or dissent; in order to disadvantage persons based on their ethnicity, race, gender, sexual orientation, or religion; or to afford a competitive commercial advantage to U.S. companies and U.S. business sectors.
- The PPD directs that signals intelligence collection be as tailored as feasible and that signals intelligence collected in bulk can only be used for specific enumerated purposes.
- The PPD directs that the Intelligence Community adopt procedures ''reasonably designed to minimize the dissemination and retention of personal information collected from signals intelligence activities,'' and in particular extending certain protections afforded to the personal information of U.S. persons to non-US person information.
- Agency procedures implementing PPD–28 have been adopted and made public.

The applicability of the procedures and protections set out herein to the Privacy Shield is clear. When data has been transferred to corporations in the United States pursuant to the Privacy Shield, or indeed by any means, U.S. intelligence agencies can seek that data from those corporations only if the request complies with FISA or is made pursuant to one of the National Security Letter statutory provisions, which are discussed below.[4] In addition, without confirming or denying media reports alleging that the U.S. Intelligence Community collects data from transatlantic cables while it is being transmitted to the United States, were the U.S. Intelligence Community to collect data from transatlantic cables, it would do so subject to the limitations and safeguards set out herein, including the requirements of PPD–28.

b. Collection Limitations

PPD–28 sets out a number of important general principles that govern the collection of signals intelligence:

- The collection of signals intelligence must be authorized by statute or Presidential authorization, and must be undertaken in accordance with the Constitution and law.
- Privacy and civil liberties must be integral considerations in planning signals intelligence activities.
- Signals intelligence will be collected only when there is a valid foreign intelligence or counterintelligence purpose.
- The United States will not collect signals intelligence for the purpose of suppressing or burdening criticism or dissent.
- The United States will not collect signals intelligence to disadvantage people based on their ethnicity, race, gender, sexual orientation, or religion.
- The United States will not collect signals intelligence to afford a competitive commercial advantage to U.S. companies and business sectors.
- U.S. signals intelligence activity must *always* be as tailored as feasible, taking into account the availability of other sources of information. This means, among other things, that whenever practicable, signals intelligence collection activities are conducted in a targeted manner rather than in bulk.

The requirement that signals intelligence activity be ''as tailored as feasible'' applies to the manner in which signals intelligence is collected, as well as to what is actually collected. For example, in determining whether to collect signals intelligence, the Intelligence Community must consider the availability of other information, including diplomatic or public sources, and prioritize collection through those means, where appropriate and feasible. Moreover, Intelligence Community element policies should require that wherever practicable, collection should be focused on specific foreign intelligence targets or topics through the use of discriminants (*e.g.,* specific facilities, selection terms and identifiers).

It is important to view the information provided to the Commission as a whole. Decisions about what is ''feasible'' or ''practicable'' are not left to the discretion of individuals but are subject to the policies that agencies have issued under PPD–28—which have been made publicly available—and to the other processes described therein.[5] As PPD–28 says, bulk collection of signals intelligence is collection that ''due to technical or operational considerations, is acquired without the use of discriminants (*e.g.,* specific identifiers, selection terms, etc.).'' In this respect, PPD–28 recognizes that Intelligence community elements must collect bulk signals intelligence in certain circumstances in order to identify new or emerging threats and other vital national security information that is often hidden within the large and complex system of modern global communications. It also recognizes the privacy and civil liberties concerns raised when bulk signals intelligence is collected. PPD–28 therefore directs the Intelligence Community to prioritize alternatives that would allow the conduct of targeted signals intelligence rather than bulk signals intelligence collection. Accordingly, Intelligence Community elements should conduct targeted signals intelligence collection activities rather than bulk signal intelligence collection activities whenever practicable.[6] These principles ensure that the exception for bulk collection will not swallow the general rule.

As for the concept of ''reasonableness,'' it is a bedrock principle of U.S. law. It signifies that Intelligence Community elements will not be required to adopt any measure theoretically possible, but rather will have to balance their efforts to protect legitimate

[2] Further information concerning U.S. foreign intelligence activities is posted online and publicly accessible through IC on the Record (*www.icontherecord.tumbir.com),* the ODNI's public website dedicated to fostering greater public visibility into the intelligence activities of the government.

[3] *Available at https://www.whitehouse.gov/the-press-office/2014/01/17/presidential-policy-directive-signals-intelligence-activities.*

[4] Law enforcement or regulatory agencies may request information from corporations for investigative purposes in the United States pursuant to other criminal, civil, and regulatory authorities that are beyond the scope of this paper, which is limited to national security authorities.

[5] *Available at www.icontherecord.tumblr.com/ppd-28/2015/privacy-civil-liberties#ppd-28.* These procedures implement the targeting and tailoring concepts discussed in this letter in a manner specific to each IC element.

[6] To cite but one example, the NSA's procedures implementing PPD–28 state that ''[w]henever practicable, collection will occur through the use of one or more selection terms in order to focus the collection on specific foreign intelligence targets (*e.g.,* a specific, known international terrorist or terrorist group) or specific foreign intelligence topics (*e.g.,* the proliferation of weapons of mass destruction by a foreign power or its agents).''

privacy and civil liberties interests with the practical necessities of signals intelligence activities. Here again, the agencies' policies have been made available, and can provide assurance that the term ''reasonably designed to minimize the dissemination and retention of personal information'' does not undermine the general rule.

PPD–28 also provides that signals intelligence collected in bulk can only be used for six specific purposes: Detecting and countering certain activities of foreign powers; counterterrorism; counter-proliferation; cybersecurity; detecting and countering threats to U.S. or allied armed forces; and combating transnational criminal threats, including sanctions evasion. The President's National Security Advisor, in consultation with the Director for National Intelligence (DNI), will annually review these permissible uses of signals intelligence collected in bulk to see whether they should be changed. The DNI will make this list publicly available to the maximum extent feasible, consistent with national security. This provides an important and transparent limitation on the use of bulk signals intelligence collection.

Additionally, the Intelligence Community elements implementing PPD–28 have reinforced existing analytic practices and standards for querying unevaluated signals intelligence.[7] Analysts must structure their queries or other search terms and techniques to ensure that they are appropriate to identify intelligence information relevant to a valid foreign intelligence or law enforcement task. To that end, IC elements must focus queries about persons on the categories of signals intelligence information responsive to a foreign intelligence or law enforcement requirement, so as to prevent the use of personal information not pertinent to foreign intelligence or law enforcement requirements.

It is important to emphasize that any bulk collection activities regarding Internet communications that the U.S. Intelligence Community performs through signals intelligence operate on a small proportion of the Internet. Additionally, the use of targeted queries, as described above, ensures that only those items believed to be of potential intelligence value are ever presented for analysts to examine. These limits are intended to protect the privacy and civil liberties of all persons, whatever their nationality and regardless of where they might reside.

The United States has elaborate processes to ensure that signals intelligence activities are conducted only in furtherance of appropriate national security purposes. Each year the President sets the nation's highest priorities for foreign intelligence collection after an extensive, formal interagency process. The DNI is responsible for translating these intelligence priorities into the National Intelligence Priorities Framework, or NIPF. PPD–28 strengthened and enhanced the interagency process to ensure that all of the IC's intelligence priorities are reviewed and approved by high-level policymakers. Intelligence Community Directive (ICD) 204 provides further guidance on the NIPF and was updated in January 2015 to incorporate the requirements of PPD–28.[8] Although the NIPF is classified, information related to specific U.S. foreign intelligence priorities is reflected annually in the DNI's unclassified *Worldwide Threat Assessment,* which is also readily available on the ODNI Web site.

The priorities in the NIPF are at a fairly high level of generality. They include topics such as the pursuit of nuclear and ballistic missile capabilities by particular foreign adversaries, the effects of drug cartel corruption, and human rights abuses in specific countries. And they apply not just to signals intelligence, but to all intelligence activities. The organization that is responsible for translating the priorities in the NIPF into actual signals intelligence collection is called the National Signals Intelligence Committee, or SIGCOM. It operates under the auspices of the Director of the National Security Agency (NSA), who is designated by Executive Order 12333 as the ''functional manager for signals intelligence,'' responsible for overseeing and coordinating signals intelligence across the Intelligence Community under the oversight of both the Secretary of Defense and the DNI. The SIGCOM has representatives from all elements of the IC and, as the United States fully implements PPD–28, also will have full representation from other departments and agencies with a policy interest in signals intelligence.

All U.S. departments and agencies that are consumers of foreign intelligence submit their requests for collection to the SIGCOM. The SIGCOM reviews those requests, ensures that they are consistent with the NIPF, and assigns them priorities using criteria such as:

- Can signals intelligence provide useful information in this case, or are there better or more cost-effective sources of information to address the requirement, such as imagery or open source information?
- How critical is this information need? If it is a high priority in the NIPF, it will most often be a high signal intelligence priority.
- What type of signals intelligence could be used?
- Is the collection as tailored as feasible? Should there be time, geographic, or other limitations?

The U.S. signals intelligence requirements process also requires explicit consideration of other factors, namely:

- Is the target of the collection, or the methodology used to collect, particularly sensitive? If so, it will require review by senior policymakers.
- Will the collection present an unwarranted risk to privacy and civil liberties, regardless of nationality?
- Are additional dissemination and retention safeguards necessary to protect privacy or national security interests?

Finally, at the end of the process, trained NSA personnel take the priorities validated by the SIGCOM and research and identify specific selection terms, such as telephone numbers or email addresses, which are expected to collect foreign intelligence responsive to these priorities. Any selector must be reviewed and approved before it is entered into NSA's collection systems. Even then, however, whether and when actual collection takes place will depend in part on additional considerations such as the availability of appropriate collection resources. This process ensures that U.S. signals intelligence collection targets reflect valid and important foreign intelligence needs. And, of course, when collection is conducted pursuant to FISA, NSA and other agencies must follow additional restrictions approved by the Foreign Intelligence Surveillance Court. In short, neither NSA nor any other U.S. intelligence agency decides on its own what to collect.

Overall, this process ensures that all U.S. intelligence priorities are set by senior policymakers who are in the best position to identify U.S. foreign intelligence requirements, and that those policymakers take into account not only the potential value of the intelligence collection but also the risks associated with that collection, including the risks to privacy, national economic interests, and foreign relations.

With respect to data transmitted to the United States pursuant to the Privacy Shield, although the United States cannot confirm or deny specific intelligence methods or operations, the requirements of PPD–28 apply to any signals intelligence operations the United States conducts, regardless of the type or source of data that is being collected. Further, the limitations and safeguards applicable to the collection of signals intelligence apply to signals intelligence collected for any authorized purpose, including both foreign relations and national security purposes.

The procedures discussed above demonstrate a clear commitment to prevent arbitrary and indiscriminate collection of signals intelligence information, and to implement—from the highest levels of our Government—the principle of reasonableness. PPD–28 and agency implementing procedures clarify new and existing limitations to and describe with greater specificity the purpose for which the United States collects and uses signals intelligence. These should provide assurance that signals intelligence activities are and will continue to be conducted only to further legitimate foreign intelligence goals.

c. Retention and Dissemination Limitations

Section 4 of PPD–28 requires that each element of the Intelligence Community have express limits on the retention and dissemination of personal information about non-U.S. persons collected by signals intelligence, comparable to the limits for U.S. persons. These rules are incorporated into procedures for each IC agency that were released in February 2015 and are publicly available. To qualify for retention or dissemination as foreign intelligence, personal information must relate to an authorized intelligence requirement, as determined in the NIPF process described

[7] *Available at http://www.dni.gov/files/documents/1017/PPD-28_Status_Report_Oct_2014.pdf.*

[8] *Available at http://www.dni.gov/files/documents/ICD/ICD%20204%20National%20Intelligence%20Priorities%20Framework.pdf.*

above; be reasonably believed to be evidence of a crime; or meet one of the other standards for retention of U.S. person information identified in Executive Order 12333, section 2.3.

Information for which no such determination has been made may not be retained for more than five years, unless the DNI expressly determines that continued retention is in the national security interests of the United States. Thus, IC elements must delete non-U.S. person information collected through signals intelligence five years after collection, unless, for example, the information has been determined to be relevant to an authorized foreign intelligence requirement, or if the DNI determines, after considering the views of the ODNI Civil Liberties Protection Officer and agency privacy and civil liberties officials, that continued retention is in the interest of national security.

In addition, all agency policies implementing PPD–28 now explicitly require that information about a person may not be disseminated solely because an individual is a non-U.S. person, and ODNI has issued a directive to all IC elements [9] to reflect this requirement. Intelligence Community personnel are specifically required to consider the privacy interests of non-U.S. persons when drafting and disseminating intelligence reports. In particular, signals intelligence about the routine activities of a foreign person would not be considered foreign intelligence that could be disseminated or retained permanently by virtue of that fact alone unless it is otherwise responsive to an authorized foreign intelligence requirement. This recognizes an important limitation and is responsive to European Commission concerns about the breadth of the definition of foreign intelligence as set forth in Executive Order 12333.

d. Compliance and Oversight

The U.S. system of foreign intelligence oversight provides rigorous and multi-layered oversight to ensure compliance with applicable laws and procedures, including those pertaining to the collection, retention, and dissemination of non-U.S. person information acquired by signals intelligence as set forth in PPD–28. These include:

- The Intelligence Community employs hundreds of oversight personnel. NSA alone has over 300 people dedicated to compliance, and other elements also have oversight offices. In addition, the Department of Justice provides extensive oversight of intelligence activities, and oversight is also provided by the Department of Defense.
- Each element of the Intelligence Community has its own Office of the Inspector General with responsibility for oversight of foreign intelligence activities, among other matters. Inspectors General are statutorily independent; have broad power to conduct investigations, audits and reviews of programs, including of fraud and abuse or violation of law; and can recommend corrective actions. While Inspector General recommendations are non-binding, the Inspector General's reports are often made public, and in any event are provided to Congress; this includes follow-up reports in case corrective action recommended in previous reports has not yet been completed. Congress is therefore informed of any non-compliance and can exert pressure, including through budgetary means, to achieve corrective action. A number of Inspector General reports about intelligence programs have been publicly released.[10]
- ODNI's Civil Liberties and Privacy Office (CLPO) is charged with ensuring that the IC operates in a manner that advances national security while protecting civil liberties and privacy rights.[11] Other IC elements have their own privacy officers.
- The Privacy and Civil Liberties Oversight Board (PCLOB), an independent body established by statute, is charged with analyzing and reviewing counterterrorism programs and policies, including the use of signals intelligence, to ensure that they adequately protect privacy and civil liberties. It has issued several public reports on intelligence activities.
- As discussed more fully below, the Foreign Intelligence Surveillance Court, a court composed of independent federal judges, is responsible for oversight and compliance of any signals intelligence collection activities conducted pursuant to FISA.
- Finally, the U.S. Congress, specifically the House and Senate Intelligence and Judiciary Committees, have significant oversight responsibilities regarding all U.S. foreign intelligence activities, including U.S. signals intelligence.

Apart from these formal oversight mechanisms, the Intelligence Community has in place numerous mechanisms to ensure that the Intelligence Community is complying with the limitations on collection described above. For example:

- Cabinet officials are required to validate their signals intelligence requirements each year.
- NSA checks signals intelligence targets throughout the collection process to determine if they are actually providing valuable foreign intelligence responsive to the priorities, and will stop collection against targets that are not. Additional procedures ensure that selection terms are reviewed periodically.
- Based on a recommendation from an independent Review Group appointed by President Obama, the DNI has established a new mechanism to monitor the collection and dissemination of signals intelligence that is particularly sensitive because of the nature of the target or the means of collection, to ensure that it is consistent with the determinations of policymakers.
- Finally, ODNI annually reviews the IC's allocation of resources against the NIPF priorities and the intelligence mission as a whole. This review includes assessments of the value of all types of intelligence collection, including signals intelligence, and looks both backward—how successful has the IC been in achieving its goals?—and forward—what will the IC need in the future? This ensures that signals intelligence resources are applied to the most important national priorities.

As evidenced by this comprehensive overview, the Intelligence Community does not decide on its own which conversations to listen to, try to collect everything, or operate free from scrutiny. Its activities are focused on priorities set by policymakers, through a process that involves input from across the government, and that is overseen both within NSA and by the ODNI, Department of Justice, and Department of Defense.

PPD–28 also contains numerous other provisions to ensure that personal information collected pursuant to signals intelligence is protected, regardless of nationality. For instance, PPD–28 provides for data security, access, and quality procedures to protect personal information collected through signals intelligence, and provides for mandatory training to ensure that the workforce understands the responsibility to protect personal information, regardless of nationality. The PPD also provides for additional oversight and compliance mechanisms. These include periodic audit and reviews by appropriate oversight and compliance officials of the practices for protecting personal information contained in signals intelligence. The reviews also must examine the agencies' compliance with the procedures for protecting such information.

Additionally, PPD–28 provides that significant compliance issues related to non-U.S. persons will be addressed at senior levels of government. Should a significant compliance issue occur involving the personal information of any person collected as a result of signals intelligence activities, the issue must, in addition to any existing reporting requirements, be reported promptly to the DNI. If the issue involves the personal information of a non-U.S. person, the DNI, in consultation with the Secretary of State and the head of the relevant IC element, will determine whether steps should be taken to notify the relevant foreign government, consistent with the protection of sources and methods and of U.S. personnel. Moreover, as directed by PPD–28, the Secretary of State has identified a senior official, Under Secretary Catherine Novelli, to serve as a point of contact for foreign governments that wish to raise concerns regarding signals intelligence activities of the United States. This commitment to high-level engagement exemplifies the efforts the U.S. government has made over the past few years to instill confidence in the numerous and overlapping privacy protections in place for U.S. person and non-U.S. person information.

e. Summary

The United States' processes for collecting, retaining, and disseminating foreign intelligence provide important privacy

[9] Intelligence Community Directive (ICD) 203, *available at http://www.dni.gov/files/documents/ICD/ICD%20203%20Analytic%20Standards.pdf.*

[10] See *e.g.,* U.S. Department of Justice Inspector General Report ''A Review of the Federal Bureau of Investigation's Activities Under Section 702 of the Foreign Intelligence Surveillance Act of 2008'' (September 2012), available at *https://oig.justice.gov/reports/2016/o1601a.pdf.*

[11] See *www.dni.gov/clpo.*

protections for the personal information of all persons, regardless of nationality. In particular, these processes ensure that our Intelligence Community focuses on its national security mission as authorized by applicable laws, executive orders, and presidential directives; safeguards information from unauthorized access, use and disclosure; and conducts its activities under multiple layers of review and oversight, including by congressional oversight committees. PPD–28 and the procedures implementing it represent our efforts to extend certain minimization and other substantial data protection principles to the personal information of all persons regardless of nationality. Personal information obtained through U.S. signals intelligence collection is subject to the principles and requirements of U.S. law and Presidential direction, including the protections set forth in PPD–28. These principles and requirements ensure that all persons are treated with dignity and respect, regardless of their nationality or wherever they might reside, and recognize that all persons have legitimate privacy interests in the handling of their personal information.

II. Foreign Intelligence Surveillance Act—Section 702

Collection under Section 702 of the Foreign Intelligence Surveillance Act [12] is not ''mass and indiscriminate'' but is narrowly focused on the collection of foreign intelligence from individually identified legitimate targets; is clearly authorized by explicit statutory authority; and is subject to both independent judicial supervision and substantial review and oversight within the Executive Branch and Congress. Collection under Section 702 is considered signals intelligence subject to the requirements of PPD–28.[13]

Collection under Section 702 is one of the most valuable sources of intelligence protecting both the United States and our European partners. Extensive information about the operation and oversight of Section 702 is publicly available. Numerous court filings, judicial decisions and oversight reports relating to the program have been declassified and released on the ODNI's public disclosure Web site, *www.icontherecord.tumblr.com*. Moreover, Section 702 was comprehensively analyzed by the PCLOB, in a report which is available at *https://www.pclob.gov/library/702-Report.pdf*.[14]

Section 702 was passed as part of the FISA Amendments Act of 2008,[15] after extensive public debate in Congress. It authorizes the acquisition of foreign intelligence information through targeting of non-U.S. persons located outside the United States, with the compelled assistance of U.S. electronic communications service providers. Section 702 authorizes the Attorney General and the DNI—two Cabinet-level officials appointed by the President and confirmed by the Senate—to submit annual certifications to the FISA Court.[16] These certifications identify specific categories of foreign intelligence to be collected, such as intelligence related to counterterrorism or weapons of mass destruction, which must fall within the categories of foreign intelligence defined by the FISA statute.[17] As the PCLOB noted, ''[t]hese limitations do *not* permit unrestricted collection of information about foreigners.'' [18]

The certifications also are required to include ''targeting'' and ''minimization'' procedures that must be reviewed and approved by the FISA Court.[19] The targeting procedures are designed to ensure that the collection takes place only as authorized by statute and is within the scope of the certifications; the minimization procedures are designed to limit the acquisition, dissemination, and retention of information about U.S. persons, but also contain provisions that provide substantial protection to information about non-U.S. persons as well, described below. Moreover, as described above, in PPD–28 the President directed that the Intelligence Community provide additional protections for personal information about non-U.S. persons, and those protections apply to information collected under Section 702.

Once the court approves the targeting and minimization procedures, collection under Section 702 is not bulk or indiscriminate, but ''consists entirely of targeting specific persons about whom an individualized determination has been made,'' as the PCLOB said.[20] Collection is targeted through the use of individual selectors, such as email addresses or telephone numbers, which U.S. intelligence personnel have determined are likely being used to communicate foreign intelligence information of the type covered by the certification submitted to the court.[21] The basis for selection of the target must be documented, and the documentation for every selector is subsequently reviewed by the Department of Justice.[22] The U.S. Government has released information showing that in 2014 there were approximately 90,000 individuals targeted under Section 702, a miniscule fraction of the over 3 billion internet users throughout the world.[23]

Information collected under Section 702 is subject to the court-approved minimization procedures, which provide protections to non-U.S. persons as well as U.S. persons, and which have been publicly released.[24] For example, communications acquired under Section 702, whether of U.S. persons or non-U.S. persons, are stored in databases with strict access controls. They may be reviewed only by intelligence personnel who have been trained in the privacy-protective minimization procedures and who have been specifically approved for that access in order to carry out their authorized functions.[25] Use of the data is limited to identification of foreign intelligence information or evidence of a crime.[26] Pursuant to PPD–28, this information may be disseminated only if there is a valid foreign intelligence or law enforcement purpose; the mere fact that one party to the communication is not a U.S. person is not sufficient.[27] And the minimization procedures and PPD–28 also set limits on how long data acquired pursuant to Section 702 may be retained.[28]

Oversight of Section 702 is extensive, and is conducted by all three branches of our government. Agencies implementing the statute have multiple levels of internal review, including by independent Inspectors General, and technological controls over access to the data. The Department of Justice and the ODNI closely review and scrutinize the use of Section 702 to verify compliance with legal rules; agencies are also under an independent obligation to report potential incidents of noncompliance. Those incidents are investigated, and all compliance incidents are reported to the Foreign Intelligence Surveillance Court, the President's Intelligence Oversight Board, and

[12] 50 U.S.C. 1881a.

[13] The United States also may obtain court orders pursuant to other provisions of FISA for the production of data, including data transferred pursuant to the Privacy Shield. *See* 50 U.S.C. 1801 *et seq*. Titles I and III of FISA, which respectively authorize electronic surveillance and physical searches, require a court order (except in emergency circumstances) and always require probable cause to believe that the target is a foreign power or an agent of a foreign power. Title IV of FISA authorizes the use of pen registers and trap and trace devices, pursuant to court order (except in emergency circumstances) in authorized foreign intelligence, counterintelligence, or counterterrorism investigations. Title V of FISA permits the FBI, pursuant to court order (except in emergency circumstances), to obtain business records that are relevant to an authorized foreign intelligence, counterintelligence, or counterterrorism investigations. As discussed below, the USA FREEDOM Act specifically prohibits the use of FISA pen register or business record orders for bulk collection, and imposes a requirement of a ''specific selection term'' to ensure that those authorities are used in a targeted fashion.

[14] Privacy and Civil Liberties Board, ''Report on the Surveillance Program Operated Pursuant to Section 702 of the Foreign Intelligence Surveillance Act'' (July 2, 2014) (''PCLOB Report'').

[15] *See* Pub. L. 110–261, 122 Stat. 2436 (2008).

[16] *See* 50 U.S.C. 1881a(a) and (b).

[17] *See id*. 1801(e).

[18] *See* PCLOB Report at 99.

[19] *See* 50 U.S.C. 1881a(d) and (e).

[20] *See* PCLOB Report at 111.

[21] *Id*.

[22] *Id*. at 8; 50 U.S.C. 1881a(l); *see also* NSA Director of Civil Liberties and Privacy Report, ''NSA's Implementation of Foreign Intelligence Surveillance Act Section 702'' (hereinafter ''NSA Report'') at 4, *available at http://icontherecord.tumblr.com/ppd-28/2015/privacy-civil-liberties*.

[23] Director of National Intelligence 2014 Transparency Report, *available at http://icontherecord.tumblr.com/transparency/odni_transparencyreport_cy2014*.

[24] Minimization procedures available at: *http://www.dni.gov/files/documents/ppd-28/2014%20NSA%20702%20Minimization%20Procedures.pdf* (''NSA Minimization Procedures''); *http://www.dni.gov/files/documents/ppd-28/2014%20FBI%20702%20Minimization%20Procedures.pdf*; and *http://www.dni.gov/files/documents/ppd-28/2014%20CIA%20702%20Minimization%20Procedures.pdf*.

[25] *See* NSA Report at 4.

[26] *See, e.g.*, NSA Minimization Procedures at 6.

[27] Intelligence Agency PPD–28 procedures available at *http://icontherecord.tumblr.com/ppd-28/2015/privacy-civil-liberties*.

[28] *See* NSA Minimization Procedures; PPD–28 Section 4.

Congress, and remedied as appropriate. [29] To date, there have been no incidents of willful attempts to violate the law or circumvent legal requirements. [30]

The FISA Court plays an important role in implementing Section 702. It is composed of independent federal judges who serve for a term of seven years on the FISA Court but who, like all federal judges, have life tenure as judges. As noted above, the Court must review the annual certifications and targeting and minimization procedures for compliance with the law. In addition, as also noted above, the Government is required to notify the Court immediately of compliance issues,[31] and several Court opinions have been declassified and released showing the exceptional degree of judicial scrutiny and independence it exercises in reviewing those incidents.

The Court's exacting processes have been described by its former Presiding Judge in a letter to Congress that has been publicly released.[32] And as a result of the USA FREEDOM Act, described below, the Court is now explicitly authorized to appoint an outside lawyer as an independent advocate on behalf of privacy in cases that present novel or significant legal issues.[33] This degree of involvement by a country's independent judiciary in foreign intelligence activities directed at persons who are neither citizens of that country nor located within it is unusual if not unprecedented, and helps ensure that Section 702 collection occurs within appropriate legal limits.

Congress exercises oversight through statutorily required reports to the Intelligence and Judiciary Committees, and frequent briefings and hearings. These include a semiannual report by the Attorney General documenting the use of Section 702 and any compliance incidents; [34] a separate semiannual assessment by the Attorney General and the DNI documenting compliance with the targeting and minimization procedures, including compliance with the procedures designed to ensure that collection is for a valid foreign intelligence purpose; [35] and an annual report by heads of intelligence elements which includes a certification that collection under Section 702 continues to produce foreign intelligence information.[36]

In short, collection under Section 702 is authorized by law; subject to multiple levels of review, judicial supervision and oversight; and, as the FISA Court stated in a recently declassified opinion, is ''not conducted in a bulk or indiscriminate manner,'' but ''through . . . discrete targeting decisions for individual [communication] facilities.'' [37]

III. USA Freedom Act

The USA FREEDOM Act, signed into law in June 2015, significantly modified U.S. surveillance and other national security authorities, and increased public transparency on the use of these authorities and on decisions of the FISA Court, as set out below.[38] The Act ensures that our intelligence and law enforcement professionals have the authorities they need to protect the Nation, while further ensuring that individuals' privacy is appropriately protected when these authorities are employed. It enhances privacy and civil liberties and increases transparency.

The Act prohibits bulk collection of any records, including of both U.S. and non-U.S. persons, pursuant to various provisions of FISA or through the use of National Security Letters, a form of statutorily authorized administrative subpoenas.[39] This prohibition specifically includes telephone metadata relating to calls between persons inside the U.S. and persons outside the U.S., and would also include collection of Privacy Shield information pursuant to these authorities. The Act requires that the government base any application for records under those authorities on a ''specific selection term''—a term that specifically identifies a person, account, address, or personal device in a way that limits the scope of information sought to the greatest extent reasonably practicable.[40] This further ensures that collection of information for intelligence purposes is precisely focused and targeted.

The Act also made significant modifications to proceedings before the FISA Court, which both increase transparency and provide additional assurances that privacy will be protected. As noted above, it authorized creation of a standing panel of security-cleared lawyers with expertise in privacy and civil liberties, intelligence collection, communications technology, or other relevant areas, who may be appointed to appear before the court as *amicus curiae* in cases that involve significant or novel interpretations of law. These lawyers are authorized to make legal arguments that advance the protection of individual privacy and civil liberties, and will have access to any information, including classified information, that the court determines is necessary to their duties.[41]

The Act also builds on the U.S. Government's unprecedented transparency about intelligence activities by requiring the DNI, in consultation with the Attorney General, to either declassify, or publish an unclassified summary of, each decision, order, or opinion issued by the FISA Court or the Foreign Intelligence Surveillance Court of Review that includes a significant construction or interpretation of any provision of law.

Moreover, the Act provides for extensive disclosures about FISA collection and National Security Letter requests. The United States must disclose to Congress and to the public each year the number of FISA orders and certifications sought and received; estimates of the number of U.S. persons and non-U.S. persons targeted and affected by surveillance; and the number of appointments of *amici curiae,* among other items of information.[42] The Act also requires additional public reporting by the government about the numbers of National Security Letter requests about both U.S. and non-U.S. persons.[43]

With regard to corporate transparency, the Act gives companies a range of options to report publicly the aggregate number of FISA orders and directives or National Security Letters they receive from the Government, as well as the number of customer accounts targeted by these orders.[44] Several companies have already made such disclosures, which have revealed the limited number of customers whose records have been sought.

These corporate transparency reports demonstrate that U.S. intelligence requests affect only a miniscule fraction of data. For example, one major company's recent transparency report shows that it received national security requests (pursuant to FISA or National Security Letters) affecting fewer than 20,000 of its accounts, at a time when it had at least 400 million subscribers. In other words, all U.S. national security requests reported by this company affected fewer than .005% of its subscribers. Even if every one of those requests had concerned Safe Harbor data, which of course is not the case, it is obvious that the requests are targeted and appropriate in scale, and are neither bulk nor indiscriminate.

Finally, while the statutes which authorize National Security Letters already restricted the circumstances under which a recipient of such a letter could be barred from disclosing

[29] *See* 50 U.S.C. 1881(l); *see also* PCLOB Report at 66–76.

[30] *See* Semiannual Assessment of Compliance with Procedures and Guidelines Issues Pursuant to Section 702 of the Foreign Intelligence Surveillance Act, Submitted by the Attorney General and the Director of National Intelligence at 2–3, *available at http://www.dni.gov/files/documents/Semiannual%20Assessment%20of%20Compliance%20with%20procedures%20and%20guidelines%20issued%20pursuant%20to%20Sect%20702%20of%20FISA.pdf.*

[31] Rule 13 of the Foreign Intelligence Surveillance Court Rules of Procedures, *available at http://www.fisc.uscourts.gov/sites/default/files/FISC%20Rules%20of%20Procedure.pdf.*

[32] July 29, 2013 Letter from The Honorable Reggie B. Walton to The Honorable Patrick J. Leahy, *available at http://fas.org/irp/news/2013/07/fisc-leahy.pdf.*

[33] *See* Section 401 of the USA FREEDOM Act, Public Law 114–23.

[34] *See* 50 U.S.C. 1881f.

[35] *See id.* 1881a(l)(1).

[36] *See id.* 1881a(l)(3). Some of these reports are classified.

[37] Mem. Opinion and Order at 26 (FISC 2014), a*vailable at http://www.dni.gov/files/documents/0928/FISC%20Memorandum%20Opinion%20and%20Order%2026%20August%202014.pdf.*

[38] *See* USA FREEDOM Act of 2015, Pub. L. 114–23, 401, 129 Stat. 268.

[39] *See id.* 103, 201, 501. National Security Letters are authorized by a variety of statutes and allow the FBI to obtain information contained in credit reports, financial records, and electronic subscriber and transaction records from certain kinds of companies, only to protect against international terrorism or clandestine intelligence activities. *See* 12 U.S.C. 3414; 15 U.S.C. 1681u-1681v; 18 U.S.C. 2709. National Security Letters are typically used by the FBI to gather critical non-content information at the early phases of counterterrorism and counterintelligence investigations—such as the identity of the subscriber to an account who may have been communicating with agents of a terrorist group such as ISIL. Recipients of a National Security Letter have the right to challenge them in court. *See* 18 U.S.C. 3511.

[40] *See id.*

[41] *See id.* section 401.

[42] *See id.* section 602.

[43] *See id.*

[44] *See id.* section 603.

it, the Act further provided that such non-disclosure requirements must be reviewed periodically; required that recipients of National Security Letters be notified when the facts no longer support a non-disclosure requirement; and codified procedures for recipients to challenge nondisclosure requirements.[45]

In sum, the USA FREEDOM Act's important amendments to U.S. intelligence authorities is clear evidence of the extensive effort taken by the United States to place the protection of personal information, privacy, civil liberties, and transparency at the forefront of all U.S. intelligence practices.

IV. Transparency

In addition to the transparency mandated by the USA FREEDOM Act, the U.S. Intelligence Community provides the public much additional information, setting a strong example with respect to transparency into its intelligence activities. The Intelligence Community has published many of its policies, procedures, Foreign Intelligence Surveillance Court decisions, and other declassified materials, providing an extraordinary degree of transparency. In addition, the Intelligence Community has substantially increased its disclosure of statistics on the government's use of national security collection authorities. On April 22, 2015, the Intelligence Community issued its second annual report presenting statistics on how often the government uses these important authorities. ODNI also has published, on the ODNI Web site and on *IC On the Record,* a set of concrete transparency principles[46] and an implementation plan that translates the principles into concrete, measurable initiatives.[47] In October 2015, the Director of National Intelligence directed that each intelligence agency designate an Intelligence Transparency Officer within its leadership to foster transparency and lead transparency initiatives.[48] The Transparency Officer will work closely with each intelligence agency's Privacy and Civil Liberties Officer to ensure that transparency, privacy, and civil liberties continue to remain top priorities.

As an example of these efforts, NSA's Chief Privacy and Civil Liberties Officer has released several unclassified reports over the past few years, including reports on activities under section 702, Executive Order 12333, and the USA FREEDOM Act.[49] In addition, the IC works closely with the PCLOB, Congress, and the U.S. privacy advocacy community to provide further transparency relating to U.S. intelligence activities, wherever feasible and consistent with the protection of sensitive intelligence sources and methods. Taken as a whole, U.S. intelligence activities are as transparent as or more transparent than those of any other nation in the world and are as transparent as it is possible to be consistent with the need to protect sensitive sources and methods.

To summarize the extensive transparency that exists about U.S. intelligence activities:

- The IC has released and posted online thousands of pages of court opinions and agency procedures outlining the specific procedures and requirements of our intelligence activities. We have also released reports on intelligence agencies' compliance with applicable restrictions.
- Senior intelligence officials regularly speak publicly about the roles and activities of their organizations, including descriptions of the compliance regimes and safeguards that govern their work.
- The IC released numerous additional documents about intelligence activities pursuant to our Freedom of Information Act.
- The President issued PPD–28, publicly setting out additional restrictions on our intelligence activities, and ODNI has issued two public reports on the implementation of those restrictions.
- The IC is now required by law to release significant legal opinions issued by the FISA Court, or summaries of those opinions.
- The government is required to report annually on the extent of its use of certain national security authorities, and companies are authorized to do so as well.
- The PCLOB has issued several detailed public reports on intelligence activities, and will continue to do so.
- The IC provides extensive classified information to Congressional oversight committees.
- The DNI issued transparency principles to govern the activities of the Intelligence Community.

This extensive transparency will continue going forward. Any information that is released publicly will, of course, be available to both the Department of Commerce and the European Commission. The annual review between Commerce and the European Commission on the implementation of the Privacy Shield will provide an opportunity for the European Commission to discuss any questions raised by any new information released, as well as any other matters concerning the Privacy Shield and its operation, and we understand that the Department may, in its discretion, invite representatives of other agencies, including the IC, to participate in that review. This is, of course, in addition to the mechanism provided in PPD–28 for EU Member States to raise surveillance-related concerns with a designated State Department official.

V. Redress

U.S. law provides a number of avenues of redress for individuals who have been the subject of unlawful electronic surveillance for national security purposes. Under FISA, the right to seek relief in U.S. court is not limited to U.S. persons. An individual who can establish standing to bring suit would have remedies to challenge unlawful electronic surveillance under FISA. For example, FISA allows persons subjected to unlawful electronic surveillance to sue U.S. government officials in their personal capacities for money damages, including punitive damages and attorney's fees. *See* 50 U.S.C. 1810. Individuals who can establish their standing to sue also have a civil cause of action for money damages, including litigation costs, against the United States when information about them obtained in electronic surveillance under FISA has been unlawfully and willfully used or disclosed. *See* 18 U.S.C. 2712. In the event the government intends to use or disclose any information obtained or derived from electronic surveillance of any aggrieved person under FISA against that person in judicial or administrative proceedings in the United States, it must provide advance notice of its intent to the tribunal and the person, who may then challenge the legality of the surveillance and seek to suppress the information. *See* 50 U.S.C. 1806. Finally, FISA also provides criminal penalties for individuals who intentionally engage in unlawful electronic surveillance under color of law or who intentionally use or disclose information obtained by unlawful surveillance. *See* 50 U.S.C. 1809.

EU citizens have other avenues to seek legal recourse against U.S. government officials for unlawful government use of or access to data, including government officials who violate the law in the course of unlawful access to or use of information for purported national security purposes. The Computer Fraud and Abuse Act prohibits intentional unauthorized access (or exceeding authorized access) to obtain information from a financial institution, a U.S. government computer system, or a computer accessed via the Internet, as well as threats to damage protected computers for purposes of extortion or fraud. *See* 18 U.S.C. 1030. Any person, of whatever nationality, who suffers damage or loss by reason of a violation of this law may sue the violator (including a government official) for compensatory damages and injunctive or other equitable relief under section 1030(g), regardless of whether a criminal prosecution has been pursued, provided the conduct involves at least one of several circumstances set forth in the statute. The Electronic Communications Privacy Act (ECPA) regulates government access to stored electronic communications and transactional records and subscriber information held by third-party communications providers. *See* 18 U.S.C. 2701–2712. ECPA authorizes an aggrieved individual to sue government officials for intentional unlawful access to stored data. ECPA applies to all persons regardless of citizenship and aggrieved persons may receive damages and attorney's fees. The Right to Financial Privacy Act (RFPA) limits the U.S. government's access to the bank and broker-dealer records of individual customers. *See* 12 U.S.C. 3401–3422. Under the RFPA, a bank or broker-dealer customer can sue the U.S. government for statutory, actual, and punitive damages for wrongfully obtaining access to the customer's records, and a finding that such wrongful access was willful automatically triggers an investigation

[45] *See id.* sections 502(f)–503.

[46] *Available at http:\\www.dni.gov/index.php/intelligence-community/intelligence-transparency-principles.*

[47] *Available at http:\\www.dni.gov/files/documents/Newsroom/Reports%20and%20Pubs/Principles%20of%20Intelligence%20Transparency%20Implementation%20Plan.pdf.*

[48] *See id.*

[49] *Available at https://www.nsa.gov/civil_liberties/_files/nsa_report_on_section_702_program.pdf; https://www.nsa.gov/civil_liberties/_files/UFA_Civil_Liberties_and_Privacy_Report.pdf; https://www.nsa.gov/civil_liberties/_files/UFA_Civil_Liberties_and_Privacy_Report.pdf.*

of possible disciplinary action against the relevant government employees. *See* 12 U.S.C. 3417.

Finally, the Freedom of Information Act (FOIA) provides a means for any person to seek access to existing federal agency records on any topic subject to certain categories of exemptions. *See* 5 U.S.C. 552(b). These include limits on access to classified national security information, personal information of other individuals, and information concerning law enforcement investigations, and are comparable to the limitations imposed by nations with their own information access laws. These limitations apply equally to Americans and non-Americans. Disputes over the release of records requested pursuant to FOIA can be appealed administratively and then in federal court. The court is required to make a de novo determination of whether records are properly withheld, 5 U.S.C. 552(a)(4)(B), and can compel the government to provide access to records. In some cases courts have overturned government assertions that information should be withheld as classified.[50] Although no monetary damages are available, courts can award attorney's fees.

VI. Conclusion

The United States recognizes that our signals intelligence and other intelligence activities must take into account that all persons should be treated with dignity and respect, regardless of their nationality or place of residence, and that all persons have legitimate privacy interests in the handling of their personal information. The United States only uses signals intelligence to advance its national security and foreign policy interests and to protect its citizens and the citizens of its allies and partners from harm. In short, the IC does not engage in indiscriminate surveillance of anyone, including ordinary European citizens. Signals intelligence collection only takes place when duly authorized and in a manner that strictly complies with these limitations; only after consideration of the availability of alternative sources, including from diplomatic and public sources; and in a manner that prioritizes appropriate and feasible alternatives. And wherever practicable, signals intelligence only takes place through collection focused on specific foreign intelligence targets or topics through the use of discriminants.

U.S. policy in this regard was affirmed in PPD–28. Within this framework, U.S. intelligence agencies do not have the legal authority, the resources, the technical capability or the desire to intercept all of the world's communications. Those agencies are not reading the emails of everyone in the United States, or of everyone in the world. Consistent with PPD–28, the United States provides robust protections to the personal information of non-U.S. persons that is collected through signals intelligence activities. To the maximum extent feasible consistent with the national security, this includes policies and procedures to minimize the retention and dissemination of personal information concerning non-U.S. persons comparable to the protections enjoyed by U.S. persons. Moreover, as discussed above, the comprehensive oversight regime of the targeted Section 702 FISA authority is unparalleled. Finally, the significant amendments to U.S. intelligence law set forth in the USA FREEDOM Act and the ODNI-led initiatives to promote transparency within the Intelligence Community greatly enhance the privacy and civil liberties of all individuals, regardless of their nationality.

Sincerely,

Robert S. Litt

Mr. Justin S. Antonipillai
Counselor
U.S. Department of Commerce
1401 Constitution Avenue, NW.
Washington, DC 20230

Mr. Ted Dean
Deputy Assistant Secretary
International Trade Administration
1401 Constitution Avenue, NW.
Washington, DC 20230

Dear Mr. Antonipillai and Mr. Dean:

I am writing to provide further information about the manner in which the United States conducts bulk collection of signals intelligence. As explained in footnote 5 of Presidential Policy Directive 28 (PPD–28), ''bulk'' collection refers to the acquisition of a relatively large volume of signals intelligence information or data under circumstances where the Intelligence Community cannot use an identifier associated with a specific target (such as the target's email address or phone number) to focus the collection. However, this does not mean that this sort of collection is ''mass'' or ''indiscriminate.'' Indeed, PPD–28 also requires that ''[s]ignals intelligence activities shall be as tailored as feasible.'' In furtherance of this mandate, the Intelligence Community takes steps to ensure that even when we cannot use specific identifiers to target collection, the data to be collected is likely to contain foreign intelligence that will be responsive to requirements articulated by U.S. policy-makers pursuant to the process explained in my earlier letter, and minimizes the amount of non-pertinent information that is collected.

As an example, the Intelligence Community may be asked to acquire signals intelligence about the activities of a terrorist group operating in a region of a Middle Eastern country, that is believed to be plotting attacks against Western European countries, but may not know the names, phone numbers, email addresses or other specific identifiers of individuals associated with this terrorist group. We might choose to target that group by collecting communications to and from that region for further review and analysis to identify those communications that relate to the group. In so doing, the Intelligence Community would seek to narrow the collection as much as possible. This would be considered collection in ''bulk'' because the use of discriminants is not feasible, but it is neither ''mass'' nor ''indiscriminate''; rather it is focused as precisely as possible.

Thus, even when targeting through the use of specific selectors is not possible, the United States does not collect all communications from all communications facilities everywhere in the world, but applies filters and other technical tools to focus its collection on those facilities that are likely to contain communications of foreign intelligence value. In so doing, the United States' signals intelligence activities touch only a fraction of the communications traversing the Internet.

Moreover, as noted in my earlier letter, because ''bulk'' collection entails a greater risk of collecting non-pertinent communications, PPD–28 limits the use that the Intelligence Community may make of signals intelligence collected in bulk to six specified purposes. PPD–28, and agency policies implementing PPD–28, also place restrictions on the retention and dissemination of personal information acquired through signals intelligence, regardless of whether the information was collected in bulk or through targeted collection, and regardless of the individual's nationality.

Thus, the Intelligence Community's ''bulk'' collection is not ''mass'' or ''indiscriminate,'' but involves the application of methods and tools to filter collection in order to focus the collection on material that will be responsive to policy-makers' articulated foreign intelligence requirements while minimizing the collection of non-pertinent information, and provides strict rules to protect the non-pertinent information that may be acquired. The policies and procedures described in this letter apply to all bulk signals intelligence collection, including any bulk collection of communications to and from Europe, without confirming or denying whether any such collection occurs.

You have also asked for more information about the Privacy and Civil Liberties Oversight Board (PCLOB) and Inspectors General, and their authorities. The PCLOB is an independent agency in the Executive Branch. Members of the bipartisan, five-member Board are appointed by the President and confirmed by the Senate.[1] Each Member of the Board serves a six-year term. Members of the Board and staff are provided appropriate security clearances in order for them to fully execute their statutory duties and responsibilities.[2]

The PCLOB's mission is to ensure that the federal government's efforts to prevent terrorism are balanced with the need to protect privacy and civil liberties. The Board has two fundamental responsibilities—oversight and advice. The PCLOB sets its own agenda and determines what oversight or advice activities it wishes to undertake.

In its *oversight* role, the PCLOB reviews and analyzes actions the Executive Branch takes to protect the nation from terrorism, ensuring that the need for such actions is balanced with the need to protect privacy and civil liberties.[3] The PCLOB's most recent

[50] *See, e.g., New York Times* v. *Department of Justice,* 756 F.3d 100 (2d Cir. 2014); *American Civil Liberties Union* v. *CIA,* 710 F.3d 422 (D.C. Cir. 2014).

[1] 42 U.S.C. 2000ee(a), (h).

[2] 42 U.S.C. 2000ee(k).

[3] 42 U.S.C. 2000ee(d)(2).

completed oversight review focused on surveillance programs operated under Section 702 of FISA.[4] It is currently conducting a review of intelligence activities operated under Executive Order 12333.[5]

In its *advisory* role, the PCLOB ensures that liberty concerns are appropriately considered in the development and implementation of laws, regulations, and policies related to efforts to protect the nation from terrorism.[6]

In order to carry out its mission, the Board is authorized by statute to have access to all relevant agency records, reports, audits, reviews, documents, papers, recommendations, and any other relevant materials, including classified information consistent with law.[7] In addition, the Board may interview, take statements from, or take public testimony from any executive branch officer or employee.[8] Additionally, the Board may request in writing that the Attorney General, on the Board's behalf, issues subpoenas compelling parties outside the Executive Branch to provide relevant information.[9]

Finally, the PCLOB has statutory public transparency requirements. This includes keeping the public informed of its activities by holding public hearings and making its reports publicly available, to the greatest extent possible consistent with the protection of classified information.[10] In addition, the PCLOB is required to report when an Executive Branch agency declines to follow its advice.

Inspectors General (IGs) in the Intelligence Community (IC) conduct audits, inspections, and reviews of the programs and activities in the IC to identify and address systemic risks, vulnerabilities, and deficiencies. In addition, IGs investigate complaints or information of allegations of violations of law, rules, or regulations, or mismanagement; gross waste of funds; abuse of authority, or a substantial and specific danger to the public health and safety in IC programs and activities. IG independence is a critical component to the objectivity and integrity of every report, finding, and recommendation an IG issues. Some of the most critical components to maintaining IG independence include the IG appointment and removal process; separate operational, budget, and personnel authorities; and dual reporting requirements to Executive Branch agency heads and Congress.

Congress established an independent IG office in each Executive Branch agency, including every IC element.[11] With the passage of the Intelligence Authorization Act for Fiscal Year 2015, almost all IGs with oversight of an IC element are appointed by the President and confirmed by the Senate, including the Department of Justice, Central Intelligence Agency, National Security Agency, and the Intelligence Community.[12] Further, these IGs are permanent, nonpartisan, officials who can only be removed by the President. While the U.S. Constitution requires that the President have IG removal authority, it has rarely been exercised and requires that the President provide Congress with a written justification 30 days before removing an IG.[13] This IG appointment process ensures that there is no undue influence by Executive Branch officials in the selection, appointment, or removal of an IG.

Second, IGs have significant statutory authorities to conduct audits, investigations, and reviews of Executive Branch programs and operations. In addition to oversight investigations and reviews required by law, IGs have broad discretion to exercise oversight authority to review programs and activities of their choosing.[14] In exercising this authority, the law ensures that IGs have the independent resources to execute their responsibilities, including the authority to hire their own staff and separately document their budget requests to Congress.[15] The law ensures that IGs have access to the information needed to execute their responsibilities. This includes the authority to have direct access to all agency records and information detailing the programs and operations of the agency regardless of classification; the authority to subpoena information and documents; and the authority to administer oaths.[16] In limited cases, the head of an Executive Branch agency may prohibit an IG's activity if, for example, an IG audit or investigation would significantly impair the national security interests of the United States. Again, the exercise of this authority is extremely unusual and requires the head of the agency to notify Congress within 30 days of the reasons for exercising it.[17] Indeed, the Director of National Intelligence has never exercised this limitation authority over any IG activities.

Third, IGs have responsibilities to keep both heads of Executive Branch agencies and Congress fully and currently informed through reports of fraud and other serious problems, abuses, and deficiencies relating to Executive Branch programs and activities.[18] Dual reporting bolsters IG independence by providing transparency into the IG oversight process and allowing agency heads an opportunity to implement IG recommendations before Congress can take legislative action. For example, IGs are required by law to complete semi-annual reports that describe such problems as well as corrective actions taken to date.[19] Executive Branch agencies take IG findings and recommendations seriously and IGs are often able to include the agencies' acceptance and implementation of IG recommendations in these and other reports provided to Congress, and in some cases the public.[20] In addition to this IG dual-report structure, IGs are also responsible for shepherding Executive Branch whistleblowers to the appropriate congressional oversight committees to make disclosures of alleged fraud, waste, or abuse in Executive Branch programs and activities. The identities of those who come forward are protected from disclosure to the Executive Branch, which shields the whistleblowers from potential prohibited personnel actions or security clearance actions taken in reprisal for reporting to the IG.[21] As whistleblowers are often the sources for IG investigations, the ability to report their concerns to the Congress without Executive Branch influences increases the effectiveness of IG oversight. Because of this independence, IGs can promote economy, efficiency, and accountability in Executive Branch agencies with objectivity and integrity.

Finally, Congress has established the Council of Inspectors General on Integrity and Efficiency. This Council, among other things, develops IG standards for audits, investigations and reviews; promotes training; and has the authority to conduct reviews of allegations of IG misconduct, which serves as a critical eye on IGs, who are entrusted to watch all others.[22]

I hope that this information is helpful to you.

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[4] *See generally https://www.pclob.gov/library.html#oversightreports.*

[5] *See generally https://www.pclob.gov/events/2015/may13.html.*

[6] 42 U.S.C. 2000ee(d)(1); *see also* PCLOB Advisory Function Policy and Procedure, Policy 2015–004, *available at https://www.pclob.gov/library/Policy-Advisory_Function_Policy_Procedure.pdf.*

[7] 42 U.S.C. 2000ee(g)(1)(A).

[8] 42 U.S.C. 2000ee(g)(1)(B).

[9] 42 U.S.C. 2000ee(g)(1)(D).

[10] 42 U.S.C. 2000eee(f).

[11] Sections 2 and 4 of the Inspector General Act of 1978, as amended (hereinafter ''IG Act''); Section 103H(b) and (e) of the National Security Act of 1947, as amended (hereinafter ''Nat'l Sec. Act''); Section 17(a) of the Central Intelligence Act (hereinafter ''CIA Act'').

[12] *See* Public Law 113–293, 128 Stat. 3990, (Dec. 19, 2014). Only the IGs for the Defense Intelligence Agency and the National Geospatial-Intelligence Agency are not appointed by the President; however the DOD IG and the IC IG have concurrent jurisdiction over these agencies.

[13] Section 3 of the IG Act of 1978, as amended; Section 103H(c) of the Nat'l Sec. Act; and Section 17(b) of the CIA Act.

[14] *See* Sections 4(a) and 6(a)(2) of the IG Act of 1947; Section 103H(e) and (g)(2)(A) of the Nat'l Sec. Act; Section 17(a) and (c) of the CIA Act.

[15] Sections 3(d), 6(a)(7) and 6(f) of the IG Act; Sections 103H(d), (i), (j) and (m) of the Nat'l Sec. Act; Sections 17(e)(7) and (f) of the CIA Act.

[16] Section 6(a)(1), (3), (4), (5), and (6) of the IG Act; Sections 103H(g)(2) of the Nat'l Sec. Act; Section 17(e)(1), (2), (4), and (5) of CIA Act.

[17] *See, e.g.,* Sections 8(b) and 8E(a) of the IG Act; Section 103H(f) of the Nat'l Sec. Act; Section 17(b) of the CIA Act.

[18] Section 4(a)(5) of the IG Act; Section 103H(a)(b)(3) and (4) of the Nat'l Sec. Act; Section 17(a)(2) and (4) of the CIA Act.

[19] Section 2(3), 4(a), and 5 of the IG Act; Section 103H(k) of the Nat'l Sec. Act; Section 17(d) of the CIA Act. The Inspector General of the Department of Justice makes its publicly released reports available on the Internet at *http://oig.justice.gov/reports/all.htm.* Similarly, the Inspector General for the Intelligence Community makes it semi-annual reports publicly available at *https://www.dni.gov/index.php/intelligence-community/ic-policies-reports/records-requested-under-foia#icig.*

[20] Section 2(3), 4(a), and 5 of the IG Act; Section 103H(k) of the Nat'l Sec. Act; Section 17(d) of the CIA Act. The Inspector General of the Department of Justice makes its publicly released reports available on the Internet at *http://oig.justice.gov/reports/all.htm.* Similarly, the Inspector General for the Intelligence Community makes it semi-annual reports publicly available at *https://www.dni.gov/index.php/intelligence-community/ic-policies-reports/records-requested-under-foia#icig.*

[21] Section 7 of the IG Act; Section 103H(g)(3) of the Nat'l Sec. Act; Section 17(e)(3) of the CIA Act.

[22] Section 11 of the IG Act.

Regards,

Robert S. Litt
General Counsel

Letter From Deputy Assistant Attorney General and Counselor for International Affairs Bruce Swartz, U.S. Department of Justice

February 19, 2016
Mr. Justin S. Antonipillai
Counselor
U.S. Department of Commerce
1401 Constitution Ave. NW.
Washington, DC 20230

Mr. Ted Dean
Deputy Assistant Secretary
International Trade Administration
1401 Constitution Ave. NW.
Washington, DC 20230

Dear Mr. Antonipillai and Mr. Dean:

This letter provides a brief overview of the primary investigative tools used to obtain commercial data and other record information from corporations in the United States for criminal law enforcement or public interest (civil and regulatory) purposes, including the access limitations set forth in those authorities.[1] These legal processes are nondiscriminatory in that they are used to obtain information from corporations in the United States, including from companies that will self-certify through the US/EU Privacy Shield framework, without regard to the nationality of the data subject. Further, corporations that receive legal process in the United States may challenge it in court as discussed below.[2]

Of particular note with respect to the seizure of data by public authorities is the Fourth Amendment to the United States Constitution, which provides that ''[t]he right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.'' U.S. Const. amend. IV. As the United States Supreme Court stated in *Berger* v. *State of New York,* ''[t]he basic purpose of this Amendment, as recognized in countless decisions of this Court, is to safeguard the privacy and security of individuals against arbitrary invasions by government officials.'' 388 U.S. 41, 53 (1967) (*citing Camara* v. *Mun. Court of San Francisco,* 387 U.S. 523, 528 (1967)). In domestic criminal investigations, the Fourth Amendment generally requires law enforcement officers to obtain a court-issued warrant before conducting a search. *See Katz* v. *United States,* 389 U.S. 347, 357 (1967). When the warrant requirement does not apply, government activity is subject to a ''reasonableness'' test under the Fourth Amendment. The Constitution itself, therefore, ensures that the U.S. government does not have limitless, or arbitrary, power to seize private information.

Criminal Law Enforcement Authorities:

Federal prosecutors, who are officials of the Department of Justice (DOJ), and federal investigative agents including agents of the Federal Bureau of Investigation (FBI), a law enforcement agency within DOJ, are able to compel production of documents and other record information from corporations in the United States for criminal investigative purposes through several types of compulsory legal processes, including grand jury subpoenas, administrative subpoenas and search warrants, and may acquire other communications pursuant to federal criminal wiretap and pen register authorities.

Grand Jury or Trial Subpoenas: Criminal subpoenas are used to support targeted law enforcement investigations. A grand jury subpoena is an official request issued from a grand jury (usually at the request of a federal prosecutor) to support a grand jury investigation into a particular suspected violation of criminal law. Grand juries are an investigative arm of the court and are impaneled by a judge or magistrate. A subpoena may require someone to testify at a proceeding, or to produce or make available business records, electronically stored information, or other tangible items. The information must be relevant to the investigation and the subpoena cannot be unreasonable because it is overbroad, or because it is oppressive or burdensome. A recipient can file a motion to challenge a subpoena based on those grounds. *See* Fed. R. Crim. P. 17. In limited circumstances, trial subpoenas for documents may be used after the case has been indicted by the grand jury.

Administrative Subpoena Authority: Administrative subpoena authorities may be exercised in criminal or civil investigations. In the criminal law enforcement context, several federal statutes authorize the use of administrative subpoenas to produce or make available business records, electronically stored information, or other tangible items in investigations involving health care fraud, child abuse, Secret Service protection, controlled substance cases, and Inspector General investigations implicating government agencies. If the government seeks to enforce an administrative subpoena in court, the recipient of the administrative subpoena, like the recipient of a grand jury subpoena, can argue that the subpoena is unreasonable because it is overbroad, or because it is oppressive or burdensome.

Court Orders For Pen Register and Trap and Traces: Under criminal pen register and trap and trace provisions, law enforcement may obtain a court order to acquire real-time, non-content dialing, routing, addressing and signaling information about a phone number or email upon certification that the information provided is relevant to a pending criminal investigation. *See* 18 U.S.C. 3121–3127. The use or installation of such a device outside the law is a federal crime.

Electronic Communications Privacy Act (ECPA): Additional rules govern the government's access to subscriber information, traffic data and stored content of communications held by ISPs telephone companies, and other third party service providers, pursuant to Title II of ECPA, also called the Stored Communications Act (SCA), 18 U.S.C. 2701–2712. The SCA sets forth a system of statutory privacy rights that limit law enforcement access to data beyond what is required under constitutional law from customers and subscribers of Internet service providers. The SCA provides for increasing levels of privacy protections depending on the intrusiveness of the collection. For subscriber registration information, IP addresses and associated time stamps, and billing information, criminal law enforcement authorities must obtain a subpoena. For most other stored, non-content information, such as email headers without the subject line, law enforcement must present specific facts to a judge demonstrating that the requested information is relevant and material to an ongoing criminal investigation. To obtain the stored content of electronic communications, generally, criminal law enforcement authorities obtain a warrant from a judge based on probable cause to believe the account in question contains evidence of a crime. The SCA also provides for civil liability and criminal penalties.

Court Orders for Surveillance Pursuant to Federal Wiretap Law: Additionally, law enforcement may intercept in real time wire, oral or electronic communications for criminal investigative purposes pursuant to the federal wiretap law. *See* 18 U.S.C. 2510–2522. This authority is available only pursuant to a court order in which a judge finds, *inter alia,* that there is probable cause to believe that the wiretap or electronic interception will produce evidence of a federal crime, or the whereabouts of a fugitive fleeing from prosecution. The statute provides for civil liability and criminal penalties for violations of the wiretapping provisions.

Search Warrant—Rule 41: Law enforcement can physically search premises in the United States when authorized to do so by a judge. Law enforcement must demonstrate to the judge based on a showing of ''probable cause'' that a crime was committed or is about to be committed and that items connected to the crime are likely to be found in the place specified by the warrant. This authority is often used when a physical search by police of a premise is needed due to the danger that evidence may be destroyed if a subpoena or other production order is served on the corporation. *See* U.S. Const. amend. IV

[1] This overview does not describe the national security investigative tools used by law enforcement in terrorism and other national security investigations, including National Security Letters (NSLs) for certain record information in credit reports, financial records, and electronic subscriber and transaction records, *see* 12 U.S.C. 3414; 15 U.S.C. 1681u; 15 U.S.C. 1681v; 18 U.S.C. 2709, and for electronic surveillance, search warrants, business records, and other collection of communications pursuant to the Foreign Intelligence Surveillance Act, *see* 50 U.S.C. 1801 *et seq.*

[2] This paper discusses federal law enforcement and regulatory authorities; violations of state law are investigated by states and are tried in state courts. State law enforcement authorities use warrants and subpoenas issued under state law in essentially the same manner as described herein, but with the possibility that state legal process may be subject to protections provided by State constitutions that exceed those of the U.S. Constitution. State law protections must be at least equal to those of the U.S. Constitution, including but not limited to the Fourth Amendment.

(discussed in further detail above), Fed. R. Crim. P. 41. The subject of a search warrant may move to quash the warrant as overbroad, vexatious or otherwise improperly obtained and aggrieved parties with standing may move to suppress any evidence obtained in an unlawful search. *See Mapp* v. *Ohio,* 367 U.S. 643 (1961).

DOJ Guidelines and Policies: In addition to these Constitutional, statutory and rule-based limitations on government access to data, the Attorney General has issued guidelines that place further limits on law enforcement access to data, and that also contain privacy and civil liberty protections. For instance, the Attorney General's Guidelines for Domestic Federal Bureau of Investigation (FBI) Operations (September 2008) (hereinafter AG FBI Guidelines), available at *http://www.justice.gov/archive/opa/docs/guidelines.pdf,* set limits on use of investigative means to seek information related to investigations that involve federal crimes. These guidelines require that the FBI use the least intrusive investigative methods feasible, taking into account the effect on privacy and civil liberties and the potential damage to reputation. Further, they note that ''it is axiomatic that the FBI must conduct its investigations and other activities in a lawful and reasonable manner that respects liberty and privacy and avoids unnecessary intrusions into the lives of law-abiding people.'' *See* AG FBI Guidelines at 5. The FBI has implemented these guidelines through the FBI Domestic Investigations and Operations Guide (DIOG), available at *https://vault.fbi.gov/FBI%20Domestic%20Investigations%20and%20Operations%20Guide%20(DIOG),* a comprehensive manual that includes detailed limits on use of investigative tools and guidance to assure that civil liberties and privacy are protected in every investigation. Additional rules and policies that prescribe limitations on the investigative activities of federal prosecutors are set out in the United States Attorneys' Manual (USAM), also available online at *http://www.justice.gov/usam/united-states-attorneys-manual.*

Civil and Regulatory Authorities (Public Interest):

There are also significant limits on civil or regulatory (*i.e.,* ''public interest'') access to data held by corporations in the United States. Agencies with civil and regulatory responsibilities may issue subpoenas to corporations for business records, electronically stored information, or other tangible items. These agencies are limited in their exercise of administrative or civil subpoena authority not only by their organic statutes, but also by independent judicial review of subpoenas prior to potential judicial enforcement. *See, e.g.,* Fed. R. Civ. P. 45. Agencies may seek access only to data that is relevant to matters within their scope of authority to regulate. Further, a recipient of an administrative subpoena may challenge the enforcement of that subpoena in court by presenting evidence that the agency has not acted in accordance with basic standards of reasonableness, as discussed earlier.

There are other legal bases for companies to challenge data requests from administrative agencies based on their specific industries and the types of data they possess. For example, financial institutions can challenge administrative subpoenas seeking certain types of information as violations of the Bank Secrecy Act and its implementing regulations. *See* 31 U.S.C. 5318, 31 CFR chapter X. Other businesses can rely on the Fair Credit Reporting Act, *see* 15 U.S.C. 1681b, or a host of other sector specific laws. Misuse of an agency's subpoena authority can result in agency liability, or personal liability for agency officers. *See, e.g.,* Right to Financial Privacy Act, 12 U.S.C. 3401–3422. Courts in the United States thus stand as the guardians against improper regulatory requests and provide independent oversight of federal agency actions.

Finally, any statutory power that administrative authorities have to physically seize records from a company in the United States pursuant to an administrative search must meet the requirements of the Fourth Amendment. *See See* v. *City of Seattle,* 387 U.S. 541 (1967).

Conclusion

All law enforcement and regulatory activities in the United States must conform to applicable law, including the U.S. Constitution, statutes, rules, and regulations. Such activities must also comply with applicable policies, including any Attorney General Guidelines governing federal law enforcement activities. The legal framework described above limits the ability of U.S. law enforcement and regulatory agencies to acquire information from corporations in the United States—whether the information concerns U.S. persons or citizens of foreign countries—and in addition permits judicial review of any government requests for data pursuant to these authorities.

Sincerely,

Bruce C. Swartz

Deputy Assistant Attorney General and Counselor for International Affairs

Dated: July 25, 2016.

Edward M Dean,

Deputy Assistant Secretary for Services, International Trade Administration, U.S. Department of Commerce.

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